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The Iowa Administrative Code Supplement is published biweekly pursuant to Iowa Code section 17A.6. The Supplement contains replacement chapters to be inserted in the loose-leaf Iowa Administrative Code (IAC) according to instructions included with each Supplement. The replacement chapters incorporate rule changes which have been adopted by the agencies and filed with the Administrative Rules Coordinator as provided in Iowa Code sections 7.17 and 17A.4 to 17A.6. To determine the specific changes in the rules, refer to the Iowa Administrative Bulletin bearing the same publication date.

In addition to the changes adopted by agencies, the replacement chapters may reflect objection to a rule or a portion of a rule filed by the Administrative Rules Review Committee (ARRC), the Governor, or the Attorney General pursuant to Iowa Code section 17A.4(6); an effective date delay imposed by the ARRC pursuant to section 17A.4(7) or 17A.8(9); rescission of a rule by the Governor pursuant to section 17A.4(8); or nullification of a rule by the General Assembly pursuant to Article III, section 40, of the Constitution of the State of Iowa.

The Supplement may also contain replacement pages for the IAC Index or the Uniform Rules on Agency Procedure.

INSTRUCTIONS

FOR UPDATING THE

IOWA ADMINISTRATIVE CODE

Agency names and numbers in bold below correspond to the divider tabs in the IAC binders. New and replacement chapters included in this Supplement are listed below. Carefully remove and insert chapters accordingly.

Editor's telephone (515) 281-3355 or (515) 281-8157

Agriculture and Land Stewardship Department[21]

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Replace “V”

AGRICULTURE AND LAND STEWARDSHIP DEPARTMENT[21]

[Created by 1986 Iowa Acts, chapter 1245]
[Prior to 7/27/88, Agriculture Department[30]]
Rules under this Department "umbrella" also include
Agricultural Development Authority[25] and Soil Conservation Division[27]

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CHAPTER 67
ANIMAL WELFARE

[Prior to 7/27/88 see Agriculture Department 30—Ch 20]

21—67.1(162) Animals included in rules. Dog, as that term is used in the rules, includes hybrid dog mixtures. Animals, as that term is used in rules relating to boarding kennels, commercial kennels, hobby kennels, commercial breeders, dealers, public auctions, animal shelters, and pounds includes dogs and cats. Animals, as that term is used in rules relating to pet shops, includes dogs, cats, rabbits, rodents, nonhuman primates, birds, fish, or other vertebrate animals.

This rule implements Iowa Code sections 162.1 and 162.8.

21—67.2(162) Housing facilities and primary enclosures.

67.2(1) *Housing facilities.*

a. Buildings shall be of adequate structure and maintained in good repair so as to ensure protection of animals from injury.

b. Shelter shall be provided to allow access to shade from direct sunlight and regress from exposure to rain or snow. Heat, insulation, or bedding adequate to provide comfort shall be provided when the atmospheric temperature is below 50° F. or that temperature to which the particular animals are acclimated. Indoor housing facilities shall be provided for dogs and cats under the age of eight weeks and for dogs and cats within two weeks of whelping.

c. Indoor and outdoor housing facilities shall at all times be provided with ventilation by means of doors, windows, vents, air conditioning or direct flow of fresh air that is adequate to provide for the good health and comfort of the animals. Such ventilation shall be environmentally provided as to minimize drafts, moisture condensation, odors or stagnant vapors of excreta.

d. Ample lighting shall be provided by natural or artificial means or both during sunrise to sunset hours to allow efficient cleaning of the facilities and routine inspection of the facilities and animals contained therein.

e. Ceilings, walls and floors shall be so constructed as to lend themselves to efficient cleaning and sanitizing. Such surfaces shall be kept in good repair and maintained so that they are substantially impervious to moisture. Floors and walls to a height of four feet shall have finished surfaces.

f. Food supplies and bedding materials shall be stored so as to adequately protect them from contamination or infestation by vermin or other factors which would render the food or bedding unclean. Separate storage facilities shall be maintained for cleaning and sanitizing equipment and supplies.

g. Washrooms, basins or sinks shall be provided within or be readily accessible to each housing facility, for maintaining cleanliness among animal caretakers and sanitizing of food and water utensils.

h. Equipment shall be available for removal and disposal of all waste materials from housing facilities to minimize vermin infestation, odors and disease hazards. Drainage systems shall be functional to effect the above purposes.

i. Facilities shall be provided to isolate diseased animals, to prevent exposure to healthy animals.

j. Outdoor dog runs and exercise areas shall be of sound construction and kept in good repair so as to safely contain the animal(s) therein without injury. Floors shall be concrete, gravel or materials which can be regularly cleaned and kept free of waste accumulation. Grass runs and exercise areas are permissible provided adequate ground cover is maintained, holes are kept filled and the ground cover is not allowed to become overgrown. Dog runs and exercise areas utilizing wire floors are permissible, provided that they are not injurious to the animals and adequately maintained.

k. Group housing is permitted for animals which are compatible with one another. Adequate space shall be provided to prevent crowding and to allow freedom of movement and comfort to animals of the size which are housed in the facility. Females in estrus shall not be housed with males, except for breeding purposes.

67.2(2) *Primary enclosures.*

a. Primary enclosures shall be of sound construction and maintained in good repair to protect the animals from injury.

b. Construction materials and maintenance shall allow the animals to be kept clean and dry. Walls and floors shall be impervious to urine and other moisture.

c. The shape and size of the enclosure shall afford ample space for the individual(s) to comfortably turn about, stand erect, sit or lie. Not more than 12 dogs or cats shall be housed in the same primary enclosure.

d. Litter pans, containing clean litter, shall be provided at all times for kittens and cats.

e. Means shall be provided to maintain that temperature and ventilation which is comfortable for the species within the primary enclosure. Lighting shall be adequate to allow observation of the animals but they shall be protected from excessive illumination.

f. Animals shall be removed from their primary enclosures at least twice in each 24-hour period and exercised, unless the primary enclosure shall be of sufficient size to provide this exercise.

g. If doghouses with chains are used as primary enclosures for dogs kept outdoors, the chains used shall be so placed or attached that they cannot become entangled with the chains of other dogs or any other objects. Such chains shall be of a type commonly used for the size dog involved and shall be attached to the dog by means of a well fitted collar. Such chains shall be at least three times the length of the dog as measured from the tip of its nose to the base of its tail and shall allow the dog convenient access to the doghouse.

67.2(3) *In-home kennel.*

a. For the purposes of this subrule, "in-home kennel" means an individual required to be licensed as a boarding kennel or as a commercial breeder under Iowa Code chapter 162 who maintains or harbors not more than six adult animals (including both breeding animals and surgically sterilized animals) in the individual's living quarters.

b. Notwithstanding subrules 67.2(1), 67.2(2), and 67.3(2), an in-home kennel shall comply with the following standards:

(1) Food supplies shall be stored so as to adequately protect them from contamination or infestation by vermin or other factors which would render the food unclean.

(2) Ample lighting shall be provided by natural or artificial means or both during sunrise to sunset hours. Animals shall be protected from excessive illumination.

(3) Building shall be of adequate structure and maintained in good repair so as to ensure protection of animals from injury.

(4) Facilities shall be provided to isolate diseased animals to prevent exposure to healthy animals.

(5) Outdoor dog runs and exercise areas shall be of sound construction and kept in good repair so as to safely contain the animal(s) therein without injury. Floors shall be concrete, gravel or materials which can be regularly cleaned and kept free of waste accumulation. Grass runs and exercise areas are permissible provided adequate ground cover is maintained, holes are kept filled and the ground cover is not allowed to become overgrown. Wire floors are permissible, provided they are not injurious to the animals and adequately maintained.

(6) Group housing is permitted for animals which are compatible with one another. Adequate space shall be provided to prevent crowding and to allow freedom of movement and comfort to animals of the size which are housed within the facility. Females in estrus shall not be housed with males, except for breeding purposes.

(7) If the animals are confined to a restricted area of the living quarters, the restricted area shall meet the space requirements set out in paragraph 67.2(2)*"c."*

(8) Litter pans, containing clean litter, shall be provided at all times for kittens and cats.

(9) Means shall be provided to maintain that temperature and ventilation which is comfortable for the species within the primary enclosure or housing facility.

(10) Animals shall be removed from their primary enclosures at least twice in each 24-hour period and exercised.

(11) Housing facilities shall be cleaned as necessary to reduce disease hazards, and an effective program shall be established and maintained for the control of vermin infestation.

This rule is intended to implement Iowa Code sections 162.8 and 162.9.

21—67.3(162) General care and husbandry standards.

67.3(1) *Feeding and watering.*

a. All species covered under Iowa Code chapter 162 shall be provided with adequate feed as defined in section 162.2(1).

b. Young animals and animals under veterinary care shall be fed at more frequent intervals and with specific diets as their needs shall dictate.

c. All species covered under Iowa Code chapter 162 shall be provided with adequate water as defined in section 162.2(2).

67.3(2) *Sanitation.*

a. Housing facilities and primary enclosures shall be cleaned a minimum of once in each 24-hour period and more frequently as may be necessary to reduce disease hazards and odors.

b. Housing facilities and primary enclosures shall be sanitized at intervals not to exceed two weeks or more frequently as may be necessary to reduce disease hazards. Primary enclosures for dogs and cats in pet shops shall be sanitized at intervals not to exceed 48 hours. Sanitizing shall be done by washing the surfaces with hot water and soap or detergent, followed by the application of a safe and effective disinfectant. Pressure water systems or live steam may be used for cleaning, if animals are removed while cleaning. Runs and exercise areas having gravel or other nonpermanent surface materials shall be sanitized by periodic removal of soiled materials, application of suitable disinfectants, and replacement with clean surface materials.

c. An effective program shall be established and maintained for the control of vermin infestation.

67.3(3) *Veterinary care.*

a. Programs of disease prevention and control shall be established and maintained.

b. Sick, diseased or injured animals shall be provided with proper veterinary care or disposed of by euthanasia.

c. All species regulated under Iowa Code chapter 162 which are infected with contagious diseases shall be immediately placed into facilities provided for in 67.2(1)*"i."*

d. All dogs and cats transported into housing facilities regulated under Iowa Code chapter 162, excluding pounds and animal shelters, shall have been vaccinated against distemper and rabies, unless exempted by direct recommendation of the owner's veterinarian or exempted by Iowa Code section 351.33 or 351.42.

e. Each commercial breeder shall enter into a written agreement with a veterinarian licensed in this state to provide veterinary care for the animals maintained in the commercial breeder's facility. The agreement shall include a requirement that the veterinarian visit the facility at least once every 12 months for the purpose of viewing all the animals in the facility, making a general determination concerning the health/disease status of the animals, and reviewing the commercial breeder's program for disease prevention and control. If during the course of the visit, the veterinarian identifies an animal that requires a more detailed individual examination to determine the specific condition of the animal or to determine an appropriate course of treatment, then such examination shall be undertaken.

f. If during an inspection of a facility the department finds an animal which appears to have a physical condition or disease which, in the opinion of the inspector, requires a veterinarian's attention, the department may order that the licensee subject the animal to a veterinarian's examination at the licensee's expense. The department may require the licensee to submit written proof of the veterinarian's examination and results of the examination within a time frame set by the department.

67.3(4) *Personnel.*

a. The owner or personnel shall be present at least once in each 24-hour period to supervise and ascertain that the care of animals and maintenance of facilities conform to all of the provisions of Iowa Code chapter 162.

b. A sufficient number of employees shall be utilized to provide the required care of animals and maintenance of facilities during normal business hours.

This rule is intended to implement Iowa Code sections 162.1 and 162.2.

21—67.4(162) Transportation.

67.4(1) *Primary enclosures.*

a. Primary enclosures utilized in transportation shall be of sound construction and maintained in good repair so as to ensure protection of animals from injury.

b. Floors and lower sides shall be so constructed or shall be covered on the inner surfaces so as to contain excreta and bedding materials.

c. Adequate space shall be provided so that the individual(s) contained therein may comfortably turn about, stand erect, sit or lie.

d. Openings shall be provided in enclosures so that adequate ventilation can be maintained when they are positioned in the transporting vehicle.

e. Primary enclosures shall be cleaned and sanitized before each trip.

f. The temperature within primary enclosures shall not be allowed to exceed the atmospheric temperature; moreover the ambient temperature shall not be allowed to exceed 95° F. for a period of more than two hours, nor be allowed at any time to fall below 45° F. unless the animals are acclimated to lower temperatures.

67.4(2) *Vehicles.*

a. Protection shall be afforded to primary enclosures transported in the vehicle, sheltering the animals from drafts and extremes of hot or cold temperatures to which they are not acclimated.

b. Primary enclosures used in transportation shall be securely positioned in the vehicle to protect the animals from injury.

67.4(3) *Care in transit.*

a. Animals in transit shall be provided adequate feed and adequate water as defined in Iowa Code sections 162.2(1) and 162.2(2).

b. Incompatible animals shall not be placed together during shipment. Females in estrus shall not be placed in the same primary enclosure with a male.

c. Animals shall be inspected at least once in each six-hour period and their emergency needs attended to immediately.

d. Animals shall be removed for exercise and their enclosures cleaned if they shall have been en route for a 24-hour period.

21—67.5(162) Purchase, sale, trade and adoption.

67.5(1) Records shall be made, and retained for a period of 12 months for each dog, cat or nonhuman primate sold, traded, or adopted from a licensee or registered pound or animal shelter. Records shall include date of sale or transfer, identification of animal, names and addresses of seller and purchaser or transferor and recipient, and source of the animal. Records shall be similarly kept on other small vertebrate animals sold or transferred, except that individual identifications shall not be required.

67.5(2) Licensees, pounds, and animal shelters shall furnish a statement of sale, transfer, or adoption to each purchaser or recipient of a dog, cat, nonhuman primate, bird, or other vertebrate animal. This statement shall include: Name and address of the seller or transferor, name and address of the purchaser or recipient, date of sale or transfer, description or identification of the vertebrate sold or transferred, prophylactic immunization(s) and date(s) administered, and internal parasite medication(s) given and date(s) administered.

67.5(3) All vertebrate animals regulated under Iowa Code chapter 162 which are known to be exposed to or show symptoms of having infectious and contagious diseases or which show symptoms of parasitism or malnutrition sufficient to adversely affect the health of the animals are restricted from sale or transfer.

The secretary may order quarantine on premises or housing facilities in which any of the above listed conditions in 67.5(3) shall exist. Quarantine shall be removed when at the discretion of the secretary or the secretary's designee, the disease conditions for which quarantined are no longer evident and the apparent health of the animals indicates absence of contagion.

67.5(4) For the purposes of determining an individual's obligation to be licensed under Iowa Code section 162.8, "breeding animal" will include any sexually intact animal over the age of 12 months.

This rule is intended to implement Iowa Code sections 162.6 and 162.8.

21—67.6(162) Public health.

67.6(1) Animal wardens aiding in the enforcement of the provisions of Iowa Code chapter 162 shall enlist veterinary aid in programming control measures to protect the public from zoonotic diseases which may be suspected to be on the premises of a licensee or registrant of said Iowa Code chapter.

67.6(2) Animals, housing facilities, or premises may be placed under quarantine by order of the secretary when it is deemed necessary to protect the public from zoonotic diseases.

21—67.7(162) Kennels, shelters and other facilities—access, seizure and impoundment.

67.7(1) *Boarding kennels and commercial kennels.*

a. Records shall be made, and retained for a period of 12 months for each animal boarded, groomed or trained. Records shall include owner's name and address, identification of animal, duration of stay, service provided and illnesses which have occurred.

b. Animals exhibiting symptoms of disease shall be promptly examined and treated by a veterinarian.

c. Group housing is permitted only if the animals are owned by the same person and are compatible.

d. Grooming and training utensils and equipment shall be cleaned and sanitized between use on animals owned by different persons.

e. Primary enclosures shall be cleaned and sanitized between use in containing animals owned by different persons.

f. Primary enclosures shall utilize latches which cannot be inadvertently opened, or shall be equipped with some form of locking device so as to prevent the accidental release of the animal contained therein.

67.7(2) *Animal shelters and pounds.*

a. Dogs, cats and other vertebrates upon which euthanasia may be permitted by law, shall be destroyed only as defined by euthanasia under Iowa Code chapter 162.

b. Animal shelters and pounds shall develop and implement a plan providing for the surgical sterilization of all dogs and cats released, unless exempted from this provision in accordance with Iowa Code section 162.20(5).

c. Sterilization agreements shall contain the following:

(1) Name, address and signature of the person receiving custody of the dog or cat.

(2) A complete description of the animal, including any identification.

(3) The signature of the representative of the pound or animal shelter.

(4) The date that the agreement is executed and the date by which sterilization must be completed.

(5) A statement which states the following:

1. Sterilization of the animal is required pursuant to Iowa Code section 162.20.

2. Ownership of the dog or cat is conditioned upon the satisfaction of the terms of the agreement.

3. Failure to satisfy the terms of the agreement constitutes a breach of contract, requiring the return of the dog or cat.

4. A person failing to satisfy the sterilization provisions of the agreement is guilty of a simple misdemeanor.

d. In addition to records required by 67.5(1), animal shelters and pounds shall maintain, for a period of 12 months, the following records:

(1) Euthanasia records, including date of entry, source of animal, and date of euthanasia.

(2) Sterilization agreements, including confirmation in the form of a receipt furnished by the office of the attending veterinarian.

(3) Disposition records of all animals lawfully claimed by owners, research facilities, or Class B federal dealers.

e. A pound or animal shelter may apply in writing for an enforcement waiver pursuant to Iowa Code section 162.20(5), paragraph *"b."* The application shall include the specific guidelines under which the waiver is being requested and a certified copy of the ordinance providing the basis for the waiver application. A waiver application fee of $10 shall accompany the application.

f. A pound or animal shelter shall be subject to civil penalties as provided in Iowa Code section 162.20(3), paragraph *"c,"* for not procuring and maintaining required records documenting compliance with the sterilization agreement, successfully seeking return of the animal from a noncompliant custodian, failing to effect a sterilization agreement when required for an animal which is released, or seeking legal recourse as provided in Iowa Code section 162.20(4). The pound or animal shelter shall be entitled to appeal pursuant to Iowa Code chapter 17A.

67.7(3) *Access to facilities and records.* The premises, housing facilities and records required by Iowa Code chapter 162 shall be open for inspection by authorized personnel of the Iowa department of agriculture and land stewardship during normal business hours.

67.7(4) *Seizure and impoundment.*

a. "Animals," as that term is used in this subrule, shall include any dog, cat, rabbit, rodent, nonhuman primate, fish other than live bait, bird, or other vertebrate animal. Animals, as that term is used in this subrule, shall not include members of the equine, bovine, porcine, ovine, or caprine species.

b. "Seizure and impoundment," as used in this subrule, may mean either of the following:

(1) The confinement of the animals to the property of the owner or custodian of the animals with provisions being made for the care of the animals pending review and final disposition.

(2) The physical removal of the animals to another facility for care pending review and final disposition.

c. Failure of any pound, animal shelter, pet shop, boarding kennel, commercial kennel, commercial breeder, public auction or dealer to adequately house, feed, water or care for the animals in the person's or facility's possession or custody may subject the animals to seizure and impoundment. Seizure and impoundment shall be at the discretion of the secretary. Standards to guide discretion shall include, but not be limited to, the following:

(1) An assessment of the condition of the animals, including, but not necessarily limited to, direct visual examination. Such assessment may include procedures and testing necessary to accurately determine disease, nutritional, and health status.

(2) An assessment as to the likelihood that the condition of the animals will deteriorate if action is not taken.

(3) An assessment as to the degree of failure to provide for the animals. Primary consideration will be based on the general health of the animals and the adequacy with which the animals are being fed, watered and sheltered.

(4) An assessment as to the history, if any, of the facility's compliance, noncompliance, and willingness to take corrective action. Such an assessment will be based on past inspection reports completed by regulatory personnel from the appropriate licensing agency.

(5) Court determination, if any, as to the existence of cruelty, abuse or neglect under Iowa Code chapter 717.

(6) The willingness of the facility to allow frequent monitoring and the ability of the department or local law enforcement officers to provide this service.

(7) A determination as to whether adequate impoundment facilities or resources exist and are available for use by the department for the seizure and impoundment of animals.

d. In proceeding under this subrule the department may either:

(1) Petition the court in the county where the facility is located for an ex parte court order authorizing seizure and impoundment, either separately or as part of an action commenced pursuant to Iowa Code chapter 717. The petition shall request an expedited hearing within seven days of the order for seizure and impoundment. The expedited hearing shall determine final disposition of the animals seized and impounded.

(2) Issue an administrative order authorizing seizure and impoundment. The order shall state the finding of facts on which the order was issued. The order shall be personally served upon the owner

or manager of the facility. If the owner or manager cannot be found after a reasonable effort to locate, the notice shall be posted conspicuously at the facility. The notice shall state the time and place of an administrative hearing to determine the appropriateness of the seizure and impoundment; and if such seizure and impoundment is upheld, then the hearing shall determine final disposition of the animals seized and impounded.

The administrative hearing shall be held within three days of the seizure unless a continuance is agreed upon by the department and the owner. A decision at the administrative hearing will not be stayed by the department for more than 48 hours pending appeal without a court order. However, the department may delay the disposition if the department determines the delay is desirable for the orderly disposition of the animals. Unless otherwise provided in this subrule, the department will follow adopted departmental rules on the conduct of the administrative hearing.

e. The release of animals for final disposition to the department will allow for the sale, adoption or euthanasia of the animals. Determination of the most appropriate option for final disposition of a specific animal shall reside with the department and be based on, but not limited to, the animal's physical health, the presence of any condition which would necessitate treatment of significant duration or expense, and the appropriateness of the animal as a pet. All due consideration shall be given to the sale or adoption of an animal as the preferable option of disposition.

f. Any moneys generated from the sale or adoption of animals shall be used to provide compensation for the cost of care of the animals while impounded or the cost of disposition. Any residual moneys shall be directed to the owner. If the moneys generated from the sale and adoption of the animals are insufficient to meet the costs incurred in caring for the animals, the difference may be recovered in an action against the owner of the animals.

g. The department may arrange for impoundment services, including final disposition, with any licensed facility able to adequately provide for the care and disposition of the animals. Animals for which an order is issued authorizing seizure and impoundment shall be individually identified and records maintained relating to their care and final disposition. The department, or their representatives, shall be allowed access during normal business hours to the records and animals impounded.

h. In lieu of seizure and impoundment, the secretary may authorize a one-time dispersal of animals, including by sale, as a remedial option. The owner may petition the department in writing for full or partial dispersal. The petition shall address the terms and conditions for dispersal which are being requested. The department may require additional terms and conditions. The terms and conditions governing dispersal will be contingent upon department approval. Such approval shall be in writing.

i. Conditions of this subrule, subrule 67.7(3), and Iowa Code sections 162.13 and 162.14 shall likewise apply to all eligible licensees and registrants, whether or not they have been properly licensed by Iowa Code chapter 162.

67.7(5) *Adoption by reference.* The secretary may adopt by reference or otherwise such provisions of the rules, regulations and standards under the federal Acts, with such changes therein appropriate to make them applicable to operations and businesses subject to Iowa Code chapter 162, which shall have the same force and effect as if promulgated under said chapter.

This rule is intended to implement Iowa Code sections 162.3, 162.4, 162.13 and 162.20.

21—67.8(162) Applicability to federally licensed facilities. Other than obtaining the certificate of registration from the secretary, any dealer or commercial breeder, and any person who operates a commercial kennel or public auction under a current and valid federal license shall not be subject to further regulation.

This rule is intended to implement Iowa Code subsection 162.11(2).

21—67.9(162) Acceptable forms of euthanasia. The euthanasia of all animals kept in facilities regulated under Iowa Code chapter 162 and these rules shall be performed in a manner deemed acceptable by and published in the 2007 American Veterinary Medical Association Guidelines on Euthanasia. A copy of this report is on file with the department.

This rule is intended to implement Iowa Code chapter 162.

21—67.10(162) Loss of license.

67.10(1) If a licensee has its license revoked or relinquishes its license while a revocation action is pending, the licensee shall not be eligible to reapply for a new license for at least three years from the date of the revocation or relinquishment. If the licensee has been found in court to have committed an act of animal cruelty or neglect, the licensee shall not be eligible for a new license for at least five years from the date of the revocation or relinquishment. The prohibition against relicensure in this subrule shall include any partnership, firm, corporation, or other legal entity in which the person has a substantial interest, financial or otherwise, and any person who has been or is an officer, agent or employee of the licensee if the person was responsible for or participated in the violation upon which the revocation or conviction was based. The department may waive the three-year bar to relicensure arising from a revocation or relinquishment of a license where a revocation action was pending. Such waiver shall be made on a case-by-case basis. Such a waiver shall only be given if the department finds that the conditions which resulted in the revocation or revocation action have been addressed and there is little likelihood that they will be replicated.

67.10(2) If a licensee has its license revoked or voluntarily relinquishes its license, the licensee shall file with the department a written plan detailing the numbers and types of animals in its facilities and how these animals are going to be legally disposed of to ensure that the animals are being humanely handled and to ensure that the remaining animals are being maintained properly. The licensee shall submit this plan to the department no later than ten calendar days from the date of revocation or relinquishment.

This rule is intended to implement Iowa Code section 162.13.

21—67.11(162) Dog day care.

67.11(1) *Definition.*

"Dog day care" means a facility licensed as a commercial kennel or a boarding kennel and designed and operated with the intention that a dog admitted to the facility is allowed, in compliance with this rule, to mingle and interact with other dogs in one or more playgroups operating in the facility. The purpose of a dog day care is to allow dogs participating in the day care to become socialized through interaction in playgroups with other compatible dogs. A kennel that operates as a dog day care shall not provide overnight boarding or other kennel activities unless, during the time that the day care operation is closed, the kennel is operated in a manner consistent with applicable kennel rules including, but not limited to, paragraph 67.2(1)*"k"* that restricts the commingling of dogs.

67.11(2) *Facility requirements.* A facility licensed to be a dog day care shall comply with the following facility requirements:

a. Buildings shall be of adequate structure and maintained in good repair so as to ensure protection of dogs from injury.

b. Shelter shall be provided to allow access to shade from direct sunlight and regress from exposure to rain or snow. Heat, insulation, or bedding adequate to provide comfort shall be provided when the atmospheric temperature is below 50° F or below that temperature to which the particular dogs are acclimated. Indoor facilities shall be provided for all dogs.

c. Indoor and outdoor facilities shall at all times be provided with ventilation by means of doors, windows, vents, air conditioning or direct flow of fresh air that is adequate to provide for the good health and comfort of the dogs. Such ventilation shall be environmentally provided to minimize drafts, moisture condensation, odors or stagnant vapors of excreta.

d. Ample lighting shall be provided by natural or artificial means or both during sunrise to sunset hours to allow efficient cleaning of the facilities and routine inspection of the facilities and dogs contained therein.

e. Ceilings, walls, floors, furniture, and play equipment shall be constructed to lend themselves to efficient cleaning and sanitizing. Such surfaces shall be kept in good repair and maintained so that they are substantially impervious to moisture. Floors and walls to a height of four feet shall have finished surfaces. Upholstered furniture or carpeting shall not be permitted in that portion of the facility to which dogs have access.

f. Food supplies and bedding materials shall be stored to adequately protect them from contamination or infestation by vermin or other factors that would render the food or bedding unclean. Separate storage facilities shall be maintained for cleaning and sanitizing equipment and supplies.

g. Washrooms, basins or sinks shall be provided within or be readily accessible to each facility for maintaining cleanliness among animal caretakers and sanitizing of food and water utensils.

h. Equipment shall be available for removal and disposal of all waste materials from the building to minimize vermin infestation, odors and disease hazards. Drainage systems shall be functional to achieve the above purposes.

i. Facilities shall be provided to isolate any dog that becomes sick or injured or that becomes otherwise incompatible with the other dogs.

j. Outdoor dog runs and exercise areas shall be of sound construction and kept in good repair so as to safely contain the dogs therein without injury. Floors shall be concrete, gravel or materials which can be regularly cleaned and kept free of waste accumulation. Grass runs and exercise areas are permissible provided adequate ground cover is maintained, holes are kept filled and the ground cover is not allowed to become overgrown.

k. Group interaction is permitted for dogs that are compatible with one another.

l. The play area for dogs shall provide for a minimum of 75 square feet per dog.

67.11(3) *Sanitation requirements.* A facility licensed to be a dog day care shall comply with the following sanitation standards:

a. All areas to which a dog has access shall be cleaned and sanitized a minimum of once in each 24-hour period and more frequently as may be necessary to reduce disease hazards and odors. Sanitizing shall be done by washing the surfaces with hot water and soap or detergent, followed by the application of a safe and effective disinfectant. Runs and exercise areas having gravel or other nonpermanent surface materials shall be sanitized by periodic removal of soiled materials, application of suitable disinfectants, and replacement with clean surface materials.

b. An effective program shall be established for the control of vermin infestation.

67.11(4) *Operations.* A facility licensed to be a dog day care shall comply with the following operational standards:

a. A dog, including a dog owned by the day care owner or a day care employee, shall be admitted into a day care only after the day care has:

(1) Subjected the dog to a preentry screening process that adequately evaluates the temperament of the dog, the dog's ability to interact with other dogs in a positive manner, and the dog's ability to interact with humans in a positive manner. The screening shall include, but is not limited to, obtaining a social history of the dog from the dog's owner. A written record of the testing shall be maintained by the facility for the time the dog is enrolled in the day care.

(2) Obtained from the dog's owner documentation of the medical history of the dog, including the dog's current vaccination status against distemper and rabies, unless exempted by direct, written recommendation of the owner's veterinarian or exempted by Iowa Code section 351.33 or 351.42.

(3) Determined through documentation or from obvious visual inspection that the dog is at least eight weeks of age.

(4) Obtained documentation that the dog has been spayed or neutered, if the dog is over six months of age.

(5) Obtained a written acknowledgment from the dog's owner that the owner understands the inherent risk of injury or disease when dogs owned by different people are allowed to commingle. This written acknowledgment shall be separately signed or initialed by the dog's owner.

b. The day care shall separate dogs in the day care into playgroups comprised of compatible dogs. Dogs of incompatible personalities or temperament shall be maintained separately.

c. The day care shall not admit any dog into the day care if the dog has a predisposition to be possessive of either the facility or a person owning or working in the facility.

d. The day care shall make advance arrangements with a veterinarian to provide emergency veterinary care for dogs at the day care.

e. A sick, diseased or injured dog shall be immediately removed from the playgroup and isolated. If circumstances indicate that immediate veterinary care is required, the dog shall be taken to a veterinarian or a veterinarian shall be called to examine the dog. The veterinarian can be either a veterinarian whose services have been contracted for by the day care or the veterinarian designated by the dog's owner, if a timely examination by that veterinarian is feasible.

f. Feeding of dogs and giving of snacks to a dog shall only be provided when the dog receiving the food or snack is outside the vision of the other dogs in the playgroup.

g. A day care shall not establish a playgroup composed of more than 15 dogs.

h. A day care shall employ sufficient staffing so that there is a minimum of one person assigned to each playgroup. The person supervising a playgroup shall be in continuous visual or auditory contact with the playgroup at all times.

This rule is intended to implement Iowa Code sections 162.6 and 162.9.

21—67.12(162) Fostering oversight organizations and foster care homes.

67.12(1) As used in this rule, unless the context otherwise requires:

"Foster care home" means a private residence that is authorized to provide temporary shelter and care for an animal which has been accepted by a fostering oversight organization.

"Fostering oversight organization" means a registered animal shelter or a registered pound, as defined in Iowa Code chapter 162, which has been authorized by the department to utilize foster care homes in its operation.

67.12(2) A registered animal shelter or registered pound shall not operate a foster care home or operate an organization that utilizes a foster care home unless the shelter or pound is in compliance with this rule and other applicable provisions of this chapter and Iowa Code chapter 162.

67.12(3) A registered animal shelter or registered pound may apply to the department for a permit authorizing the shelter or pound to utilize one or more foster care homes in carrying out its mission of providing for the care and maintenance of an animal which has been taken in or entrusted to the animal shelter or pound. For purposes of this rule, an animal shelter or pound which has been granted such authorization shall be considered a fostering oversight organization.

67.12(4) Neither a registered animal shelter nor a registered pound may utilize a foster care home unless the shelter or pound has been granted authorization by the department to be a fostering oversight organization. An animal shelter or pound which uses a foster care home without first obtaining a permit authorizing the shelter or pound to be a fostering oversight organization shall be considered to be operating illegally, shall be subject to suspension or revocation of its license to operate, and may be subject to other penalties authorized in Iowa Code chapter 162.

67.12(5) A registered animal shelter or registered pound seeking to obtain a permit to be a fostering oversight organization shall make application to the department on a form prescribed by the department. When feasible, the application shall be submitted to the department at the same time that the registered animal shelter or registered pound submits its certificate of registration renewal application. The permit application shall provide sufficient information to allow the department to determine the ability of the proposed fostering oversight organization to provide adequate screening and oversight of any foster care home operating under the authority of the fostering oversight organization. Such application shall include, but is not limited to, the following information:

a. The proposed fostering oversight organization's plan for screening a prospective foster care home. Such plan shall include the criteria to be used by the fostering oversight organization in determining whether a person who will be operating a foster care home is capable of caring for the animals that may be placed in the foster care home.

b. The proposed fostering oversight organization's plan for providing oversight to the foster care home. The plan shall include the frequency of inspections of the foster care home by the fostering oversight organization and the criteria to be used by the fostering oversight organization in reviewing the foster care home during periodic inspections. The plan shall also include the actions to be taken by the fostering oversight organization in the event that the fostering oversight organization determines that the foster care home is not adequately providing for the animals in the foster care home.

c. The name, address, and telephone number of the staff person connected with the proposed fostering oversight organization who will have primary responsibility for administering the proposed foster care program.

d. The name, address, and telephone number of a secondary staff person connected with the proposed fostering oversight organization who will have responsibility for administering the proposed foster care program in the absence of the primary administrator.

67.12(6) The initial approval of a fostering oversight organization shall be in effect only until the next expiration date of the registered pound or registered animal shelter's license. Thereafter, a fostering oversight organization permit renewal shall be concurrent with the facility's certificate of registration renewal, unless circumstances otherwise require.

67.12(7) A fostering oversight organization shall require that all persons seeking to operate a foster care home under the fostering oversight organization submit a written application to the fostering oversight organization specifying the proposed foster care home's qualifications, including, but not limited to, the ability of the foster care home to provide adequate care, exercise, feed, water, shelter, space, and veterinary care.

67.12(8) A fostering oversight organization shall not be authorized to approve more than 20 foster care homes. In granting a permit to a fostering oversight organization, the department may further restrict the number of foster care homes a particular fostering oversight organization may utilize if the department determines that the fostering oversight organization does not have adequate personnel to supervise the number of foster care homes for which authorization was sought. The department may authorize the fostering oversight organization to approve more than 20 foster care homes only if the department finds that the fostering oversight organization has and maintains adequate personnel assigned to provide sufficient oversight of foster care homes.

67.12(9) A fostering oversight organization shall not authorize a foster care home to have in its care more than 4 foster care animals over four months of age or 12 foster care animals less than four months of age, unless the foster care animals less than four months of age are from no more than two biological litters. When a nursing litter is placed in a foster care home, the nursing mother shall not be counted toward any applicable animal limitations for two weeks after the litter is weaned. Any approval of a foster care home shall not be interpreted to limit or override any local government's limitations on the number of animals that may be kept on a single premises.

67.12(10) A person who has been found to have engaged in or participated in an act constituting animal abandonment, neglect, cruelty, or abuse shall not be authorized to operate a foster care home. In addition, if a person has had a license or permit issued under Iowa Code chapter 162 or under the United States Department of Agriculture's animal care program revoked or has surrendered that person's license in lieu of revocation, then that person shall not be authorized to operate a foster care home.

67.12(11) A fostering oversight organization shall not place a sexually intact animal in a foster care home where there is a sexually intact animal of the opposite sex of the same species, unless the fostering oversight organization determines that the fostered animal is too young to breed. If the fostering oversight organization determines that a sexually intact animal may be placed in a foster care home with another sexually intact animal of the opposite sex of the same species because the fostered animal is too young to breed, then the fostering oversight organization shall monitor the physical development of the fostered animal to either remove the animal before it is capable of breeding or to neuter or spay the fostered animal.

67.12(12) The fostering oversight organization shall retain a copy of all the following documents for a period of 24 months and shall make such documents available for inspection by the department during regular business hours:

a. Applications to operate a foster care home, including any written approvals, conditional approvals, or denials.

b. Inspections or other reports relating to the operation of a foster care home.

c. Any written complaints or notes written by staff of the fostering oversight organization relating to an oral complaint against a foster care home.

d. Any documents relating to the investigation or other resolution of a complaint regarding a foster care home.

e. Any documents relating to the revocation or suspension of a foster care home's authorization.

67.12(13) The fostering oversight organization shall maintain detailed records as to which animals have been placed in a foster care home, when each animal was placed in a foster care home, and the ultimate disposition of each animal.

67.12(14) All adoptions and euthanasias of animals placed in a foster care home shall be the responsibility of the fostering oversight organization and shall not be performed by the foster care home, unless an emergency euthanasia must be performed by a licensed veterinarian to prevent the needless suffering of the animal.

67.12(15) All deaths, injuries, or emergency euthanasias occurring within a foster care home shall be reported to the fostering oversight organization within 24 hours of the event.

67.12(16) It is the primary responsibility of the fostering oversight organization to provide for oversight and regulation of its foster care homes; however, the department may choose to inspect a foster care home if the department determines that it would be in the best interests of the animals being maintained in the foster care home to conduct the inspection or if the department deems an inspection is desirable to determine whether a fostering oversight organization is properly fulfilling its role of screening and oversight of foster care homes. If the department determines that either serious or chronic problems exist in a foster care home, the department may order the fostering oversight organization to suspend or rescind the authorization of the foster care home. The fostering oversight organization shall immediately obtain physical examinations of all animals previously placed in the foster care home.

67.12(17) If the department determines that a fostering oversight organization is not providing adequate screening or oversight of its foster care homes, then the department may suspend or rescind the fostering oversight organization's authorization to use foster care homes.

67.12(18) If the department suspends or revokes the license of an animal shelter or pound and that animal shelter or pound is also a fostering oversight organization, then the authorization of the animal shelter or pound to operate as a fostering oversight organization shall immediately cease, and the authorization of the foster care homes operating under that fostering oversight organization shall also immediately cease.

This rule is intended to implement Iowa Code chapter 162.

21—67.13(162) Greyhound breeder or farm fee. A person who owns, keeps, breeds, or transports a greyhound dog for pari-mutuel wagering at a racetrack as provided in Iowa Code chapter 99D shall pay a fee of $40 for the issuance or renewal of a state license.

This rule is intended to implement 2010 Iowa Acts, House File 2280, section 5.

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CHAPTER 2
REGISTRATION

[Prior to 7/13/88, see Architectural Examiners, Board of[80]]

193B—2.1(544A,17A) Definitions. The following definitions apply as used in Iowa Code chapter 544A, and this chapter of the architectural examining board rules, unless the context otherwise requires.

"Applicant" means an individual who has submitted an application for registration to the board.

"Architectural Intern" means an individual who holds a professional degree from an NAAB-accredited program, has completed or is currently enrolled in the NCARB Intern Development Program and intends to actively pursue registration by completing the Architect Registration Examination.

"ARE" means the current Architect Registration Examination, as prepared and graded by the National Council of Architectural Registration Boards (NCARB).

"Examination" means the current Architect Registration Examination (ARE) accepted by the board.

"IDP" means Intern Development Program.

"IDP applicant" means an individual who has completed the IDP training requirements set forth in the NCARB Handbook for Interns and Architects and has submitted an application for registration to the board.

"Inactive" means that an architect is not engaged in Iowa in any practice for which a certificate of registration is required.

"Intern Architect" has the same meaning as "Architectural Intern."

"Issuance" means the date of mailing of a decision or order or the date of delivery if service is by other means unless another date is specified in the order.

"NAAB" means the National Architectural Accrediting Board.

"NCARB" means the National Council of Architectural Registration Boards.

"NCARB Handbook for Interns and Architects" means the most current edition of a document by the same title published by the National Council of Architectural Registration Boards. The document outlines the requirements for examination and registration as an architect and is available through the National Council of Architectural Registration Boards, 1801 K Street NW, Suite 1100, Washington, D.C. 20006; NCARB's Web site www.ncarb.org; the architectural examining board or the state law library.

"Retired" means that an architect is not engaged in the practice of architecture or earning monetary compensation by providing professional architectural services in any licensing jurisdiction of the United States or a foreign country.

193B—2.2(544A,17A) Application by reciprocity. Applicants for registration are required to make application to the National Council of Architectural Registration Boards (NCARB) for a certificate. A completed state application form (available on the board's Web site) and a completed NCARB certificate shall be filed in the board office before an application will be considered by the board.

2.2(1) *Registration requirements.* The board or its executive officer may waive examination requirements for applicants who, at the time of application, are registered as architects in a different jurisdiction, where the applicant's qualifications for registration are substantially equivalent to those required of applicants for initial registration in this state. All such applicants who hold an active NCARB certificate shall be deemed to possess qualifications that are substantially equivalent to those required of applicants for initial registration in this state.

2.2(2) *Applicants seeking architectural commission in Iowa.* A person seeking an architectural commission in this state may be admitted to this state for the purpose of offering to provide architectural services, and for that purpose only, without first being registered in this state if:

a. The person holds an NCARB certificate; and

b. The person holds a current and valid registration issued by a registration authority recognized by this state; and

c. The person notifies the board in writing on a form provided by the board that the person:

(1) Holds an NCARB certificate and a current and valid registration issued by a registration authority recognized by this state,

(2) Is not currently registered in this state but will be present in this state for the purpose of offering to provide architectural services on a temporary basis, and

(3) Has no previous or pending disciplinary action by any registration authority; and

d. The person delivers a copy of the notice referred to in paragraph *"c"* to every potential client to whom the person offers to provide architectural services; and

e. The person provides the board with a sworn statement of intent to apply immediately to the board for registration if selected as the architect for a project in this state.

The person is prohibited from actually providing architectural services until the person has been issued a valid registration in this state.

2.2(3) *Board refusal to issue registration.* The board may refuse to issue a certificate of registration to any person otherwise qualified upon any of the grounds for which a certificate of registration may be revoked or suspended or may otherwise discipline a registrant based upon a suspension, revocation, or other disciplinary action taken by a licensing authority in this or another jurisdiction. For purposes of this subrule, "disciplinary action" includes the voluntary surrender of a registration to resolve a pending disciplinary investigation or proceeding. A certified copy of the record or order of suspension, revocation, voluntary surrender, or other disciplinary action is prima facie evidence of such fact.

[**ARC 7737B**, IAB 5/6/09, effective 6/10/09]

193B—2.3(544A,17A) Application for registration by examination.

2.3(1) To be admitted to the examination, an applicant for registration shall have completed the eligibility requirements of the education standards for NCARB certification which include a professional degree from a program accredited by the National Architectural Accrediting Board (NAAB) or the Canadian Architectural Certification Board (CACB) and shall be enrolled in the NCARB Intern Development Program. NCARB shall notify the testing service of the applicant's eligibility prior to the applicant's scheduling of an examination.

2.3(2) Documentation of IDP training units shall be submitted on IDP report forms, published by NCARB, verified by signatures of registered architects serving as (1) the intern architect's supervisor in accordance with the requirements outlined in the NCARB Handbook for Interns and Architects, and (2) the intern architect's mentor, usually outside the intern's firm, with whom the intern has met for guidance and evaluation of the intern's progress in the IDP. The completed IDP report form shall demonstrate attainment of an aggregate of the minimum number of value units in each training area and shall be submitted to NCARB for evaluation.

2.3(3) All eligibility requirements shall have been verified and satisfied in accordance with the NCARB Handbook for Interns and Architects. The Handbook is available through NCARB, the architectural examining board or the state law library.

2.3(4) Applicants who have passed one or more but not all divisions of the ARE by January 1, 2006, shall have a rolling five-year period to pass each of the remaining divisions. A passing grade for any remaining division shall be valid for five years, after which time the division must be retaken if all remaining divisions have not been passed. The rolling five-year period shall commence after January 1, 2006, on the date when the first division that has been passed is administered. Applicants who have passed no divisions of the ARE by January 1, 2006, shall be governed by the above rolling five-year requirement. The rolling five-year period shall commence on the date when the first division that has been passed is administered. Any division passed prior to January 1, 2006, shall no longer remain valid if all remaining divisions have not been passed by July 1, 2014.

Effective January 1, 2011, and thereafter, the Authorization to Test of any applicant shall terminate unless the applicant has passed or failed a division of the ARE within a period of five years, which includes the five-year period prior to January 1, 2011. Any applicant whose authorization is so terminated must establish a new eligibility under the then-current procedures of the board.

2.3(5) To be eligible for registration, all applicants shall have passed all divisions of the ARE prepared and provided by NCARB, have completed the NCARB Intern Development Program, and

have attained an NCARB council record. A completed NCARB council record shall be transmitted to and filed in the board office. Upon receipt of the council record, the board shall provide the applicant with an application for registration form. The board shall issue a registration number to the applicant upon receipt of the completed application form and appropriate fee.

2.3(6) The board may refuse to issue a certificate of registration to any person otherwise qualified upon any of the grounds for which a registration may be revoked or suspended or may otherwise discipline a registrant based upon a suspension, revocation, or other disciplinary action taken by a licensing authority in this or another jurisdiction. For purposes of this subrule, "disciplinary action" includes the voluntary surrender of a registration to resolve a pending disciplinary investigation or proceeding. A certified copy of the record or order of suspension, revocation, voluntary surrender, or other disciplinary action is prima facie evidence of such fact.

[**ARC 8638B**, IAB 4/7/10, effective 5/12/10]

193B—2.4(544A,17A) Examination. Examinations for registration as an architect shall be conducted by the board or its authorized representative.

2.4(1) *Content and grading of the examination.* The board shall make use of the ARE prepared and graded by NCARB under a plan of cooperation with the architectural examining boards of all states and territories of the United States.

2.4(2) *Testing service.* The board may make use of a testing service selected by NCARB to administer the examination, provided the examination is held in at least one location within the boundaries of this state.

193B—2.5(17A,272C,544A) Renewal of certificates of registration.

2.5(1) *Active status.* Certificates of registration expire biennially on June 30. In order to maintain authorization to practice in Iowa, a registrant is required to renew the certificate of registration prior to the expiration date. A registrant who fails to renew by the expiration date is not authorized to practice architecture in Iowa until the certificate is reinstated as provided in rule 193B—2.6(544A,17A).

a. A registrant whose last name begins with the letter A through K shall renew in even-numbered years, and a registrant whose last name begins with the letter L through Z shall renew in odd-numbered years.

b. It is the policy of the board to mail to each registrant a notice of the pending expiration date at the registrant's last-known address approximately one month prior to the date the certificate of registration is scheduled to expire. Failure to receive this notice does not relieve the registrant of the responsibility to timely renew the certificate and pay the renewal fee. A registrant should contact the board office if the registrant does not receive a renewal notice prior to the date of expiration.

c. Upon the board's receipt of a timely and sufficient renewal application as provided in 193—subrule 7.40(3), the board's executive secretary shall issue a new certificate of registration reflecting the next expiration date, unless grounds exist for denial of the application.

d. If grounds exist to deny a timely and sufficient application to renew, the board shall send written notification to the applicant by restricted certified mail, return receipt requested. Grounds may exist to deny an application to renew if, for instance, the registrant failed to satisfy the continuing education as required as a condition for registration. If the basis for denial is pending disciplinary action or disciplinary investigation which is reasonably expected to culminate in disciplinary action, the board shall proceed as provided in 193—Chapter 7. If the basis for denial is not related to a pending or imminent disciplinary action, the applicant may contest the board's decision as provided in 193—subrule 7.40(1).

e. When a registrant appears to be in violation of mandatory continuing education requirements, the board may, in lieu of proceeding to a contested case hearing on the denial of a renewal application as provided in rule 193—7.40(546,272C), offer a registrant the opportunity to sign a consent order. While the terms of the consent order will be tailored to the specific circumstances at issue, the consent order will typically impose a penalty between $50 and $250, depending on the severity of the violation; establish deadlines for compliance; and require that the registrant complete hours equal to double the deficiency in addition to the required hours; and may impose additional educational requirements on the registrant.

Any additional hours completed in compliance with the consent order cannot again be claimed at the next renewal. The board will address subsequent offenses on a case-by-case basis. A registrant is free to accept or reject the offer. If the offer of settlement is accepted, the registrant will be issued a renewed certificate of registration and will be subject to disciplinary action if the terms of the consent order are not complied with. If the offer of settlement is rejected, the matter will be set for hearing, if timely requested by the applicant pursuant to 193—subrule 7.40(1).

f. The board may notify a registrant whose certificate of registration has expired. The failure of the board to provide this courtesy notification or the failure of the registrant to receive the notification shall not extend the date of expiration.

g. A registrant who continues to practice architecture in Iowa after the registration has expired shall be subject to disciplinary action. Such unauthorized activity may also be grounds to deny a registrant's application for reinstatement.

2.5(2) *Inactive status.* This subrule establishes a procedure under which a person issued a certificate of registration as an architect may apply to the board to register as inactive. Registration under this subrule is available to a certificate holder residing within or outside the state of Iowa who is not engaged in Iowa in any practice for which a certificate of registration as an architect is required. A person eligible to register as inactive may, as an alternative to such registration, allow the certificate of registration to lapse. During any period of inactive status, a person shall not use the title "architect" or any other title that might imply that the person is offering services as an architect by such an action in violation of Iowa Code section 544A.15. The board will continue to maintain a data base of persons registered as inactive, including information which is not routinely maintained after a certificate has lapsed through the person's failure to renew. A person who registers as inactive will accordingly receive renewal applications, board newsletters and other mass communications from the board.

a. *Affirmation.* The renewal application form shall contain a statement in which the applicant affirms that the applicant will not engage in any of the practices in Iowa that are listed in Iowa Code section 544A.16 without first complying with all rules governing reinstatement to active status. A person in inactive status may reinstate to active status at any time pursuant to rule 193B—2.8(544A).

b. *Renewal.* A person registered as inactive may renew the person's certificate of registration on the biennial schedule described in 193B—2.5(17A,272C,544A). This person shall be exempt from the continuing education requirements and will be charged a reduced renewal fee as provided in 193B—2.11(544A,17A). An inactive certificate of registration shall lapse if not timely renewed.

c. *Permitted practices.* A person may, while registered as inactive, perform for a client, business, employer, government body, or other entity those services which may lawfully be provided by a person to whom a certificate of registration has never been issued. Such services may be performed as long as the person does not in connection with such services use the title "architect" or any other title restricted for use only by architects pursuant to Iowa Code section 544A.15 (with or without additional designations such as "inactive). Restricted titles may be used only by active architects who are subject to continuing education requirements to ensure that the use of such titles is consistently associated with the maintenance of competency through continuing education.

d. *Prohibited practices.* A person who, while registered as inactive, engages in any of the practices described in Iowa Code sections 544A.15 and 544A.16 is subject to disciplinary action.

2.5(3) *Retired status.* A person registered as retired who does not reasonably expect to return to the workforce in any capacity for which a certificate of registration is required due to bona fide retirement or disability may use the title "architect retired" in the context of non-income-producing personal activities.

193B—2.6(544A,17A) Reinstatement of lapsed certificate of registration to active status. An individual may reinstate a lapsed certificate of registration to active status as follows:

2.6(1) If the individual's registration has been lapsed for up to 24 months, the individual may reinstate the registration by selecting either Option 1 or Option 2 as follows:

a. *Option 1.* The individual shall:

(1) Pay the reinstatement fee of $25 per month of expired registration;

(2) Pay the current renewal fee;

(3) Provide a written statement outlining the professional activities of the applicant during the period of nonregistration. The statement shall include a list of all projects with which the applicant had involvement and shall explain the service provided by the applicant; and

(4) Submit documented evidence of completion of 12 contact hours (8 hours in public protection subjects) of continuing education requirements for each year or portion of a year of expired registration in compliance with requirements in 193B—Chapter 3 in addition to the 24 hours (16 hours in public protection subjects) which should have been reported on the June 30 renewal date on which the applicant failed to renew. The continuing education hours used for reinstatement may not be used again at the next renewal. Out-of-state residents may submit a statement from their resident state's licensing board as documented evidence of compliance with their resident state's mandatory continuing education requirements during the period of nonregistration. The statement shall bear the seal of the licensing board. Out-of-state residents whose resident state has no mandatory continuing education shall comply with the documented evidence requirements outlined in this subrule.

b. *Option 2.* The individual shall:

(1) File a new application for registration as prescribed in rules 193B—2.2(544A,17A) and 193B—2.3(544A,17A), particularly subrules 2.2(1) and 2.3(3); and

(2) Provide a written statement outlining the professional activities of the applicant during the period of nonregistration. The statement shall include a list of all projects with which the applicant had involvement and shall explain the service provided by the applicant.

2.6(2) If an individual's registration has been lapsed for more than 24 months, the individual may reinstate the registration by selecting either Option 1 or Option 2 as follows:

a. *Option 1.* The individual shall:

(1) Pay the reinstatement fee of $25 per month of expired registration, up to a maximum of $750;

(2) Pay the current renewal fee;

(3) Provide a written statement outlining the professional activities of the applicant during the period of nonregistration. The statement shall include a list of all projects with which the applicant had involvement and shall explain the service provided by the applicant; and

(4) Submit documented evidence of completion of 12 contact hours (8 hours in public protection subjects) of continuing education requirements for each year or portion of a year of expired registration in compliance with requirements in 193B—Chapter 3 up to a maximum of 48 contact hours (32 hours in public protection subjects). The continuing education hours used for reinstatement may not be used again at the next renewal. Out-of-state residents may submit a statement from their resident state's licensing board as documented evidence of compliance with their resident state's mandatory continuing education requirements during the period of nonregistration. The statement shall bear the seal of the licensing board. Out-of-state residents whose resident state has no mandatory continuing education shall comply with the documented evidence requirements outlined in this subrule.

b. *Option 2.* The individual shall:

(1) File a new application for registration as prescribed in rules 193B—2.2(544A,17A) and 193B—2.3(544A,17A), particularly subrules 2.2(1) and 2.3(3); and

(2) Provide a written statement outlining the professional activities of the applicant during the period of nonregistration. The statement shall include a list of all projects with which the applicant had involvement and shall explain the service provided by the applicant.

193B—2.7(544A,17A) Reinstatement of lapsed certificate of registration to inactive status. An individual may reinstate a lapsed certificate of registration to inactive status as follows:

1. Pay the reinstatement fee of $25 per month of expired registration up to a maximum of $750;
2. Pay the current renewal fee;
3. Provide a written statement in which the applicant affirms that the applicant has not engaged in any of the practices in Iowa that are listed in Iowa Code section 544A.16 during the period of lapsed registration.

193B—2.8(544A) Reinstatement from inactive status or retired status to active status.

2.8(1) An individual may reinstate an inactive registration or retired registration to active registration as follows:

a. Pay the current active registration fee. If reinstating to active status at a date that is less than 12 months from the next biennial renewal date, one-half of the current active registration fee shall be paid.

b. Submit documented evidence of completion of 24 contact hours (16 contact hours in public protection subjects) of continuing education in compliance with requirements in 193B—Chapter 3. The hours used to reinstate to active status cannot again be used to renew.

(1) At the first biennial renewal date of July 1 that is less than 12 months from the date of the filing of the application to restore the certificate of registration to active status, the person shall not be required to report continuing education.

(2) At the first biennial renewal date of July 1 which is more than 12 months, but less than 24 months, from the date of the filing of the application to restore the certificate of registration to active status, the person shall report 12 hours of previously unreported continuing education.

2.8(2) An individual shall not be allowed to reinstate to inactive status from retired status.

193B—2.9(544A,17A) Finding of probable cause for unlicensed practice. The board may find probable cause to file charges for unlicensed practice if the individual continues to offer services defined as the practice of architecture outlined in Iowa Code section 544A.16 while using the title "architect," "architectural designer," or similar designation during the period of lapsed registration.

193B—2.10(544A) Practice by business entities. Before engaging in the practice of architecture in this state, a foreign or domestic business corporation, a foreign professional corporation, a partnership, or sole proprietorship shall acquire an Authorization to Practice Architecture as a Business Entity from the board as provided in Iowa Code section 544A.21.

2.10(1) Application for the authorization shall be made to the board on forms prescribed by the board and shall be accompanied by the proper fee as provided in rule 193B—2.11(544A,17A). The application shall include but not be limited to the following:

a. Name and address of the business entity;

b. Type of business entity, the federal identification number of the business entity or social security number if a sole proprietorship;

c. Names, addresses, and titles of the registered agent if a corporation, and of all officers, directors, partners, beneficial owners, or other principals of the business entity, or of the sole proprietor;

d. Name and address of each registered architect in responsible charge of the practice of architecture on behalf of the business entity in the state of Iowa;

e. Signature of an officer of a corporation, a partner of a partnership, or the sole proprietor.

2.10(2) A domestic professional corporation or professional limited liability company shall file with the board an application for Authorization to Practice Architecture as a Business Entity along with a copy of its annual report to the secretary of state.

2.10(3) A sole proprietorship shall file with the board an application for Authorization to Practice Architecture as a Business Entity only if practicing under an impersonal or fictitious name.

2.10(4) Upon approval of the Authorization to Practice Architecture as a Business Entity, the business entity shall not be required to apply for renewal of the authorization.

2.10(5) The business entity shall send notice to the board within 90 days of any change in name, address, registered agent if a corporation, officers, directors, partners, beneficial owners, or other principals of the business entity or any change in the name or address of each registered architect in responsible charge of the practice of architecture on behalf of the business entity in the state of Iowa.

2.10(6) A business entity which, after receiving authorization to practice architecture, is not in compliance with Iowa Code section 544A.21 or these rules as a result of a change in ownership or personnel shall take corrective action to bring the business entity back into compliance as soon as possible or apply to modify or amend the authorization. The board may grant a reasonable period of time, up to 90 days unless an extension is requested, for an entity to take such corrective action. Failure

to comply within a period of time deemed reasonable by the board shall result in the suspension or revocation of the authorization to practice architecture as a business entity.

2.10(7) A business entity that loses its authorization by cancellation or other board action shall immediately cease to conduct architectural practice in the state of Iowa.

2.10(8) When a business entity is issued a new federal identification number, a new application for authorization must be filed with the board.

193B—2.11(544A,17A) Fee schedule. Under the authority provided in Iowa Code chapter 544A, the following fees are hereby adopted:

Examination fees:	
Fees for examination subjects shall be paid directly to the testing service selected by NCARB	
Initial registration fee	$ 50
(plus $5 per month until renewal)	
Reciprocal application and registration fee	$200
Biennial renewal fee	$200
Biennial renewal fee (inactive)	$100
Biennial renewal fee (retired)	$ 50
Reinstatement of lapsed individual registration (per month)	$ 25
Duplicate wall certificate fee	$ 50

These rules are intended to implement Iowa Code chapters 544A and 17A.

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TITLE III
COMMUNITY COLLEGES

CHAPTER 21
COMMUNITY COLLEGES

[Prior to 9/7/88, see Public Instruction Department[670] Ch 5]
[Former Ch 21 Rescinded, IAB 9/7/88]

DIVISION I
APPROVAL STANDARDS

281—21.1(260C) Definitions. For purposes of this chapter, the indicated terms are defined as follows:

"Department" means the Iowa department of education.

"Director" means the director of the department.

[**ARC 8646B**, IAB 4/7/10, effective 5/12/10]

281—21.2(260C) Administration.

21.2(1) *Policy manual.* A community college board of directors shall develop and maintain a policy manual which adequately describes the official policies of the institution.

21.2(2) *Administrative staff.* A community college shall develop an administrative staff appropriate to the size and the purpose of the institution and one which permits the institution to function effectively and efficiently. This administrative staff shall provide effective leadership for the major divisions of the institution including administrative services, adult and continuing education, career and technical education, college parallel education, and student services.

21.2(3) *Chief executive officer.* A community college shall have a chief executive officer who shall also be the executive officer of the board of directors. The executive officer shall be responsible for the operation of the community college with respect to its educational program, its faculty and student services programs, and the use of its facilities. The executive officer shall delegate to the staff all necessary administrative and supervisory responsibilities to ensure an efficient operation of the institution.

21.2(4) *Financial records and reports.* The community college shall maintain accurate financial records and make reports in the form and pursuant to the timeline prescribed by the department and other state agencies.

21.2(5) *Enrollment.* A community college shall meet minimum enrollment requirements if it offers instruction as authorized in Iowa Code chapter 260C, and if, to the satisfaction of the state board of education, it is able to provide classes of reasonable economic size as needed by students, meets the needs of the students, and shows by its past and present enrollment and placement record that it meets individual and employment needs.

21.2(6) *Catalog.* The catalog shall be the official publication of the community college. It shall include accurate information on institutional policies, admissions requirements, procedures and fees, refund policies, residency requirements, program enrollment and degree requirements, due process procedures, affirmative action, and other information as recommended by the department. Students' rights and responsibilities may be included in the catalog or in a separate document.

21.2(7) *Admissions and program/course enrollment requirements.* The community college shall maintain an open-door admission policy for students of postsecondary age. This admission policy shall recognize that students should demonstrate a reasonable prospect for success in the program in which they are admitted. Applicants who cannot demonstrate a reasonable prospect for success in the program for which they apply should be assisted to enroll in courses where deficiencies may be remediated or into programs appropriate to the individual's preparation and objectives. The community college may set reasonable requirements for student enrollment in specified programs and courses. Admissions and program enrollment requirements established by each community college shall be published in the community college catalog.

21.2(8) *Academic year.* The academic year of the community college shall consist of semester, trimester, or quarter terms, and shall be a period of time beginning with the first day of the fall term and

continuing through the day preceding the start of the next fall term as indicated in the official college calendar. A community college may offer instruction in units of length (i.e., days and weeks) consistent with the identified scope and depth of the instructional content.

21.2(9) *Award requirements.* The director shall approve all new credit certificate, diploma, and degree award programs in accordance with Iowa Code section 260C.14. Awards from a community college shall be certified by the issuance of appropriate recognition, pursuant to award approval requirement guidelines issued by the department, indicating the type of program the student has completed. The minimum number and maximum number of credit hours required for each award type contained within this subrule may be waived pursuant to paragraph 21.2(13)*"i."*

a. Associate of arts (AA). The degree is awarded upon completion of a college parallel (transfer) course of study that provides a strong general education component to satisfy the lower division general education liberal arts and sciences requirements for a baccalaureate degree. An associate of arts degree shall consist of a minimum of 60 semester (90 quarter) credit hours and a maximum of 64 semester (96 quarter) credit hours.

b. Associate of science (AS). The degree is awarded upon completion of a course of study that requires a strong background in mathematics or science. The degree is intended to prepare students to transfer and initiate upper-division work in baccalaureate programs or prepare them for employment. An associate of science degree may also be awarded upon completion of a state-approved associate of science-career option (AS-CO) program of study that includes core technical coursework needed to complete a concentration in a specific field of study. The AS-CO program shall prepare students for entry-level careers and to complete requirements for transfer to a baccalaureate degree. An associate of science degree awarded upon completion of an arts and sciences course of study shall consist of a minimum of 60 semester (90 quarter) credit hours and a maximum of 64 semester (96 quarter) credit hours. An associate of science degree awarded upon completion of an AS-CO course of study shall consist of a minimum of 60 semester (90 quarter) credit hours and a maximum number of credit hours stated in program guidelines issued by the department. An associate of science degree awarded upon completion of an AS-CO course of study shall not consist of more than 70 semester (117 quarter) credit hours without an approved waiver pursuant to paragraph 21.2(13)*"i."*

c. Associate of general studies (AGS). The degree is awarded upon completion of a course of study that is primarily designed for the acquisition of a broad educational background rather than the pursuit of a specific college major or professional/technical program. It is intended as a flexible course of study and may include specific curriculum in lower division transfer, occupational education, or professional-technical education. An associate of general studies degree shall consist of a minimum of 60 semester (90 quarter) credit hours and a maximum of 64 semester (96 quarter) credit hours.

d. Associate of applied science (AAS). The degree is awarded upon completion of a state-approved program of study that is intended to prepare students for entry-level career and technical occupations. An associate of applied science degree shall consist of a minimum of 60 semester (90 quarter) credit hours and a maximum of 86 semester (129 quarter) credit hours. The general education component of the associate of applied science degree program shall consist of a minimum of 12 semester (18 quarter) credit hours of general education and shall include at least one course from each of the following areas: communications, social science or humanities, and mathematics or science. The technical specialty component of the associate of applied science degree shall constitute a minimum of 50 percent of the course credits.

e. Associate of applied arts (AAA). The degree is awarded upon completion of a state-approved program of study that is primarily intended for career training in providing students with professional skills for employment in a specific field of work such as arts, humanities, or graphic design. An associate of applied arts degree shall consist of a minimum of 60 semester (90 quarter) credit hours and a maximum of 86 semester (129 quarter) credit hours. The general education component of the associate of applied arts degree program shall consist of a minimum of 12 semester (18 quarter) credit hours of general education and shall include at least one course from each of the following: communications, social science or humanities, and mathematics or science. The technical specialty component of the associate of applied arts degree shall constitute a minimum of 50 percent of the course credits.

f. *Diploma.* The diploma is awarded upon completion of a state-approved program of study that is a coherent sequence of courses consisting of a minimum of 15 semester (22.5 quarter) credit hours and a maximum of 48 semester (72 quarter) credit hours including at least 3 semester (4.5 quarter) credit hours of general education. The general education component shall be from any of the following areas: communications, social science or humanities, and mathematics or science. A diploma may be a component of and apply toward subsequent completion of an associate of applied science or associate of applied arts degree.

g. *Certificate.* The certificate is awarded upon completion of a state-approved program of study that is designed for entry-level employment and shall consist of a maximum of 48 semester (72 quarter) credit hours. A certificate may be a component of and apply toward subsequent completion of a diploma or associate of applied science or associate of applied arts degree and may be developed in rapid response to the needs of business and industry. A certificate may consist of only career and technical courses and no general education course requirements.

21.2(10) *Academic records.* The community college shall maintain in perpetuity for each student the complete academic record including every course attempted and grade received. An official transcript must be created at the time of course enrollment. The credit hour(s) and grade must be recorded on the student's official transcripts upon completion of a community college course. These records shall be kept in disaster-resistant storage, unless other equivalent safeguards are used, such as maintaining duplicate files (electronic or otherwise) in separate facilities. The method of storage shall be consistent with current technology to ensure the ability to retrieve records. The community college shall implement a security plan that ensures the confidentiality of student records.

21.2(11) *Resident policy.* There shall be adopted for all community colleges a uniform policy for the determination of permanent residence for tuition purposes.

21.2(12) *Credit hours.* Credit hours shall be determined consistent with the following procedures.

a. Specifically stated criteria are minimal requirements only, which institutions may exceed at their discretion.

b. Conventional instruction is subdivided into four instructional methods as herein defined.

(1) Classroom work — lecture and formalized classroom instruction under the supervision of an instructor.

(2) Laboratory work — experimentation and practice by students under the supervision of an instructor.

(3) Clinical practice — applied learning experience in a health agency or office under the supervision of an instructor.

(4) Work experience — employment-related experience planned and coordinated by an institutional representative and the employer, with control and supervision of the student on the job being the responsibility of the employer.

c. No registration or orientation hours may be included when determining credit hours.

d. Institutions shall take into account the soundness of the learning environment being created by the scheduling sequence and length of classroom, laboratory, clinical, and work experience sessions. However, the final decision on these matters is left to the institutional administration so long as minimal standards are met.

e. Only minutes for students officially registered for courses or programs, including audit registration, may be included when determining credit hours.

f. Each community college must establish a policy that defines its methods of equating alternative instruction to credit hours and the process for evaluating the effectiveness of the alternative instruction to meet or exceed the expected student outcomes as if the course were taught utilizing conventional methods in paragraph 21.2(12)*"b."* Colleges will be held accountable for evaluating and maintaining high-quality programs, and their evaluations may be subject to department review. Students shall be expected to meet all approved course requirements and shall be expected to demonstrate the acquisition of knowledge and competencies/outcomes at the same level as those obtained in traditional classroom settings, in the time frames set by the institution. Alternative courses or programs of study must be approved by the college's review processes including faculty review and input. Courses shall be listed

in the college catalog. Instructional formats for which alternative methods of determining credit hours are applicable include the following:

(1) Accelerated courses (study, programs). Courses or programs of study that allow students to complete courses or programs at a faster pace than if offered by conventional methods. Courses and programs shall be tailored to involve more student participation and self-directed study. Instructors may teach in traditional classroom settings or by alternative methods specified in this subrule.

(2) Distance education. Courses or programs of study taught over the Internet, Iowa Communications Network (ICN), or other electronic means that allow students to receive instruction in the classroom or other sites, over personal computers, television, or other electronic means. Courses may or may not be interactive with direct communication between the teacher and students. Credit hours shall be awarded in accordance with the credit hours that would have been assigned if the course or program were taught by conventional methods.

1. Correspondence courses. Courses offered outside the classroom setting in which the instruction is delivered indirectly to the student. Instruction is provided through another medium, such as written material, computer, television, or electronic means. Course materials are sent to a student who follows a detailed syllabus to complete assignments. Students correspond with and transmit assignments to the instructor by telephone, computer, mail, or electronic means. A third party may administer tests.

2. Television courses. Courses or programs delivered primarily via broadcast television such as Iowa Public Television, digital video disc, or other media allowing students to receive instruction in a classroom or equipped remote location.

3. Video conference courses. Courses or programs delivered via a closed synchronous audio-video conferencing system such as the Iowa Communications Network or similar system which allows students to receive instruction in a classroom or any equipped remote location via an audio-video feed to a television, computer, or other electronic device.

4. Internet courses. Courses or programs delivered via the Internet. Courses may be taken using computers in a classroom setting or using personal computers or other electronic devices from the student's home or other location using an online content management system or mixed-media methods. Students may be linked at times directly with the instructor or with other students electronically. Interaction may be direct (synchronous) or indirect (asynchronous) allowing students to participate during their own time frames.

5. In-class hybrid courses. Courses or programs that combine traditional classroom and computer-based instruction. In-class sessions are offered with online instructional activities to promote independent learning and reduce seat-time.

(3) Self-paced instruction. Courses or programs that permit a student to enter at variable times or progress at the student's own rate of speed. Start and end dates may or may not correspond to the official college calendar. Contact or credit hours for self-paced programs or courses shall be computed by assigning to each registration the total number of credit or contact hours the student would have received if the student enrolled in a conventional program or course with stipulated beginning and ending dates.

(4) Arranged study. Instruction offered to students at times other than stated or scheduled class times to accommodate specific scheduling or program needs of students. Credit hours shall be awarded in accordance with the credit hours that would have been assigned if the course or program were taught by conventional methods.

(5) Multiformat nontraditional instruction. Instruction utilizing a variety of nontraditional methods that may incorporate self-paced learning, text, video, computer instructional delivery, accelerated training, independent study, Internet delivery, or other methods that do not follow standard classroom work guidelines. Credit hours shall be awarded in accordance with the credit hours that would have been assigned if the course or program were taught by conventional methods.

g. Individualized learning experiences for which an equivalent course is not offered shall have the program length computed from records of attendance using such procedures as a time clock or sign-in records. Individualized learning experiences means independent study courses in which an equivalent course is not offered by the college or listed in the college catalog. Independent study permits in-depth or focused learning on special topics of particular interest to the student.

h. Each course must have a minimum length of one credit hour. A fractional unit of credit may be awarded provided the course exceeds the minimum length of one credit hour.

i. Each credit hour shall consist of a minimum number of contact hours as defined in paragraphs 21.2(12)*"h"* to *"m."* One contact hour equals 50 minutes.

j. Classroom work.

(1) The minimal requirement for one semester hour of credit shall be 800 minutes (16 contact hours) of scheduled instruction.

(2) The minimal requirement for one quarter hour of credit shall be 533 minutes (10.7 contact hours) of scheduled instruction.

k. Laboratory work.

(1) The minimal requirement for one semester hour of credit shall be 1,600 minutes (32 contact hours) of scheduled laboratory work.

(2) The minimal requirement for one quarter hour of credit shall be 1,066 minutes (21.3 contact hours) of scheduled laboratory work.

l. Clinical practice.

(1) The minimal requirement for one semester hour of credit shall be 2,400 minutes (48 contact hours) of scheduled clinical practice.

(2) The minimal requirement for one quarter hour of credit shall be 1,599 minutes (32 contact hours) of scheduled clinical practice.

m. Work experience.

(1) The minimal requirement for one semester hour of credit shall be 3,200 minutes (64 contact hours) of scheduled work experience.

(2) The minimal requirement for one quarter hour of credit shall be 2,132 minutes (42.6 contact hours) of scheduled work experience.

21.2(13) *Career and technical program length.*

a. Program length for the associate of applied science (AAS) degree in career and technical education and for the associate of applied arts (AAA) degree shall consist of an academic program not to exceed two academic years. All required course offerings are to be available within two academic years. All required offerings in AAS and AAA degree programs shall not exceed a maximum of 86 semester (129 quarter) credit hours unless the department of education has granted a waiver pursuant to paragraph 21.2(13)*"i."* Programs shall not exceed an average of 19 credit hours per regular term.

b. All credit-bearing courses required for program admittance or graduation, or both, must be included in the 86 semester (129 quarter) credit hour maximum, with the exception of developmental credit hours. Prerequisites that provide an option to students for either credit or noncredit shall be counted toward the program maximum of 86 semester (129 quarter) credit hours. Prerequisite options that are only offered for noncredit will not be counted toward the 86 semester (129 quarter) credit hour maximum.

c. Associate of applied science (AAS) and associate of applied arts (AAA) programs that receive accreditation from nationally recognized accrediting bodies may appeal maximum credit hour length requirements to the department for consideration of a waiver. All AAS and AAA degree programs over the 86 semester (129 quarter) credit hour maximum must have approved program-length waivers pursuant to paragraph 21.2(13)*"i."*

d. Program length for the state-approved associate of science degree shall consist of an academic program that includes core technical coursework needed to complete a concentration in a specific field of study. The associate of science-career option program may prepare students for entry-level careers or allow students to complete requirements for a transfer to a baccalaureate degree. The associate of science-career option program shall not exceed the credit hour limit stated in department guidelines. To facilitate the transfer of students enrolling in associate of science-career option programs and awarded the associate of science transfer degree, each program shall have articulation agreements with baccalaureate degree programs meeting the articulation agreement requirements stated in department guidelines. The associate of science-career option program shall under no circumstances exceed a maximum of 70 semester (117 quarter) credit hours unless the department has granted a waiver pursuant to paragraph 21.2(13)*"i."*

e. All credit certificate and diploma programs as defined in subrule 21.2(9) shall not exceed 48 semester (72 quarter) credit hours.

f. Each course offered in the area of career and technical education shall be taught in the shortest practical period of time at a standard consistent with the quality and quantity of work needed to prepare the student for successful employment in the occupation for which instruction is being offered.

g. A full-time student in career and technical education shall be defined as a student enrolling in 12 or more semester credit hours or the equivalent in career and technical education.

h. Curricula in full-time career and technical education programs shall ordinarily be offered on the basis of student workload of 20 to 30 contact hours per week.

i. Waiver process. A college may petition the department to suspend in whole or in part a program-length requirement contained in paragraphs 21.2(12)*"h"* to *"m"* as applied to a specific program on the basis of the particular circumstances of that program.

(1) Waivers shall be issued at the director's sole discretion. Waivers shall be narrowly tailored and granted for a period no longer than two academic years, after which reapplication is required. A waiver may be granted on a long-term basis not to exceed ten years if issuing the waiver for a shorter period is not practical.

(2) All petitions for waiver must be submitted in writing to the department. A petition shall include the following information: specific waiver request including scope and duration, the relevant facts that the petitioner believes would justify a waiver, a detailed statement of the impact on student achievement, any information known regarding the department's treatment of similar cases, and any additional information deemed relevant by the petitioner. The department shall acknowledge a petition upon receipt.

(3) The department shall ensure that, within 30 calendar days, notice of pendency of the petition and a concise summary of its contents have been provided to a committee consisting of the chief academic officers of each community college. In addition, the department may give notice to other persons.

(4) A committee consisting of the chief academic officers of a majority of community colleges shall review the waiver request and provide a recommendation to the department regarding whether approval should be granted. Within 90 calendar days of receiving the recommendation, the department shall review the petition and issue a ruling. Failure of the department to grant or deny a petition within the required time period shall be deemed a denial of that petition. If a waiver is issued, the department shall provide a description of the precise scope and operative period to all interested parties.

21.2(14) *Faculty organization.* The faculty shall be organized in such a way as to promote communication among administration, faculty and students and to encourage faculty participation in the development of the curriculum, instructional procedures, general policies, and such other matters as are appropriate.

21.2(15) *Faculty salary allocation plan.* Pursuant to the appropriation of funds from the state general fund to the department for the purpose of supplementing community college faculty salaries, the department follows the formula herein when distributing such funds to community colleges.

a. For purposes of this subrule, the following definitions apply.

(1) "Full-time faculty" means those nonadministrative instructors, counselors, and librarians who are classified as full-time employees as defined in the college's collective bargaining agreement or written policy.

(2) "Part-time faculty" means those nonadministrative instructors, counselors, and librarians who are employed less than full-time as defined in the college's collective bargaining agreement and who are covered by the college's collective bargaining agreement. For purposes of the definition of "eligible full-time equivalent instructor," each part-time faculty person shall be counted as a fraction that accurately reflects the person's percentage of employment by the college when compared to a full-time faculty person.

(3) "Temporary/seasonal faculty" means those nonadministrative instructors, counselors, and librarians who are employed, full-time or part-time, by the college for short periods of time for specific purposes.

(4) "Adjunct faculty" means those nonadministrative instructors, counselors, and librarians who are employed without a continuing contract, whose teaching load does not exceed one-half time for two full semesters or three full quarters per calendar year.

(5) "Eligible full-time equivalent instructor" means the total of full-time faculty and part-time faculty where each full-time faculty counts as one, and each part-time faculty counts as a fraction that accurately reflects the person's percentage of employment by the college when compared to a full-time faculty person.

b. The appropriation shall be distributed to the community colleges based on their proportional share of eligible full-time equivalent instructors.

c. Moneys distributed to each community college pursuant to this subrule shall be rolled into the funding allocation for all future years. The use of the funds shall remain as described herein for all future years. The appropriation will be distributed to the community colleges in equal monthly payments made on or about the fifteenth of each month.

d. Moneys appropriated and distributed to community colleges pursuant to this subrule shall be used to supplement and not supplant any approved faculty salary increases or negotiated agreements, excluding the distribution of the funds herein. Eligible expenditures for the moneys appropriated are for salary expenditures and the required college contribution to FICA and IPERS or an alternative retirement benefits system. These moneys shall then be considered as part of the instructor's salary in future years.

e. Moneys distributed to a community college pursuant to this subrule shall be allocated to all full-time faculty and shall include part-time faculty covered by a collective bargaining agreement. The moneys shall be allocated pursuant to any existing negotiated agreements according to Iowa Code chapter 20. If no language exists to specify the method of allocation, the moneys shall be allocated equally to all full-time faculty with part-time faculty who are covered by a collective bargaining agreement receiving a prorated share.

f. A community college receiving funds distributed pursuant to this subrule shall determine the amount to be paid to instructors in accordance with Iowa Code section 260C.18D, subsection 4, and the amount determined to be paid to an individual instructor shall be divided evenly and paid in each pay period of the fiscal year.

This rule is intended to implement Iowa Code section 260C.33.

[**ARC 8646B**, IAB 4/7/10, effective 5/12/10]

281—21.3(260C) Faculty. Rescinded IAB 4/7/10, effective 5/12/10.

281—21.4(260C) Curriculum and evaluation.

21.4(1) *General education.* General education is intended to provide breadth of learning to the community college experience. General education imparts common knowledge, promotes intellectual inquiry, and stimulates the examination of different perspectives, thus enabling people to function effectively in a complex and changing world. General education tends to emphasize oral and written communication, critical analysis of information, knowledge and appreciation of diverse cultures, ways of knowing and human expression, knowledge of mathematical processes and natural sciences investigations, and ethics. General education courses are not intended to be developmental in nature. Each community college is responsible for clarifying, articulating, publicizing, and assessing its general education program.

21.4(2) *College parallel or transfer.*

a. This program shall offer courses that are the equivalent of the first two years of a baccalaureate program and may also include: such courses as may be necessary to develop skills that are prerequisite to other courses and objectives; and specialized courses required to provide career options within the college parallel or transfer program. College parallel or transfer programs are associate of arts and associate of science degree programs. General education courses in college parallel or transfer programs are required to be college transfer courses. A follow-up of students terminating shall be conducted to determine how well students have succeeded and which adjustments in the curriculum, if any, need to be made.

b. Courses of a developmental or remedial nature or prefreshman level shall not bear college transfer credit and shall be clearly identified in the college catalog. Developmental courses on the transcript shall be identifiable through the adoption of the community college common course numbering system.

21.4(3) *Career and technical education.* Instruction shall be offered in career and technical education programs in no less than five different occupational fields as defined by the department. College parallel or transfer courses may be offered as needed in career and technical education programs. Career and technical education programs, including associate of science-career option programs, must meet program approval requirements set by the state board of education. The director shall approve new career and technical education programs. Instruction shall be offered in career and technical education programs, ensuring that they are competency-based, contain all minimum competencies required by the department, articulate with local school districts' career and technical education programs, and comply with any applicable requirements in Iowa Code chapter 258. The occupational fields in which instruction is offered shall be determined by merged area and geographical area needs as identified by surveys in these areas. Occupational advisory committees may be used to assist in developing and maintaining instructional content, including leadership development.

21.4(4) *Adult and continuing education.* Adult education shall be offered and may include adult basic education, adult continuing and general education, college parallel or transfer, high school completion, supplementary and preparatory career education programs, and other programs and experiences as may be required to meet the needs of people in the merged area.

21.4(5) *Community services.* The community colleges shall provide a program of community services designed to meet the needs of persons residing in the merged area. The purpose of the community service program shall be to foster agricultural, business, cultural, industrial, recreational and social development in the area.

[**ARC 8646B**, IAB 4/7/10, effective 5/12/10]

281—21.5(260C) Library or learning resource center.

21.5(1) *Facilities.* Community college libraries or learning resource centers shall provide the facilities and resources needed to support the total educational program of the institution and shall show evidence that the facilities and the resources are being used effectively and efficiently. Adequate consideration shall be given to the seating, comfort, setting, and technology of the facility used to house the collection and learning resources.

21.5(2) *Staffing.* The library or learning resource center shall be adequately staffed with qualified professionals and skilled nonprofessional personnel.

21.5(3) *Collection.* The library and learning resource center materials collection of a community college shall be accessible and adequate in size and scope to serve effectively the number and variety of programs offered and the number of students enrolled, including distance and satellite sites. The library and learning resource center materials collection shall show evidence of having been selected by faculty as well as professional library or learning resource staff and shall be kept up-to-date through a planned program of acquisition and deletion. The library and learning resource center materials collection shall contain a range and number of print and nonprint materials and appropriate electronic information resources.

21.5(4) *Expenditures.* The budget of the library or learning resource center shall be appropriate for the programs and services offered by the institution. New programs and new curricula shall be reflected in library or learning resource center expenditures.

[**ARC 8646B**, IAB 4/7/10, effective 5/12/10]

281—21.6(260C) Student services. A program of student services shall be provided to meet the needs of students in the community college. The program of student services shall include, but not be limited to, the following functional areas:

1. Orientation to college and career opportunities and requirements.
2. Appraisal of individual potential.
3. Consultation with students about their plans, progress and problems.

4. Participation of students in activities that supplement classroom experiences.
5. Regulation to provide an optimal climate for social and academic development.
6. Services that facilitate community college attendance through a program of financial assistance, and facilitate transition to further education or employment.
7. Organization that provides for continuing articulation, evaluation and improvement of the student services program.
8. Campus safety and security as required by Iowa Code chapter 260C and the federal Clery Act, 20 U.S.C. Section 1092(f), 34 CFR Section 668.46.

[**ARC 8646B**, IAB 4/7/10, effective 5/12/10]

281—21.7(260C) Laboratories, equipment and supplies. Laboratories, equipment and supplies shall be comparable with those used in the occupations for which instruction is offered. Similarly, college parallel or transfer courses shall be supported in a manner comparable to those conditions which prevail in standard, regionally accredited colleges and universities in which students may wish to transfer college credits.

[**ARC 8646B**, IAB 4/7/10, effective 5/12/10]

281—21.8(260C) Physical plant. The site, buildings and equipment of the community college shall be well maintained and in good condition. At a minimum, a five-year ongoing, systematic maintenance and facilities plan approved by the local community college board shall be in evidence. The physical plant shall be adequate in size and properly equipped for the program offered. All remodeling of existing facilities shall comply with Iowa Code chapter 104A and the federal Americans With Disabilities Act, 42 U.S.C. Section 12101 et seq.

[**ARC 8646B**, IAB 4/7/10, effective 5/12/10]

281—21.9(260C) Nonreimbursable facilities. No facility intended primarily for events for which admission may be charged nor any facility specially designed for athletic or recreational activities, other than physical education, shall be constructed with state-appropriated funds.

[**ARC 8646B**, IAB 4/7/10, effective 5/12/10]

281—21.10(260C) Accreditation. Rescinded IAB 4/7/10, effective 5/12/10.

281—21.11(260C) Community college accreditation process. Rescinded IAB 4/7/10, effective 5/12/10.

281—21.12(260C) Standards for community colleges. Rescinded IAB 4/7/10, effective 5/12/10.

281—21.13 to **21.19** Reserved.

The rules in this division are intended to implement Iowa Code chapter 260C and 2007 Iowa Acts, Senate File 601.

DIVISION II
COMMUNITY COLLEGE ENERGY APPROPRIATIONS

281—21.20 to **21.29** Reserved.

DIVISION III
INSTRUCTIONAL COURSE FOR DRINKING DRIVERS

281—21.30(321J) Purpose. The purpose of the instructional course for drinking drivers is designed to inform the offender about drinking and driving and encourage the offender to assess the offender's own drinking and driving behavior in order to select practical alternatives.

281—21.31(321J) Course. A course provided according to this chapter shall be offered on a regular basis at each community college or by a substance abuse treatment program licensed under Iowa Code

chapter 125, and may be offered at a state correctional facility listed in Iowa Code section 904.102. However, a community college shall not be required to offer the course if a substance abuse treatment program licensed under Iowa Code chapter 125 offers the course within the merged area served by the community college.

Enrollment in the course is not limited to persons ordered to enroll, attend, and successfully complete the course required under Iowa Code sections 321J.1 and 321J.17, subsection 2. However, any person under the age of 18 who is required to attend the courses for violation of Iowa Code section 321J.2 or 321J.17 must attend a course offered by a substance abuse treatment program licensed under Iowa Code chapter 125.

Any instructional course shall be approved by the department of education in consultation with the community colleges, substance abuse treatment programs licensed under Iowa Code chapter 125, the Iowa department of public health, and the Iowa department of corrections. Each course of instruction shall establish the following:

1. An understanding that alcohol-related problems could happen to anyone and that a person's drinking choices matter. The course illustrates common views of society that prevent people from taking drinking choices seriously. Research is presented to challenge common views with an understanding that alcohol problems are related to lifestyle choices.
2. An understanding that specific low-risk choices will help reduce the risk of experiencing alcohol-related problems at any point in life. The course presents research-based, low-risk guidelines.
3. Methods of providing support for making low-risk choices.
4. An accurate description of the progression of drinking to the development of alcoholism to help people weigh the risk involved with high-risk drinking and to see how high-risk choices may jeopardize their lives and the lives of others.
5. Opportunities to develop a specific plan of action to follow through with low-risk choices. A list of community resources is provided for ongoing support and treatment as needed.

281—21.32(321J) Tuition fee established.

1. Each person enrolled in an instructional course for drinking drivers shall pay to the community college, a substance abuse treatment program licensed under Iowa Code chapter 125, or a state correctional facility a tuition fee of $85 for the approved 12-hour course, plus a reasonable book fee or $185 for the court-ordered approved 28-hour weekend course, plus a reasonable book fee. For the court-ordered approved 28-hour weekend course, the community college or the substance abuse treatment program licensed under Iowa Code chapter 125 shall set a reasonable fee for lodging, meals, and security.
2. A person shall not be denied enrollment in a course by reason of a person's indigency. For court-ordered placement, the court shall determine a person's indigency. In all other instances, the community college, substance abuse treatment program licensed under Iowa Code chapter 125, or state correctional facility shall determine indigence upon application.

281—21.33(321J) Administrative fee established.

21.33(1) *Students enrolled in Iowa.* Beginning January 1, 2003, each person enrolled in Iowa in an instructional course for drinking drivers under this chapter shall be charged an administrative fee of $10. This fee is in addition to tuition and shall be collected by the provider of the instructional course in conjunction with the tuition fee established under 281—21.32(321J). The administrative fee shall be forwarded to the department of education on a quarterly basis as prescribed by the department. If a student has been declared by the court as indigent, no administrative fee will be charged to that student.

21.33(2) *Students enrolled in another state.* Beginning January 1, 2004, each person enrolled outside the state of Iowa in an instructional course for drinking drivers under this chapter shall be charged an administrative fee of $25. This fee is in addition to tuition and shall be paid directly to the department of education by the student. Upon payment of the fee, the department of education shall review the educational component of the course taken by the student and shall inform the department of transportation whether the educational component is approved by the department of education.

281—21.34 Reserved.

The rules in this division are intended to implement Iowa Code section 321J.22 as amended by 2008 Iowa Acts, House File 2651, section 16.

DIVISION IV
JOBS NOW CAPITALS ACCOUNT

281—21.35 to **21.44** Reserved.

DIVISION V
STATE COMMUNITY COLLEGE FUNDING PLAN

281—21.45(260C) Purpose. A distribution plan for general state financial aid to Iowa's community colleges is established for the fiscal year commencing July 1, 1999, and succeeding fiscal years. Funds appropriated by the general assembly to the department of education for general financial aid to community colleges shall be allocated to each community college in the manner defined in this chapter.

21.45(1) Distribution formula. Moneys appropriated by the general assembly from the general fund to the department for community college purposes for general state financial aid for a budget year shall be allocated to each community college by the department according to the provisions of Iowa Code section 260C.18C.

21.45(2) Each community college shall provide student and financial information in the manner and form as determined by the department and before the deadline announced by the department. If the community college fails to provide the student or financial information as required, the department shall estimate the full-time equivalent enrollment (FTEE) of that college that will be used in the state general aid distribution formula.

21.45(3) Each community college shall be required to hire an auditing firm to complete and submit the schedule of credit-hour and contact-hour enrollment and a letter certifying that specified department of education procedures were followed. These schedules will be used in calculating the college's FTEE utilized in the community college state general aid distribution formula.

This rule is intended to implement Iowa Code section 260C.18C.

[**ARC 8646B**, IAB 4/7/10, effective 5/12/10]

DIVISION VI
INTERCOLLEGIATE ATHLETIC COMPETITION

281—21.46 to **21.56** Reserved.

DIVISION VII
QUALITY INSTRUCTIONAL CENTER INITIATIVE

281—21.57(260C) Purpose. Rescinded IAB 4/7/10, effective 5/12/10.

281—21.58(260C) Definitions. Rescinded IAB 4/7/10, effective 5/12/10.

281—21.59(260C) Eligibility requirements. Rescinded IAB 4/7/10, effective 5/12/10.

281—21.60(260C) Timelines. Rescinded IAB 4/7/10, effective 5/12/10.

281—21.61(260C) Evaluation and selection criteria. Rescinded IAB 4/7/10, effective 5/12/10.

281—21.62(260C) Funding. Rescinded IAB 4/7/10, effective 5/12/10.

281—21.63(260C) Annual report. Rescinded IAB 4/7/10, effective 5/12/10.

DIVISION VIII
PROGRAM AND ADMINISTRATIVE SHARING INITIATIVE
Rules 281—21.64(280A) to 21.71(280A), effective 12/20/91 were rescinded IAB 2/5/92, effective 1/7/92; these rules were readopted IAB 4/1/92, effective 5/6/92.

281—21.64(260C) Purpose. Rescinded IAB 4/7/10, effective 5/12/10.

281—21.65(260C) Definitions. Rescinded IAB 4/7/10, effective 5/12/10.

281—21.66(260C) Eligibility requirements. Rescinded IAB 4/7/10, effective 5/12/10.

281—21.67(260C) Timelines. Rescinded IAB 4/7/10, effective 5/12/10.

281—21.68(260C) Evaluation and selection criteria. Rescinded IAB 4/7/10, effective 5/12/10.

281—21.69(260C) Funding. Rescinded IAB 4/7/10, effective 5/12/10.

281—21.70(260C) Annual report. Rescinded IAB 4/7/10, effective 5/12/10.

281—21.71(260C) Combining merged areas—election. Rescinded IAB 4/7/10, effective 5/12/10.

DIVISION IX
APPRENTICESHIP PROGRAM

281—21.72(260C) Purpose. The purpose of the apprenticeship program is to provide individuals, at least 16 years of age, except where a higher minimum age standard is otherwise fixed by law, employment to learn a skilled trade or an occupation; and to authorize each community college to establish or contract for the establishment of apprenticeship programs for apprenticeable occupations.

281—21.73(260C) Definitions. For the purpose of Division IX, the following definitions shall apply:

"Apprentice" shall mean a worker at least 16 years of age, except where a higher minimum age standard is otherwise fixed by law, who is employed to learn a skilled trade or occupation under the standards of apprenticeship.

"Apprenticeable occupation" is a skilled trade which possesses all of the following characteristics:

1. It is customarily learned in a practical way through a structured, systematic program of on-the-job, supervised training.
2. It is clearly identified and commonly recognized throughout an industry.
3. It involves manual, mechanical or technical skills and knowledge which require a minimum of 2,000 hours of on-the-job work experience.
4. It requires related instruction to supplement on-the-job training.

"Apprenticeship agreement" shall mean a written agreement between an apprentice and the apprentice's employer, or an apprenticeship committee acting as the agent for the employer(s). The agreement contains the terms and conditions of the employment and training of the apprentice.

"Apprenticeship committee" shall mean those persons designated by the sponsor to act for it in the administration of the program. A committee may be "joint," i.e., composed of an equal number of representatives of the employer(s) and of the employees represented by a bona fide collective bargaining agent(s), and is established to conduct, operate, or administer an apprenticeship program and enter into apprenticeship agreements with apprentices. A committee may be "unilateral" or "nonjoint" and shall mean a program sponsor in which a bona fide collective bargaining agent is not a participant.

"Apprenticeship instructor" shall mean an instructor who delivers related and technical instruction in apprenticeship programs and who must meet the department's requirements for career and technical instructors or be recognized as a subject matter expert. It is recommended that all apprenticeship instructors have training in teaching techniques and adult learning styles.

"Apprenticeship program" shall mean a plan containing all terms and conditions for the qualification, recruitment, selection, employment and training of apprentices, including such matters

as required under 29 CFR Parts 29 and 30, including the requirement for a written apprenticeship agreement.

"Cancellation" shall mean the termination of the registration or approval status of a program at the request of the sponsor or termination of an apprenticeship agreement at the request of the apprentice.

"Certification" or *"certificate"* shall mean documentary evidence that at least one of the following has been met:

1. The Office of Apprenticeship has approved a set of National Guidelines for Apprenticeship Standards developed by a national committee or organization, joint or unilateral, or policy or guideline used by local affiliates, as conforming to the standards of apprenticeship set forth in 29 CFR Section 29.5;
2. A registration agency has established that an individual is eligible for probationary employment as an apprentice under a registered apprenticeship program.
3. A registration agency has registered an apprenticeship program as evidenced by a certificate of registration or other written indicia;
4. A registration agency has determined that an apprenticeship has successfully met the requirements to receive an interim credential; or
5. A registration agency has determined that an individual has successfully completed an apprenticeship.

"Competency" shall mean the attainment of manual or technical skill and knowledge as specified by an occupational standard.

"Employer" shall mean any person or organization employing an apprentice whether or not such person or organization is a party to an apprenticeship agreement with the apprentice.

"Journeyworker" shall mean a worker who has attained a level of skill and competency recognized within an industry as having mastered the skills and competencies required for the occupation.

"Office of Apprenticeship" shall mean the office designated by the Employment and Training Administration to administer the National Apprenticeship System or its successor organization.

"Registration agency" shall mean the Office of Apprenticeship.

"Registration of an apprenticeship agreement" shall mean the acceptance and recording of an apprenticeship agreement by the Office of Apprenticeship as evidence of the apprentice's participation in a particular registered apprenticeship program.

"Related instruction" or *"related technical instruction"* shall mean an organized and systematic form of instruction designed to provide the apprentice with the core knowledge of the theoretical and technical subjects related to the apprentice's occupation. Such instruction may be given in a classroom through occupational or industrial courses, by correspondence courses of equivalent value, by electronic media, or by other forms of self-study approved by the registration agency.

"Sponsor" shall mean any person, association, committee or organization operating an apprenticeship program and in whose name the program is (or is to be) registered or approved.

"Supplemental instruction" shall mean instruction in non-core-related requirements; for example, job site management, leadership, communications, first aid/CPR, field trips, and new technologies.

[**ARC 8646B**, IAB 4/7/10, effective 5/12/10]

281—21.74(260C) Apprenticeship programs. For an apprenticeship program to be offered by a community college or a local educational agency, the program must be approved by the U.S. Department of Labor, Office of Apprenticeship, and meet all requirements outlined in the National Apprenticeship Act, 29 U.S.C. Section 50, 29 CFR Parts 29 and 30.

[**ARC 8646B**, IAB 4/7/10, effective 5/12/10]

The rules in this division are intended to implement Iowa Code section 260C.44 and the National Apprenticeship Act, 29 U.S.C. Section 50, and 29 CFR Parts 29 and 30.

DIVISION X
MISCELLANEOUS PROVISIONS

281—21.75(260C,82GA,SF358) Used motor vehicle dealer education program. An applicant for a license from the department of transportation as a used motor vehicle dealer shall complete a minimum of eight hours of prelicensing education program courses pursuant to 2007 Iowa Acts, Senate File 358, prior to submitting the application. The education program courses are provided by community colleges or by the Iowa Independent Automobile Dealers Association in conjunction with a community college. The fee for both the prelicensing education program courses and continuing education courses shall not exceed $50 per contact hour of instruction, which shall include course materials and administrative costs.

This rule is intended to implement Iowa Code chapter 260C and 2007 Iowa Acts, Senate File 358.

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◊ Two or more ARCs

CHAPTER 23
ADULT EDUCATION

[Prior to 9/7/88, see Public Instruction Department[670] Ch 34]

281—23.1(260C) Planning process.

23.1(1) *Basis.* A state plan for adult education shall be developed as required by federal legislation. The plan shall be in such detail as the state director of education shall prescribe. Current federal rules and regulations shall be followed in developing the state plan.

23.1(2) *Participatory planning committee.* The department of education shall involve a participatory planning committee in the development of the plan. The participatory planning committee shall include representatives of various agencies, groups, and organizations. The state plan shall provide for the selection of representatives and the manner in which the representatives will be involved in the development of the state plan. If the participatory planning committee is not able to agree upon a final plan, the department of education shall make the final decision. The state plan shall include notation of recommendations rejected and the reason for the rejection.

[**ARC 8645B**, IAB 4/7/10, effective 5/12/10]

281—23.2(260C) Final plan. The final plan shall be approved by the state board of education and implemented statewide. A copy of the final plan shall be made available to all individuals in the state upon request to the department of education.

[**ARC 8645B**, IAB 4/7/10, effective 5/12/10]

These rules are intended to implement Iowa Code section 260C.1.

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CHAPTER 24
COMMUNITY COLLEGE ACCREDITATION

281—24.1(260C) Purpose. As set forth in Iowa Code section 260C.1, the purpose of accreditation of Iowa's community colleges is to confirm that each college is offering, to the greatest extent possible, educational opportunities and services, when applicable, but not be limited to:

1. The first two years of college work including preprofessional education.
2. Career and technical training.
3. Programs for in-service training and retraining of workers.
4. Programs for high school completion for students of post-high school age.
5. Programs for all students of high school age, who may best serve themselves by enrolling for career and technical training, while also enrolled in a local high school, public or private.
6. Programs for students of high school age to provide advanced college placement courses not taught at a student's high school while the student is also enrolled in the high school.
7. Student personnel services.
8. Community services.
9. Career and technical education for persons who have academic, socioeconomic, or other disabilities which prevent succeeding in regular career and technical education programs.
10. Training, retraining, and all necessary preparation for productive employment of all citizens.
11. Career and technical training for persons who are not enrolled in a high school and who have not completed high school.
12. Developmental education for persons who are academically or personally underprepared to succeed in their program of study.

[**ARC 8644B**, IAB 4/7/10, effective 5/12/10]

281—24.2(260C) Scope. Each community college is subject to accreditation by the state board of education, as provided in Iowa Code section 260C.47. The state board of education shall grant accreditation if a community college meets the standards established in this chapter.

281—24.3(260C) Definitions. For purposes of interpreting rule 281—24.5(260C), the following definitions shall apply:

"Department." Department refers to the Iowa department of education.

"Director." Director refers to the director of the department.

"Field of instruction." The determination of what constitutes each field of instruction should be based on accepted practices of regionally accredited two- and four-year institutions of higher education.

"Full-time instructor." An instructor is considered to be full-time if the community college board of directors designates the instructor as full-time. Consideration of determining full-time status shall be based on local board-approved contracts.

"Higher Learning Commission." The Higher Learning Commission is the accrediting authority within the North Central Association of Colleges and Schools. Iowa Code sections 260C.47 and 260C.48 require that the state accreditation process be integrated with that of the North Central Association of Colleges and Schools.

"Instructors meeting minimum requirements." A community college instructor meeting the minimum requirements of Iowa Code Supplement section 260C.48(1) as amended by 2008 Iowa Acts, House File 2679, is an instructor under contract for at least half-time or more teaching college credit courses. Beginning July 1, 2011, a community college instructor meeting the minimum requirements is an instructor teaching college credit courses. Credit courses shall meet requirements as specified in rule 281—21.2(260C), and meet program requirements for college parallel, career and technical education, and career-option programs as specified in rule 281—21.4(260C) and Iowa Code chapter 260C.

"Joint enrollment." Joint enrollment refers to any community college credit course offered to students enrolled in a secondary school. Courses offered for joint enrollment include courses delivered through contractual agreements between school districts and community colleges, courses delivered

through the postsecondary enrollment options program, and college credit courses taken independently by tuition-paying secondary school students.

"Minimum of 12 graduate hours." Full-time arts and sciences instructors must possess a master's degree and complete a minimum of 12 graduate hours in their field of instruction. The 12 graduate hours may be within the master's degree requirements or independent of the master's degree, but all hours must be in the instructor's field of instruction.

"Organization." Organization is synonymous with community college and is used in this chapter to align with accreditation terminology used by the Higher Learning Commission.

"Recent and relevant work experience." An hour of recent and relevant work experience is equal to 60 minutes. The community college shall determine what constitutes recent and relevant work experience that relates to the instructor's occupational and teaching area. The college shall maintain documentation of the instructor's educational and work experience.

[**ARC 8644B**, IAB 4/7/10, effective 5/12/10]

281—24.4(260C) Accreditation components and criteria—Higher Learning Commission. In order to be accredited by the state board of education and maintain accreditation status, a community college must meet the accreditation criteria of the Higher Learning Commission and additional state standards. Accreditation shall be maintained either by the Program to Evaluate Academic Quality (PEAQ) or the alternative Academic Quality Improvement Program (AQIP) process. The Higher Learning Commission criteria for accreditation are as follows:

24.4(1) *Mission and integrity.* The organization operates with integrity to ensure the fulfillment of its mission through structures and processes that involve the board, administration, faculty, staff, and students.

a. The organization's mission documents are clear and articulate publicly the organization's commitments.

b. In its mission documents, the organization recognizes the diversity of its learners, other constituencies, and the greater society it serves.

c. Understanding of and support for the mission pervade the organization.

d. The organization's governance and administrative structures promote effective leadership and support collaborative processes that enable the organization to fulfill its mission.

e. The organization upholds and protects its integrity.

24.4(2) *Preparing for the future.* The organization's allocation of resources and its processes for evaluation and planning demonstrate its capacity to fulfill its mission, improve the quality of its education, and respond to future challenges and opportunities.

a. The organization realistically prepares for a future shaped by multiple societal and economic trends.

b. The organization's resource base supports its educational programs and its plans for maintaining and strengthening the program's quality in the future.

c. The organization's ongoing evaluation and assessment processes provide reliable evidence of institutional effectiveness that clearly informs strategies for continuous improvement.

d. All levels of planning align with the organization's mission, thereby enhancing the organization's capacity to fulfill that mission.

24.4(3) *Student learning and effective teaching.* The organization provides evidence of student learning and effective teaching that demonstrates it is fulfilling its educational mission.

a. The organization's goals for student learning outcomes are clearly stated for each educational program and make effective assessment possible.

b. The organization values and supports effective teaching.

c. The organization creates effective learning environments.

d. The organization's learning resources support student learning and effective teaching.

24.4(4) *Acquisition, discovery, and application of knowledge.* The organization promotes a life of learning for its faculty, administration, staff, and students by fostering and supporting inquiry, creativity, practice, and social responsibility in ways consistent with its mission.

a. The organization demonstrates, through the actions of its board, administrators, students, faculty, and staff, that it values a life of learning.

b. The organization demonstrates that acquisition of a breadth of knowledge and skills and the exercise of intellectual inquiry are integral to its educational programs.

c. The organization assesses the usefulness of its curricula to students who will live and work in a global, diverse, and technological society.

d. The organization provides support to ensure that faculty, students, and staff acquire, discover, and apply knowledge responsibly.

24.4(5) *Engagement and service.* As called for by its mission, the organization identifies its constituencies and serves them in ways both value.

a. The organization learns from the constituencies it serves and analyzes its capacity to serve their needs and expectations.

b. The organization has the capacity and the commitment to engage with its identified constituencies and communities.

c. The organization demonstrates its responsiveness to those constituencies that depend on the organization for service.

d. Internal and external constituencies value the services the organization provides.

24.4(6) *Documentation.* Documents and materials provided in accordance with the accreditation requirements of the Higher Learning Commission shall also be provided to the department for the state accreditation process.

[**ARC 8644B**, IAB 4/7/10, effective 5/12/10]

281—24.5(260C) Accreditation components and criteria—additional state standards. To be granted accreditation by the state board of education, an Iowa community college shall also meet additional standards pertaining to minimum or quality assurance standards for faculty (Iowa Code section 260C.48(1)); faculty load (Iowa Code section 260C.48(2)); special needs (Iowa Code section 260C.48(3)); career and technical education program evaluation (Iowa Code section 258.4(7)); quality faculty plan (Iowa Code section 260C.36); and senior year plus programs (Iowa Code chapter 261E).

24.5(1) *Faculty.* Community college-employed instructors who are under contract for at least half-time or more, and by July 1, 2011, all instructors who teach in career and technical education or arts and sciences shall meet minimum standards. In accordance with Iowa Code Supplement section 260C.48(1) as amended by 2008 Iowa Acts, House File 2679, standards shall at a minimum require that community college instructors who are under contract for at least half-time or more, and by July 1, 2011, all instructors meet the following requirements:

a. Instructors in the subject area of career and technical education shall be registered, certified, or licensed in the occupational area in which the state requires registration, certification, or licensure, and shall hold the appropriate registration, certificate, or license for the occupational area in which the instructor is teaching, and shall meet either of the following qualifications:

(1) A baccalaureate or graduate degree in the area or a related area of study or occupational area in which the instructor is teaching classes.

(2) Special training and at least 6,000 hours of recent and relevant work experience in the occupational area or related occupational area in which the instructor teaches classes if the instructor possesses less than a baccalaureate degree.

b. Instructors in the subject area of arts and sciences shall meet either of the following qualifications:

(1) Possess a master's degree from a regionally accredited graduate school, and have successfully completed a minimum of 12 credit hours of graduate level courses in each field of instruction in which the instructor is teaching classes.

(2) Have two or more years of successful experience in a professional field or area in which the instructor is teaching classes and in which postbaccalaureate recognition or professional licensure is necessary for practice, including but not limited to the fields or areas of accounting, engineering, law, law enforcement, and medicine.

c. Developmental education and adult education instructors employed half-time or more may or may not meet minimum requirements depending on their teaching assignments and the relevancy of standards to the courses they are teaching and the transferability of such courses. If instructors are teaching credit courses reported in arts and sciences or career and technical education, it is recommended that these instructors meet minimum standards set forth in 281—subrule 21.3(1), paragraph *"a"* or *"b."* By July 1, 2011, all instructors teaching credit courses shall meet minimum standards.

24.5(2) *Faculty load.*

a. *College parallel or transfer.* The full-time teaching load of an instructor in college parallel or transfer programs shall not exceed a maximum of 16 credit hours within a traditional semester or the equivalent. An instructor may also have a teaching assignment outside of the normal school hours, provided the instructor consents to this additional assignment and the total workload does not exceed the equivalent of 18 credit hours within a traditional semester or the equivalent thereof.

b. *Career and technical education.* The full-time teaching load of an instructor in career and technical education programs shall not exceed 6 hours per day, and an aggregate of 30 hours per week or the equivalent. An instructor may also teach the equivalent of an additional 3 credit hours, provided the instructor consents to this additional assignment. When the teaching assignment includes classroom subjects (nonlaboratory), consideration shall be given to establishing the teaching load more in conformity with that of paragraph 24.5(2)*"a."*

24.5(3) *Special needs.* Community colleges shall provide equal access in recruitment, enrollment, and placement activities for students with disabilities. Students with disabilities shall be given access to the full range of course offerings at a college through reasonable accommodations.

24.5(4) *Career and technical education evaluation.* The director of the department shall annually review at least 20 percent of the approved career and technical programs as a basis for continuing approval. The community college career and technical program review and evaluation system must ensure that the programs:

a. Are compatible with educational reform efforts.

b. Are capable of responding to technological change and innovation.

c. Meet educational needs of the students and employment community, including students with disabilities, both male and female students, and students from diverse racial and ethnic groups.

d. Enable students enrolled to perform the minimum competencies independently.

e. Are articulated/integrated with the total school curriculum.

f. Enable students with a secondary career and technical background to pursue other educational interests in a postsecondary setting, if desired.

g. Provide students with support services and eliminate access barriers to education and employment for both traditional and nontraditional students, men and women, persons from diverse racial and ethnic groups, and persons with disabilities.

24.5(5) *Facilities, parking lots and roads.*

a. *Facilities master planning.* Each community college shall present evidence of adequate planning, including a board-approved facilities plan. Planning includes tentative program approval, a master campus plan, written educational specifications, site plot showing location of proposed and existing facilities, elevations and floor plans.

b. *Accessibility and safety.* All new or remodeled facilities (buildings and programs offered in such facilities) and services in such facilities shall be made functional and usable for persons with special needs and shall comply with Iowa Code chapter 104A and the Americans With Disabilities Act, 42 U.S.C. § 12101, and address issues of campus safety and security as required by Iowa Code chapter 260C and by the federal Clery Act, 20 U.S.C. § 1092(f). All parking areas and roads shall comply with all state and federal rules and regulations dealing with roads, parking ramps, and accessibility requirements.

c. *Adequate facilities.* All administrative facilities, classrooms, laboratories, and related facilities shall be educationally adequate for the purpose for which they are designed.

d. *Library or learning resource center.* A library or learning resource center shall be planned as part of the master campus plan and space made for library or learning resource center services within the initial construction.

e. *Student center.* An area of the college shall be provided where students may gather informally and where food is available.

24.5(6) *Strategic planning.* The community college shall prepare a five-year strategic plan to guide the college and its decision making. Consideration shall be given to the five-year statewide strategic plan, as required by Iowa Code section 256.31(4)(a), in the development of the college's strategic plan.

24.5(7) *Quality faculty plan.* The community college shall establish a quality faculty committee consisting of instructors and administrators to develop and maintain a plan for hiring and developing quality faculty. The committee shall have equal representatives of arts and sciences and career and technical faculty with no more than a simple majority of members of the same gender. Faculty shall be appointed by the certified employee organization representing faculty, if any, and administrators shall be appointed by the college's administration. If no faculty-certified employee organization representing faculty exists, the faculty shall be appointed by administration pursuant to Iowa Code section 260C.48(4). The committee shall submit the plan to the board of directors for consideration, approval and submittal to the department of education.

a. For purposes of this subrule, the following definitions shall apply.

(1) "Counselor" means those who are classified as counselors as defined in the college's collective bargaining agreement or written policy.

(2) "Media specialist" means those who are classified as media specialists as defined in the college's collective bargaining agreement or written policy.

b. The institutional quality faculty plan is applicable to all community college-employed faculty teaching college credit courses, counselors, and media specialists. The plan requirements may be differentiated for each type of employee. The plan shall include, at a minimum, each of the following components:

(1) Plan maintenance. The quality faculty committee shall submit proposed plan modifications to the board of directors for consideration and approval. It is recommended that the plan be updated at least annually.

(2) A determination of the faculty and staff to be included in the plan including, but not limited to, all instructors teaching college credit courses, counselors, and media specialists.

(3) Orientation for new faculty. It is recommended that new faculty orientation be initiated within six months from the hiring date. It is recommended that the orientation of new faculty be flexible to meet current and future needs and provide options other than structured college courses for faculty to improve teaching strategies, curriculum development and evaluation strategies. It is recommended that the college consider developing a faculty mentoring program.

(4) Continuing professional development for faculty. It is recommended that the plan clearly specify required components including time frame for continuing professional development for faculty. It is recommended that the plan include the number of hours, courses, workshops, professional and academic conferences or other experiences such as industry internships, cooperatives and exchange programs that faculty may use for continuing professional development. It is recommended that the plan include prescribed and elective topics such as discipline-specific content and educational trends and research. Examples of topics that may be considered include dealing with the complexities of learners, skills in teaching adults, curriculum development, assessment, evaluation, enhancing students' retention and success, reaching nontraditional and minority students, improving skills in implementing technology and applied learning, leadership development, and issues unique to a particular college. The institutional quality faculty plan shall include professional development components for all instructional staff, counselors, and media specialists and may include reciprocity features that facilitate movement from one college to another.

(5) Procedures for accurate record keeping and documentation for plan monitoring. It is recommended that the plan identify the college officials or administrators responsible for the administration, record keeping and ongoing evaluation and monitoring of the plan. It is recommended the plan monitoring, evidence collected, and records maintained showing implementation of the plan be comprehensive in scope. It is recommended that the plan provide for the documentation that each faculty member appropriately possesses, attains or progresses toward attaining minimum competencies.

(6) Consortium arrangements where appropriate, cost-effective and mutually beneficial. It is recommended that the plan provide an outline of existing and potential consortium arrangements including a description of the benefits, cost-effectiveness, and method of evaluating consortium services.

(7) Specific activities that ensure that faculty attain and demonstrate instructional competencies and knowledge in their subject or technical areas. It is recommended that the plan identify faculty minimum competencies and explain the method or methods of determining and assessing competencies. It is recommended that the plan contain procedures for reporting faculty progress. It is recommended that faculty be notified at least once a year of their progress in attaining competencies. It is recommended that the plan include policies and provisions for length of provisional status for faculty who do not meet the minimum standards in Iowa Code section 260C.48. It is recommended that provisional status of individual faculty members not exceed five years.

(8) Procedures for collection and maintenance of records demonstrating that each faculty member has attained or documented progress toward attaining minimum competencies. It is recommended that the plan specify data collection procedures that demonstrate how each full-time faculty member has attained or has documented progress toward attaining minimum competencies. It is recommended that the plan incorporate the current department of education management information system data submission requirements by which each college submits complete human resources data files electronically as a part of the college's year-end reporting.

(9) Compliance with the faculty accreditation standards of the North Central Association of Colleges and Schools and with faculty standards required under specific programs offered by the community college that are accredited by other accrediting agencies. It is recommended that the plan provide for the uniform reports with substantiating data currently required for North Central Association of Colleges and Schools accreditation.

c. The department of education shall notify the community college when the department requires that a modified quality faculty plan be submitted. The department shall review the plan during the state accreditation on-site visits to ensure each community college's compliance and progress in implementing a quality faculty plan as approved by the local board of directors. The department shall review the following:

(1) Documents submitted by the college that demonstrate that the plan includes each component required by paragraph *"b"* of this subrule.

(2) Documentation submitted by the college that the board of directors approved the plan.

(3) Documentation submitted by the college that the college is implementing the approved plan, including, but not limited to, evidence of plan monitoring, evaluation and updating; evidence that the faculty has attained, or is progressing toward attaining, minimum competencies and standards contained in Iowa Code section 260C.48 as amended by 2008 Iowa Acts, House File 2679, and 2007 Iowa Acts, Senate File 588; evidence that faculty members have been notified of their progress toward attaining minimum competencies and standards; and evidence that the college meets the minimum accreditation requirements for faculty required by the North Central Association of Colleges and Schools.

(4) Documentation that the college administration encourages the continued development of faculty potential as defined in Iowa Code Supplement section 260C.36 as amended by 2008 Iowa Acts, House File 2679.

(5) Documentation of the human resources report submitted by the college through the department's community college management information system.

24.5(8) *Senior year plus.* The community college shall provide access to joint enrollment opportunities for high school age students. Each college shall comply with the appropriate standards defined in Iowa Code chapter 261E.

[**ARC 8644B**, IAB 4/7/10, effective 5/12/10]

281—24.6(260C) Accreditation process.

24.6(1) *Components.* The community college accreditation process shall include the following components:

a. Each community college shall submit information on an annual basis to the department of education to comply with program evaluation requirements adopted by the state board of education.

b. The department of education shall conduct an on-site accreditation evaluation of each community college during the same academic year as the evaluation by the Higher Learning Commission of the North Central Association of Colleges and Schools. An interim evaluation midway between comprehensive evaluations shall also be conducted. The department shall have the authority to conduct focus evaluation visits as needed.

24.6(2) *Accreditation team.* The size and composition of the accreditation team shall be determined by the director of the department, but the team shall include members of the department of education staff and staff members from community colleges other than the community college being evaluated for accreditation, and any other technical experts as needed.

24.6(3) *Accreditation team action.* After a visit to a community college, the accreditation team shall evaluate whether the accreditation standards have been met and shall make a report to the director of the department and the state board of education, together with a recommendation as to whether the community college shall remain accredited. The accreditation team shall report strengths and opportunities for improvement, if any, for each standard and criterion and shall advise the community college of available resources and technical assistance to further enhance strengths and address areas for improvement. A community college may respond to the accreditation team's report.

24.6(4) *State board of education consideration of accreditation.* The state board of education shall determine whether a community college shall remain accredited. Approval of accreditation for a community college by the state board of education shall be based upon the recommendation of the director of the department after study of the factual and evaluative evidence on record pursuant to the standards and criteria described in this chapter, and based upon the timely submission of information required by the department of education in a format provided by the department of education. With the approval of the director of the department, a focus visit may be conducted if the situation at a particular college warrants such a visit.

a. *Accreditation granted.* Continuation of accreditation, if granted, shall be for a term consistent with the term of accreditation by the Higher Learning Commission of the North Central Association of Colleges and Schools; however, approval for a lesser term may be granted by the state board of education if the board determines that conditions so warrant.

b. *Accreditation denied or conditional accreditation.* If the state board of education denies accreditation or grants conditional accreditation, the director of the department of education, in cooperation with the board of directors of the community college, shall establish a plan prescribing the procedures that must be taken to correct deficiencies in meeting the standards and criteria and shall establish a deadline for correction of the deficiencies. The plan shall be submitted to the director within 45 days following the notice of accreditation denial or conditional accreditation. The plan shall include components which address correcting deficiencies, sharing or merger options, discontinuance of specific programs or courses of study, and any other options proposed by the state board of education or the accreditation team to allow the college to meet the accreditation standards and criteria.

c. *Implementation of plan.* During the time specified in the plan for its implementation, the community college remains accredited. The accreditation team shall revisit the community college to evaluate whether the deficiencies in the standards or criteria have been corrected and shall make a report and recommendation to the director and the state board of education. The state board of education shall review the report and recommendation, may request additional information, and shall determine whether the deficiencies have been corrected.

d. *Removal of accreditation.* The director shall give a community college which fails to meet accreditation standards, as determined by the state board of education, at least one year's notice prior to removal of accreditation. The notice shall be sent by certified mail or restricted certified mail addressed to the chief executive officer of the community college and shall specify the reasons for removal of accreditation. The notice shall also be sent to each member of the board of directors of the community college. If, during the year, the community college remedies the reasons for removal of accreditation and satisfies the director that the community college will comply with the accreditation standards and

criteria in the future, the director shall continue the accreditation and shall transmit notice of the action to the community college by certified mail or restricted certified mail.

e. *Failure to correct deficiencies.* If the deficiencies have not been corrected in a program of a community college, the community college board of directors shall take one of the following actions within 60 days from removal of accreditation:

(1) Merge the deficient program or programs with a program or programs from another accredited community college.

(2) Contract with another accredited postsecondary educational institution for purposes of program delivery at the community college.

(3) Discontinue the program or programs which have been identified as deficient.

f. *Appeal process provided.* The action of the director to remove the state accreditation of a community college program may be appealed to the state board of education as provided in Iowa Code section 260C.47, subsection 7.

[**ARC 8644B**, IAB 4/7/10, effective 5/12/10]

These rules are intended to implement Iowa Code section 258.4(7) and chapters 260C and 261E.

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CHAPTER 13
ISSUANCE OF TEACHER LICENSES AND ENDORSEMENTS

[Prior to 1/14/09, see Educational Examiners Board[282] Ch 14]

282—13.1(272) All applicants desiring Iowa licensure. Licenses are issued upon application filed on a form provided by the board of educational examiners and upon completion of the following:

13.1(1) *National criminal history background check.* An initial applicant will be required to submit a completed fingerprint packet that accompanies the application to facilitate a national criminal history background check. The fee for the evaluation of the fingerprint packet will be assessed to the applicant.

13.1(2) *Iowa division of criminal investigation background check.* An Iowa division of criminal investigation background check will be conducted on initial applicants. The fee for the evaluation of the DCI background check will be assessed to the applicant.

13.1(3) *Temporary permits.* The executive director may issue a temporary permit to an applicant for any type of license, certification, or authorization issued by the board, after receipt of a fully completed application, including certification from the applicant of completion of the Praxis II examination, if required; determination that the applicant meets all applicable prerequisites for issuance of the license, certification, or authorization; and satisfactory evaluation of the Iowa criminal history background check. The temporary permit shall serve as evidence of the applicant's authorization to hold a position in Iowa schools, pending the satisfactory completion of the national criminal history background check and the board's receipt of verification of completion of the Praxis II examination. The temporary permit shall expire upon issuance of the requested license, certification, or authorization or 90 days from the date of issuance of the permit, whichever occurs first, unless the temporary permit is extended upon a finding of good cause by the executive director.

282—13.2(272) Applicants from recognized Iowa institutions. An applicant for initial licensure shall complete either the teacher, administrator, or school service personnel preparation program from a recognized Iowa institution or an alternative program recognized by the Iowa board of educational examiners. A recognized Iowa institution is one which has its program of preparation approved by the state board of education according to standards established by said board, or an alternative program recognized by the state board of educational examiners. Applicants shall complete the requirements set out in rule 282—13.1(272) and shall also have the recommendation for the specific license and endorsement(s) or the specific endorsement(s) from the designated recommending official at the recognized education institution where the preparation was completed.

282—13.3(272) Applicants from non-Iowa institutions.

13.3(1) *Requirements for applicants from non-Iowa institutions.* An applicant for licensure who completes the teacher, administrator, or school service personnel preparation program from a non-Iowa institution shall verify the requirements of either subrule 13.18(4) or 13.18(5).

13.3(2) *Requirements for applicants from non-Iowa traditional teacher preparation programs.* Provided all requirements for Iowa licensure have been met through a state-approved regionally accredited teacher education program at the graduate or undergraduate level in which college or university credits were given and student teaching was required, the applicant shall:

a. Provide a recommendation for the specific license and endorsement(s) from the designated recommending official at the recognized institution where the preparation was completed, and

b. Submit a copy of a valid regular teaching certificate or license exclusive of a temporary, emergency or substitute license or certificate, and

c. Provide verification of successfully passing mandated tests in the state in which the applicant is currently licensed if the applicant has fewer than three years of teaching experience.

13.3(3) *Requirements for applicants from out-of-state nontraditional teacher preparation programs.* An applicant who holds a valid license from another state and whose preparation was completed through a state-approved nontraditional teacher preparation program must:

a. Hold a baccalaureate degree with a minimum cumulative grade point average of 2.50 on a 4.0 scale from a regionally accredited institution.

b. Provide a valid out-of-state teaching license based on a state-approved nontraditional teacher preparation program.

c. Provide a recommendation from a regionally accredited institution, department of education, or a state's standards board indicating the completion of an approved nontraditional teacher preparation program.

d. Provide an official institutional transcript(s) to be analyzed for the requirements necessary for full Iowa licensure based on 13.9(4)*"a"*(1) to (7), 13.9(4)*"c"*(1) to (5), 13.18(2), 282—13.28(272), and 282—14.2(272).

e. Meet the recency requirements listed in 13.10(3).

f. If the applicant has fewer than three years of teaching experience, provide verification from the state licensing agency/department in the state where the nontraditional teacher preparation program was completed indicating that the applicant has successfully passed that state's mandated tests.

g. Complete a student teaching or internship experience or verify three years of teaching experience.

h. If through a transcript analysis the professional education core requirements set forth in 13.9(4)*"a"*(1) to (7), 13.9(4)*"c"*(1) to (5), and 13.18(2) and the content endorsement requirements pursuant to 282—13.28(272) may be identified by course titles, published course descriptions, and grades, then the transcripts will be reviewed to determine the applicant's eligibility for an Iowa teaching license. However, if the professional education core requirements of 13.9(4)*"a"*(1) to (7), 13.9(4)*"c"*(1) to (5), and 13.18(2) and the content endorsement requirements cannot be reviewed in this manner, a portfolio review and evaluation process will be utilized.

13.3(4) *Portfolio review and evaluation process.* An applicant whose professional education core requirements pursuant to 13.9(4)*"a"*(1) to (7), 13.9(4)*"c"*(1) to (5), and 13.18(2) or whose content endorsement requirements for special education (282—subrule 14.2(2)) could not be reviewed through transcript analysis may submit to the board a portfolio in the approved format for review and evaluation.

a. An applicant must demonstrate proficiency in seven of the nine standards in the Iowa professional education core, set forth in 13.18(4)*"a"* to *"i,"* to be eligible to receive a license.

b. An applicant must have completed at least 75 percent of the endorsement requirements through a two- or four-year institution in order for the endorsement to be included on the license. An applicant who does not have at least 75 percent of one content endorsement area as described in 282—13.28(272) completed will not be issued a license.

c. An applicant must meet with the board of educational examiners to answer any of the board's questions concerning the portfolio.

d. Any deficiencies in the professional education core as set forth in 13.18(4)*"a"* to *"i"* or in the special education content endorsement area that are identified during the portfolio review and evaluation process shall be met through coursework with course credits completed at a state-approved, regionally accredited institution or through courses approved by the executive director. Other content deficiencies may be met through coursework in a two- or four-year institution in which course credits are given.

13.3(5) *Definitions.*

"Nontraditional" means any method of teacher preparation that falls outside the traditional method of preparing teachers, that provides at least a one- or two-year sequenced program of instruction taught at regionally accredited and state-approved colleges or universities, that includes commonly recognized pedagogy classes being taught for course credit, and that requires a student teaching component.

"Proficiency," for the purposes of 13.3(4)*"a,"* means that an applicant has passed all parts of the standard.

"Recognized non-Iowa teacher preparation institution" means an institution that is state-approved and is accredited by the regional accrediting agency for the territory in which the institution is located.

[**ARC 8139B**, IAB 9/9/09, effective 10/14/09; **ARC 8610B**, IAB 3/10/10, effective 4/14/10]

282—13.4(272) Applicants from foreign institutions. An applicant for initial licensure whose preparation was completed in a foreign institution must obtain a course-by-course credential evaluation report completed by one of the board-approved credential evaluation services and then file this report with the board of educational examiners for a determination of eligibility for licensure.

282—13.5(272) Teacher licenses. A license may be issued to applicants who fulfill the general requirements set out in subrule 13.5(1) and the specific requirements set out for each license.

13.5(1) *General requirements.* The applicant shall:

a. Have a baccalaureate degree from a regionally accredited institution.

b. Have completed a state-approved teacher education program which meets the requirements of the professional education core.

c. Have completed an approved human relations component.

d. Have completed the exceptional learner component.

e. Have completed the requirements for one of the basic teaching endorsements.

f. Meet the recency requirement of subrule 13.10(3).

13.5(2) *Renewal requirements.* Renewal requirements for teacher licenses are set out in 282—Chapter 20.

282—13.6(272) Specific requirements for an initial license. An initial license valid for two years may be issued to an applicant who meets the general requirements set forth in subrule 13.5(1).

282—13.7(272) Specific requirements for a standard license. A standard license valid for five years may be issued to an applicant who:

1. Meets the general requirements set forth in subrule 13.5(1), and
2. Shows evidence of successful completion of a state-approved mentoring and induction program by meeting the Iowa teaching standards as determined by a comprehensive evaluation and two years' successful teaching experience. In lieu of completion of an Iowa state-approved mentoring and induction program, the applicant must provide evidence of three years' successful teaching experience in an Iowa nonpublic school or three years' successful teaching experience in an out-of-state K-12 educational setting.

282—13.8(272) Specific requirements for a master educator's license. A master educator's license is valid for five years and may be issued to an applicant who:

1. Is the holder of or is eligible for a standard license as set out in rule 282—13.7(272), and
2. Verifies five years of successful teaching experience, and
3. Completes one of the following options:

- Master's degree in a recognized endorsement area, or
- Master's degree in curriculum, effective teaching, or a similar degree program which has a focus on school curriculum or instruction.

282—13.9(272) Teacher intern license.

13.9(1) *Authorization.* The teacher intern is authorized to teach in grades 7 to 12.

13.9(2) *Term.* The term of the teacher intern license will be one year from the date of issuance. This license is nonrenewable. The fee for the teacher intern license is in 282—Chapter 12.

13.9(3) *Teacher intern requirements.* A teacher intern license shall be issued upon application provided that the following requirements have been met. The applicant shall:

a. Hold a baccalaureate degree with a minimum cumulative grade point average of 2.50 on a 4.0 scale from a regionally accredited institution.

b. Meet the requirements of at least one of the board's secondary (5-12) teaching endorsements listed in rule 282—13.28(272).

c. Possess a minimum of three years of postbaccalaureate work experience. An authorized official at a college or university with an approved teacher intern program will evaluate this experience.

d. Successfully complete the teacher intern program requirements listed in subrule 13.9(4) and approved by the state board of education.

e. Successfully pass a basic skills test at the level approved by the teacher education institution.

13.9(4) *Program requirements.* The teacher intern shall:

a. Complete the following requirements prior to the internship year:

(1) Learning environment/classroom management. The intern uses an understanding of individual and group motivation and behavior to create a learning environment that encourages positive social interaction, active engagement in learning, and self-motivation.

(2) Instructional planning. The intern plans instruction based upon knowledge of subject matter, students, the community, curriculum goals, and state curriculum models.

(3) Instructional strategies. The intern understands and uses a variety of instructional strategies to encourage students' development of critical thinking, problem solving, and performance skills.

(4) Student learning. The intern understands how students learn and develop and provides learning opportunities that support intellectual, career, social, and personal development.

(5) Diverse learners. The intern understands how students differ in their approaches to learning and creates instructional opportunities that are equitable and are adaptable to diverse learners.

(6) Collaboration, ethics and relationships. The intern fosters relationships with parents, school colleagues, and organizations in the larger community to support students' learning and development.

(7) Assessment. The intern understands and uses formal and informal assessment strategies to evaluate the continuous intellectual, social, and physical development of the learner.

(8) Field experiences that provide opportunities for interaction with students in an environment that supports learning in context. These experiences shall total at least 50 contact hours in the field prior to the beginning of the academic year of the candidate's initial employment as a teacher intern.

b. Complete four semester hours of a teacher intern seminar during the teacher internship year to include support and extension of coursework from the teacher intern program.

c. Complete the coursework and competencies in the following areas:

(1) Foundations, reflection, and professional development. The intern continually evaluates the effects of the practitioner's choices and actions on students, parents, and other professionals in the learning community and actively seeks out opportunities to grow professionally.

(2) Communication. The intern uses knowledge of effective verbal, nonverbal, and media communication techniques, and other forms of symbolic representation, to foster active inquiry and collaboration and to support interaction in the classroom.

(3) Exceptional learner program, which must include preparation that contributes to the education of individuals with disabilities and the gifted and talented.

(4) Preparation in the integration of reading strategies into the content area.

(5) Computer technology related to instruction.

(6) An advanced study of the items set forth in 13.9(4)*"a"*(1) to (7) above.

13.9(5) *Local school district requirements.* The local school district shall:

a. Provide an offer of employment to an individual who has been evaluated by a college or university for eligibility or acceptance in the teacher intern program.

b. Participate in a mentoring and induction program.

c. Provide a district mentor for the teacher intern.

d. Provide other support and supervision, as needed, to maximize the opportunity for the teacher intern to succeed.

e. Not overload the teacher intern with extracurricular duties not directly related to the teacher intern's teaching assignment.

f. Provide evidence to the board from a licensed evaluator that the teacher intern is participating in a mentoring and induction program.

g. At the board's request, provide information including, but not limited to, the teacher intern selection and preparation program, institutional support, local school district mentor, and local school district support.

13.9(6) *Requirements to convert the teacher intern license to the initial license.*

a. An initial license shall be issued upon application provided that the teacher intern has met all of the following requirements:

(1) Successful completion of the coursework and competencies in the teacher intern program approved by the state board of education.

(2) Verification from a licensed evaluator that the teacher intern served successfully for a minimum of 160 days.

(3) Verification from a licensed evaluator that the teacher intern is participating in a mentoring and induction program and is being assessed on the Iowa teaching standards.

(4) Recommendation by a college or university offering an approved teacher intern program that the individual is eligible for an initial license.

(5) At the board's request, the teacher intern shall provide to the board information including, but not limited to, the teacher intern selection and preparation program, institutional support, local school district mentor, and local school district support.

b. The teacher intern year will count as one of the years that is needed for the teacher intern to convert the initial license to the standard license if the conditions listed in paragraph 13.9(6)*"a"* have been met.

13.9(7) *Requirements to obtain the initial license if the teacher intern does not complete the internship year.* An initial license shall be issued upon application provided that the teacher intern has met all of the following requirements:

a. Successful completion of the coursework and competencies in the teacher intern program approved by the state board of education.

b. Verification by a college or university that the teacher intern successfully completed the college's or university's state-approved student teaching requirements.

c. Recommendation by a college or university offering an approved teacher intern program that the individual is eligible for an initial license.

d. At the board's request, the teacher intern shall provide to the board information including, but not limited to, the teacher intern selection and preparation program, institutional support, local school district mentor, and local school district support.

13.9(8) *Requirements to extend the teacher intern license if the teacher intern does not complete all of the education coursework during the term of the teacher intern license.*

a. A one-year extension of the teacher intern license may be issued upon application provided that the teacher intern has met both of the following requirements:

(1) Successful completion of 160 days of teaching experience during the teacher internship.

(2) Verification by the recommending official at the approved teacher intern program that the teacher intern has not completed all of the coursework required for the initial license.

b. Only one year of teaching experience during the term of the teacher intern license or the extension of a teacher intern license may be used to convert the teacher intern license to a standard teaching license.

[**ARC 8688B**, IAB 4/7/10, effective 5/12/10]

282—13.10(272) Specific requirements for a Class A license. A nonrenewable Class A license valid for one year may be issued to an individual who has completed a teacher education program under any one of the following conditions:

13.10(1) *Professional core requirements.* The individual has not completed all of the required courses in the professional core, 13.18(4)*"a"* through *"j."*

13.10(2) *Human relations component.* The individual has not completed an approved human relations component.

13.10(3) *Recency.* The individual meets the requirements for a valid license, but has had fewer than 160 days of teaching experience during the five-year period immediately preceding the date of application or has not completed six semester hours of college credit from a recognized institution within the five-year period. To obtain the desired license, the applicant must complete recent credits and, where

recent credits are required, these credits shall be taken in professional education or in the applicant's endorsement area(s).

13.10(4) *Degree not granted until next regular commencement.* Rescinded IAB 9/9/09, effective 10/14/09.

13.10(5) *Based on an expired Iowa certificate or license, exclusive of a Class A or Class B license.* The holder of an expired license, exclusive of a Class A or Class B license, shall be eligible to receive a Class A license upon application. This license shall be endorsed for the type of service authorized by the expired license on which it is based.

13.10(6) *Based on a mentoring and induction program.* An applicant may be eligible for a Class A license if the school district, after conducting a comprehensive evaluation, recommends and verifies that the applicant shall participate in the mentoring program for a third year.

13.10(7) *Based on an administrative decision.* The executive director is authorized to issue a Class A license to an applicant whose services are needed to fill positions in unique need circumstances.

[**ARC 7987B**, IAB 7/29/09, effective 9/2/09; **ARC 8134B**, IAB 9/9/09, effective 10/14/09]

282—13.11(272) Specific requirements for a Class B license. A Class B license, which is valid for two years and which is nonrenewable, may be issued to an individual under the following conditions:

13.11(1) *Endorsement in progress.* The individual has a valid license and one or more endorsements, but is seeking to obtain some other endorsement. A Class B license may be issued if requested by an employer and if the individual seeking to obtain some other endorsement has completed at least two-thirds of the requirements, or one-half of the content requirements in a state-designated shortage area, leading to completion of all requirements for the endorsement.

13.11(2) *Program of study for special education endorsement.* The college or university must outline the program of study necessary to meet the special education endorsement requirements. This program of study must be attached to the application.

13.11(3) *Request for exception.* A school district administrator may file a written request with the board for an exception to the minimum content requirements on the basis of documented need and benefit to the instructional program. The board will review the request and provide a written decision either approving or denying the request.

13.11(4) *Provisional occupational license.* If an individual is eligible for a provisional occupational license but has not met all of the experience requirements, a Class B license may be issued while the individual earns the necessary experience.

13.11(5) *Expiration.* This license will expire on June 30 of the fiscal year in which it was issued plus one year.

[**ARC 7987B**, IAB 7/29/09, effective 9/2/09; **ARC 8133B**, IAB 9/9/09, effective 10/14/09]

282—13.12(272) Specific requirements for a Class C license. Rescinded IAB 7/29/09, effective 9/2/09.

282—13.13(272) Specific requirements for a Class D occupational license. Rescinded IAB 7/29/09, effective 9/2/09.

282—13.14(272) Specific requirements for a Class E license. A nonrenewable license valid for one year may be issued to an individual as follows:

13.14(1) *Expired license.* Based on an expired Class A, Class B, or teacher exchange license, the holder of the expired license shall be eligible to receive a Class E license upon application and submission of all required materials.

13.14(2) *Application.* The application process will require transcripts of coursework completed during the term of the expired license, a program of study indicating the coursework necessary to obtain full licensure, and registration for coursework to be completed during the term of the Class E license. The Class E license will be denied if the applicant has not completed any coursework during the term of the Class A or Class B license unless extenuating circumstances are verified.

[**ARC 7987B**, IAB 7/29/09, effective 9/2/09]

282—13.15(272) Specific requirements for a Class G license. A nonrenewable Class G license valid for one year may be issued to an individual who must complete a school guidance counseling practicum or internship in an approved program in preparation for the school guidance counselor endorsement. The Class G license may be issued under the following limited conditions:

1. Verification of a baccalaureate degree from a regionally accredited institution.
2. Verification from the institution that the individual is admitted and enrolled in an approved school guidance counseling program.
3. Verification that the individual has completed the coursework and competencies required prior to the practicum or internship.
4. Written documentation of the requirements listed in "1" to "3" above, provided by the official at the institution where the individual is completing the approved school guidance counseling program and forwarded to the Iowa board of educational examiners with the application form for licensure.

282—13.16(272) Specific requirements for a substitute teacher's license.

13.16(1) *Substitute teacher requirements.* A substitute teacher's license may be issued to an individual who:

a. Has been the holder of, or presently holds, a license in Iowa; or holds or held a regular teacher's license or certificate in another state, exclusive of temporary, emergency, or substitute certificate or license, or a certificate based on an alternative certification program; or

b. Has successfully completed all requirements of an approved teacher education program and is eligible for the initial license, but has not applied for and been issued this license, or who meets all requirements for the initial license with the exception of the degree but whose degree will be granted at the next regular commencement; or

c. Has successfully completed all requirements of an approved Iowa teacher education program, but did not apply for an Iowa teacher's license at the time of completion of the approved program.

13.16(2) *Validity.* A substitute license is valid for five years and for not more than 90 days of teaching in one assignment during any one school year. A school district administrator may file a written request with the board for an extension of the 90-day limit in one assignment on the basis of documented need and benefit to the instructional program. The board will review the request and provide a written decision either approving or denying the request.

13.16(3) *Authorization.* The holder of a substitute license is authorized to teach in any school system in any position in which a regularly licensed teacher was employed to begin the school year. In addition to the authority inherent in the initial, standard, master educator, professional administrator, two-year exchange, and permanent professional licenses and the endorsement(s) held, the holder of one of these regular licenses may substitute on the same basis as the holder of a substitute license while the regular license is in effect.

282—13.17(272) Specific requirements for exchange licenses. An applicant seeking Iowa licensure who completes the teacher preparation program from a recognized non-Iowa institution shall verify the requirements of subrules 13.18(4) and 13.18(5) through traditional course-based preparation program and transcript review. A recognized non-Iowa teacher preparation institution is one that is state-approved and is accredited by the regional accrediting agency for the territory in which the institution is located. Applicants for nontraditional exchange licenses are not required to have received their preparation through regionally approved teacher education programs.

13.17(1) *One-year teacher exchange license.*

a. For an applicant applying under 13.3(2), a one-year nonrenewable exchange license may be issued to the applicant under the following conditions:

(1) The applicant has completed a state-approved, regionally accredited teacher education program; and

(2) The applicant has the recommendation for the specific license and endorsement(s) from the designated recommending official at the recognized non-Iowa institution where the preparation was completed; and

(3) The applicant holds and submits a copy of a valid regular certificate or license in the state in which the preparation was completed, exclusive of a temporary, emergency or substitute license or certificate; and

(4) If the applicant has fewer than three years of teaching experience or is being recommended for a K-6 elementary education endorsement, the applicant must verify successful completion of mandated tests in the state in which the applicant is currently licensed; and

(5) Each exchange license shall be limited to the area(s) and level(s) of instruction as determined by an analysis of the application, the transcripts and the license or certificate held in the state in which the basic preparation for licensure was completed or of the application and the credential evaluation report. The applicant must have completed at least 50 percent of the endorsement requirements through a two- or four-year institution in order for the endorsement to be included on the exchange license; and

(6) The applicant is not subject to any pending disciplinary proceedings in any state or country; and

(7) The applicant complies with all requirements with regard to application processes and payment of licensure fees.

b. After the term of the exchange license has expired, the applicant may apply to be fully licensed if the applicant has completed all requirements and is eligible for full licensure.

13.17(2) *Two-year nontraditional exchange license.* For an applicant applying under 13.3(3) and 13.3(4), a two-year nontraditional teacher exchange license may be issued to the applicant from state-approved preparation programs, under the following conditions:

a. The applicant has met the requirements of 13.3(4)*"a"* and *"b."*

b. The applicant has met the requirements of 13.17(1)*"a"*(3) through (7).

c. To convert the two-year nontraditional exchange license, the applicant must meet all deficiencies as well as meet the Iowa teaching standards as determined by a comprehensive evaluation by a licensed evaluator, and the applicant shall have two years of successful teaching experience in Iowa. The evaluator may recommend extending the license for a third year to meet Iowa teaching standards.

d. The license may be extended to meet the requirements for two years of successful teaching in Iowa with proof of employment.

13.17(3) *International teacher exchange license.*

a. A nonrenewable international exchange license may be issued to an applicant under the following conditions:

(1) The applicant has completed a teacher education program in another country; and

(2) The applicant is not subject to any pending disciplinary proceedings in any state or country; and

(3) The applicant complies with all requirements with regard to application processes and payment of licensure fees; and

(4) The applicant is a participant in a teacher exchange program administered through the Iowa department of education.

b. Each exchange license shall be limited to the area(s) and level(s) of instruction as determined by an analysis of the application and the credential evaluation report.

c. This license shall not exceed three years.

d. After the term of the exchange license has expired, the applicant may apply to be fully licensed if the applicant has completed all requirements and is eligible for full licensure.

[**ARC 8138B**, IAB 9/9/09, effective 10/14/09; **ARC 8604B**, IAB 3/10/10, effective 4/14/10]

282—13.18(272) General requirements for an original teaching subject area endorsement. Following are the general requirements for the issuance of a license with an endorsement.

13.18(1) Baccalaureate degree from a regionally accredited institution.

13.18(2) Completion of an approved human relations component.

13.18(3) Completion of the exceptional learner program, which must include preparation that contributes to the education of individuals with disabilities and the gifted and talented.

13.18(4) Professional education core. Completed coursework or evidence of competency in:

a. Student learning. The practitioner understands how students learn and develop, and provides learning opportunities that support intellectual, career, social and personal development.

b. Diverse learners. The practitioner understands how students differ in their approaches to learning and creates instructional opportunities that are equitable and are adaptable to diverse learners.

c. Instructional planning. The practitioner plans instruction based upon knowledge of subject matter, students, the community, curriculum goals, and state curriculum models.

d. Instructional strategies. The practitioner understands and uses a variety of instructional strategies to encourage students' development of critical thinking, problem solving, and performance skills.

e. Learning environment/classroom management. The practitioner uses an understanding of individual and group motivation and behavior to create a learning environment that encourages positive social interaction, active engagement in learning, and self-motivation.

f. Communication. The practitioner uses knowledge of effective verbal, nonverbal, and media communication techniques, and other forms of symbolic representation, to foster active inquiry, collaboration, and support interaction in the classroom.

g. Assessment. The practitioner understands and uses formal and informal assessment strategies to evaluate the continuous intellectual, social, and physical development of the learner.

h. Foundations, reflection and professional development. The practitioner continually evaluates the effects of the practitioner's choices and actions on students, parents, and other professionals in the learning community, and actively seeks out opportunities to grow professionally.

i. Collaboration, ethics and relationships. The practitioner fosters relationships with parents, school colleagues, and organizations in the larger community to support students' learning and development.

j. Computer technology related to instruction.

k. Completion of pre-student teaching field-based experiences.

l. Methods of teaching with an emphasis on the subject and grade level endorsement desired.

m. Student teaching in the subject area and grade level endorsement desired.

n. Preparation in reading programs, including reading recovery, and integration of reading strategies into content area methods coursework.

13.18(5) Content/subject matter specialization. The practitioner understands the central concepts, tools of inquiry, and structure of the discipline(s) the practitioner teaches and creates learning experiences that make these aspects of subject matter meaningful for students. This is evidenced by completion of a 30-semester-hour teaching major which must minimally include the requirements for at least one of the basic endorsement areas, special education teaching endorsements, or secondary level occupational endorsements.

282—13.19(272) NCATE-accredited programs. Rescinded IAB 6/17/09, effective 7/22/09.

282—13.20 Reserved.

282—13.21(272) Human relations requirements for practitioner licensure. Preparation in human relations shall be included in programs leading to teacher licensure. Human relations study shall include interpersonal and intergroup relations and shall contribute to the development of sensitivity to and understanding of the values, beliefs, lifestyles and attitudes of individuals and the diverse groups found in a pluralistic society.

13.21(1) Beginning on or after August 31, 1980, each applicant for an initial practitioner's license shall have completed the human relations requirement.

13.21(2) On or after August 31, 1980, each applicant for the renewal of a practitioner's license shall have completed an approved human relations requirement.

13.21(3) Credit for the human relations requirement shall be given for licensed persons who can give evidence that they have completed a human relations program which meets board of educational examiners criteria (see rule 282—13.24(272)).

282—13.22(272) Development of human relations components. Human relations components shall be developed by teacher preparation institutions. In-service human relations components may also be developed by educational agencies other than teacher preparation institutions, as approved by the board of educational examiners.

13.22(1) *Advisory committee.* Education agencies developing human relations components shall give evidence that in the development of their programs they were assisted by an advisory committee. The advisory committee shall consist of equal representation of various minority and majority groups.

13.22(2) *Standards for approved components.* Human relations components will be approved by the board of educational examiners upon submission of evidence that the components are designed to develop the ability of participants to:

a. Be aware of and understand the values, lifestyles, history, and contributions of various identifiable subgroups in our society.

b. Recognize and deal with dehumanizing biases such as sexism, racism, prejudice, and discrimination and become aware of the impact that such biases have on interpersonal relations.

c. Translate knowledge of human relations into attitudes, skills, and techniques which will result in favorable learning experiences for students.

d. Recognize the ways in which dehumanizing biases may be reflected in instructional materials.

e. Respect human diversity and the rights of each individual.

f. Relate effectively to other individuals and various subgroups other than one's own.

13.22(3) *Evaluation.* Educational agencies providing the human relations components shall indicate the means to be utilized for evaluation.

282—13.23 to **13.25** Reserved.

282—13.26(272) Requirements for elementary endorsements.

13.26(1) *Teacher—prekindergarten-kindergarten.*

a. *Authorization.* The holder of this endorsement is authorized to teach at the prekindergarten/kindergarten level.

b. *Program requirements.*

(1) Degree—baccalaureate, and

(2) Completion of an approved human relations program, and

(3) Completion of the professional education core. See subrule 13.18(3).

c. *Content.*

(1) Human growth and development: infancy and early childhood, unless completed as part of the professional education core. See subrule 13.18(4).

(2) Curriculum development and methodology for young children.

(3) Child-family-school-community relationships (community agencies).

(4) Guidance of young children three to six years of age.

(5) Organization of prekindergarten-kindergarten programs.

(6) Child and family nutrition.

(7) Language development and learning.

(8) Kindergarten: programs and curriculum development.

13.26(2) *Teacher—prekindergarten through grade three.*

a. *Authorization.* The holder of this endorsement is authorized to teach children from birth through grade three.

b. *Program requirements.*

(1) Degree—baccalaureate.

(2) Completion of an approved human relations program.

(3) Completion of the professional education core. See subrules 13.18(3) and 13.18(4).

(4) Highly qualified teacher (HQT) status. Applicants from non-Iowa institutions who have completed the requirements for this endorsement must verify their HQT status. The board shall

determine the test and the minimum passing score for HQT status. Verification must be provided through one of the following:

1. Written verification from the department of education in the state in which the applicant completed the elementary teacher preparation program that the applicant has achieved HQT status in that state; or

2. Written verification from the department of education in the state where the applicant is currently teaching that the applicant has achieved HQT status in that state; or

3. Submission of the official test score report indicating the applicant has met the qualifying score for licensure in the state in which the applicant completed the elementary teacher preparation program; or

4. Obtaining the qualifying score set by the Iowa board of educational examiners if the applicant has not been teaching within the last five years and completion of a teacher preparation program prior to enactment of the federal highly qualified teacher legislation (June 2006). This option may also be utilized by applicants from outside the United States.

5. For applicants who have completed the requirements for one of the Iowa elementary endorsements, verification of HQT status by meeting the minimum score set by the Iowa board of educational examiners if the applicant has not been teaching within the last five years and completion of a teacher preparation program prior to enactment of the federal highly qualified teacher legislation (June 2006). This option may also be utilized by applicants who have been teaching outside the United States.

c. Content.

(1) Child growth and development with emphasis on cognitive, language, physical, social, and emotional development, both typical and atypical, for infants and toddlers, preprimary, and primary school children (grades one through three), unless combined as part of the professional education core. See subrule 13.18(4) of the licensure rules for the professional core.

(2) Historical, philosophical, and social foundations of early childhood education.

(3) Developmentally appropriate curriculum with emphasis on integrated multicultural and nonsexist content including language, mathematics, science, social studies, health, safety, nutrition, visual and expressive arts, social skills, higher-thinking skills, and developmentally appropriate methodology, including adaptations for individual needs, for infants and toddlers, preprimary, and primary school children.

(4) Characteristics of play and creativity, and their contributions to the cognitive, language, physical, social and emotional development and learning of infants and toddlers, preprimary, and primary school children.

(5) Classroom organization and individual interactions to create positive learning environments for infants and toddlers, preprimary, and primary school children based on child development theory emphasizing guidance techniques.

(6) Observation and application of developmentally appropriate assessments for infants and toddlers, preprimary, and primary school children recognizing, referring, and making adaptations for children who are at risk or who have exceptional educational needs and talents.

(7) Home-school-community relationships and interactions designed to promote and support parent, family and community involvement, and interagency collaboration.

(8) Family systems, cultural diversity, and factors which place families at risk.

(9) Child and family health and nutrition.

(10) Advocacy, legislation, and public policy as they affect children and families.

(11) Administration of child care programs to include staff and program development and supervision and evaluation of support staff.

(12) Pre-student teaching field experience with three age levels in infant and toddler, preprimary, and primary programs, with no less than 100 clock hours, and in different settings, such as rural and urban, socioeconomic status, cultural diversity, program types, and program sponsorship.

(13) Student teaching experiences with two different age levels, one before kindergarten and one from kindergarten through grade three.

13.26(3) *Teacher—prekindergarten through grade three, including special education.*

a. Authorization. The holder of this endorsement is authorized to teach children from birth through grade three.

b. Program requirements.

(1) Degree—baccalaureate, and

(2) Completion of an approved human relations program, and

(3) Completion of the professional education core. See subrules 13.18(3) and 13.18(4).

(4) Highly qualified teacher (HQT) status. Applicants from non-Iowa institutions who have completed the requirements for this endorsement must verify their HQT status. The board shall determine the test and the minimum passing score for HQT status. Verification must be provided through one of the following:

1. Written verification from the department of education in the state in which the applicant completed the elementary teacher preparation program that the applicant has achieved HQT status in that state; or

2. Written verification from the department of education in the state where the applicant is currently teaching that the applicant has achieved HQT status in that state; or

3. Submission of the official test score report indicating the applicant has met the qualifying score for licensure in the state in which the applicant completed the elementary teacher preparation program; or

4. Obtaining the qualifying score set by the Iowa board of educational examiners if the applicant has not been teaching within the last five years and completion of a teacher preparation program prior to enactment of the federal highly qualified teacher legislation (June 2006). This option may also be utilized by applicants from outside the United States.

5. For applicants who have completed the requirements for one of the Iowa elementary endorsements, verification of HQT status by meeting the minimum score set by the Iowa board of educational examiners if the applicant has not been teaching within the last five years and completion of a teacher preparation program prior to enactment of the federal highly qualified teacher legislation (June 2006). This option may also be utilized by applicants who have been teaching outside the United States.

c. Content.

(1) Child growth and development.

1. Understand the nature of child growth and development for infants and toddlers (birth through age 2), preprimary (age 3 through age 5) and primary school children (age 6 through age 8), both typical and atypical, in areas of cognition, language development, physical motor, social-emotional, aesthetics, and adaptive behavior.

2. Understand individual differences in development and learning including risk factors, developmental variations and developmental patterns of specific disabilities and special abilities.

3. Recognize that children are best understood in the contexts of family, culture and society and that cultural and linguistic diversity influences development and learning.

(2) Developmentally appropriate learning environment and curriculum implementation.

1. Establish learning environments with social support, from the teacher and from other students, for all children to meet their optimal potential, with a climate characterized by mutual respect, encouraging and valuing the efforts of all regardless of proficiency.

2. Appropriately use informal and formal assessment to monitor development of children and to plan and evaluate curriculum and teaching practices to meet individual needs of children and families.

3. Plan, implement, and continuously evaluate developmentally and individually appropriate curriculum goals, content, and teaching practices for infants, toddlers, preprimary and primary children based on the needs and interests of individual children, their families and community.

4. Use both child-initiated and teacher-directed instructional methods, including strategies such as small and large group projects, unstructured and structured play, systematic instruction, group discussion and cooperative decision making.

5. Develop and implement integrated learning experiences for home-, center- and school-based environments for infants, toddlers, preprimary and primary children.

6. Develop and implement integrated learning experiences that facilitate cognition, communication, social and physical development of infants and toddlers within the context of parent-child and caregiver-child relationships.

7. Develop and implement learning experiences for preprimary and primary children with focus on multicultural and nonsexist content that includes development of responsibility, aesthetic and artistic development, physical development and well-being, cognitive development, and emotional and social development.

8. Develop and implement learning experiences for infants, toddlers, preprimary, and primary children with a focus on language, mathematics, science, social studies, visual and expressive arts, social skills, higher-thinking skills, and developmentally appropriate methodology.

9. Develop adaptations and accommodations for infants, toddlers, preprimary, and primary children to meet their individual needs.

10. Adapt materials, equipment, the environment, programs and use of human resources to meet social, cognitive, physical motor, communication, and medical needs of children and diverse learning needs.

(3) Health, safety and nutrition.

1. Design and implement physically and psychologically safe and healthy indoor and outdoor environments to promote development and learning.

2. Promote nutritional practices that support cognitive, social, cultural and physical development of young children.

3. Implement appropriate appraisal and management of health concerns of young children including procedures for children with special health care needs.

4. Recognize signs of emotional distress, physical and mental abuse and neglect in young children and understand mandatory reporting procedures.

5. Demonstrate proficiency in infant-child cardiopulmonary resuscitation, emergency procedures and first aid.

(4) Family and community collaboration.

1. Apply theories and knowledge of dynamic roles and relationships within and between families, schools, and communities.

2. Assist families in identifying resources, priorities, and concerns in relation to the child's development.

3. Link families, based on identified needs, priorities and concerns, with a variety of resources.

4. Use communication, problem-solving and help-giving skills in collaboration with families and other professionals to support the development, learning and well-being of young children.

5. Participate as an effective member of a team with other professionals and families to develop and implement learning plans and environments for young children.

(5) Professionalism.

1. Understand legislation and public policy that affect all young children, with and without disabilities, and their families.

2. Understand legal aspects, historical, philosophical, and social foundations of early childhood education and special education.

3. Understand principles of administration, organization and operation of programs for children from birth to age 8 and their families, including staff and program development, supervision and evaluation of staff, and continuing improvement of programs and services.

4. Identify current trends and issues of the profession to inform and improve practices and advocate for quality programs for young children and their families.

5. Adhere to professional and ethical codes.

6. Engage in reflective inquiry and demonstration of professional self-knowledge.

(6) Pre-student teaching field experiences. Complete 100 clock hours of pre-student teaching field experience with three age levels in infant and toddler, preprimary, and primary programs and in different settings, such as rural and urban, encompassing differing socioeconomic status, ability levels, cultural and linguistic diversity and program types and sponsorship.

(7) Student teaching. Complete a supervised student teaching experience of a total of at least 12 weeks in at least two different classrooms which include children with and without disabilities in two of three age levels: infant and toddler, preprimary, and primary.

13.26(4) *Teacher—elementary classroom.*

a. Authorization. The holder of this endorsement is authorized to teach in kindergarten and grades one through six.

b. Program requirements.

(1) Degree—baccalaureate, and

(2) Completion of an approved human relations component, and

(3) Completion of the professional education core. See subrules 13.18(3) and 13.18(4).

(4) Highly qualified teacher (HQT) status. Applicants from non-Iowa institutions who have completed the requirements for this endorsement must verify their HQT status. The board shall determine the test and the minimum passing score for HQT status. Verification must be provided through one of the following:

1. Written verification from the department of education in the state in which the applicant completed the elementary teacher preparation program that the applicant has achieved HQT status in that state; or

2. Written verification from the department of education in the state where the applicant is currently teaching that the applicant has achieved HQT status in that state; or

3. Submission of the official test score report indicating the applicant has met the qualifying score for licensure in the state in which the applicant completed the elementary teacher preparation program; or

4. Obtaining the qualifying score set by the Iowa board of educational examiners if the applicant has not been teaching within the last five years and completion of a teacher preparation program prior to enactment of the federal highly qualified teacher legislation (June 2006). This option may also be utilized by applicants from outside the United States.

5. For applicants who have completed the requirements for one of the Iowa elementary endorsements, verification of HQT status by meeting the minimum score set by the Iowa board of educational examiners if the applicant has not been teaching within the last five years and completion of a teacher preparation program prior to enactment of the federal highly qualified teacher legislation (June 2006). This option may also be utilized by applicants who have been teaching outside the United States.

c. Content.

(1) Child growth and development with emphasis on the emotional, physical and mental characteristics of elementary age children, unless completed as part of the professional education core. See subrule 13.18(4).

(2) Methods and materials of teaching elementary language arts.

(3) Methods and materials of teaching elementary reading.

(4) Elementary curriculum (methods and materials).

(5) Methods and materials of teaching elementary mathematics.

(6) Methods and materials of teaching elementary science.

(7) Children's literature.

(8) Methods and materials of teaching elementary social studies.

(9) Methods and materials in two of the following areas:

1. Methods and materials of teaching elementary health.

2. Methods and materials of teaching elementary physical education.

3. Methods and materials of teaching elementary art.

4. Methods and materials of teaching elementary music.

(10) Pre-student teaching field experience in at least two different grades.

(11) A field of specialization in a single discipline or a formal interdisciplinary program of at least 12 semester hours.

13.26(5) *Teacher—elementary classroom.* Effective September 1, 2015, the following requirements apply to persons who wish to teach in the elementary classroom:

a. *Authorization.* The holder of this endorsement is authorized to teach in kindergarten and grades one through six.

b. *Program requirements.*

(1) Degree—baccalaureate, and

(2) Completion of an approved human relations component, and

(3) Completion of the professional education core. See subrules 13.18(3) and 13.18(4).

c. *Content.*

(1) Child growth and development with emphasis on the emotional, physical and mental characteristics of elementary age children, unless completed as part of the professional education core. See subrule 13.18(4).

(2) At least 9 semester hours in literacy which must include:

1. Content:

- Children's literature;
- Oral and written communication skills for the twenty-first century.

2. Methods:

- Assessment, diagnosis and evaluation of student learning in literacy;
- Integration of the language arts (to include reading, writing, speaking, viewing, and listening);
- Integration of technology in teaching and student learning in literacy;
- Current best-practice, research-based approaches of literacy instruction;
- Classroom management as it applies to literacy methods;
- Pre-student teaching clinical experience in teaching literacy.

(3) At least 9 semester hours in mathematics which must include:

1. Content:

- Numbers and operations;
- Algebra/number patterns;
- Geometry;
- Measurement;
- Data analysis/probability.

2. Methods:

- Assessment, diagnosis and evaluation of student learning in mathematics;
- Current best-practice, research-based instructional methods in mathematical processes (to include problem solving; reasoning; communication; the ability to recognize, make and apply connections; integration of manipulatives; the ability to construct and to apply multiple connected representations; and the application of content to real world experiences);
- Integration of technology in teaching and student learning in mathematics;
- Classroom management as it applies to mathematics methods;
- Pre-student teaching clinical experience in teaching mathematics.

(4) At least 9 semester hours in social sciences which must include:

1. Content:

- History;
- Geography;
- Political science/civic literacy;
- Economics;
- Behavioral sciences.

2. Methods:

- Current best-practice, research-based approaches to the teaching and learning of social sciences;
- Integration of technology in teaching and student learning in social sciences;
- Classroom management as it applies to social science methods.

(5) At least 9 semester hours in science which must include:

1. Content:

- Physical science;
- Earth/space science;

- Life science.

2. Methods:

- Current best-practice, research-based methods of inquiry-based teaching and learning of science;
- Integration of technology in teaching and student learning in science;
- Classroom management as it applies to science methods.

(6) At least 3 semester hours to include all of the following:

1. Methods of teaching elementary physical education, health, and wellness;
2. Methods of teaching visual arts for the elementary classroom;
3. Methods of teaching performance arts for the elementary classroom.

(7) Pre-student teaching field experience in at least two different grade levels to include one primary and one intermediate placement.

(8) A field of specialization in a single discipline or a formal interdisciplinary program of at least 12 semester hours.

[**ARC 8400B**, IAB 12/16/09, effective 1/20/10; **ARC 8401B**, IAB 12/16/09, effective 1/20/10; **ARC 8402B**, IAB 12/16/09, effective 1/20/10; **ARC 8607B**, IAB 3/10/10, effective 4/14/10]

282—13.27(272) Requirements for middle school endorsements.

13.27(1) *Authorization.* The holder of this endorsement is authorized to teach in the two concentration areas in which the specific requirements have been completed as well as in other subject areas in grades five through eight which are not the core content areas. The holder is not authorized to teach art, industrial arts, music, reading, physical education and special education.

13.27(2) *Program requirements.*

a. Be the holder of a currently valid Iowa teacher's license with either the general elementary endorsement or one of the subject matter secondary level endorsements set out in rule 282—13.28(272) or 282—subrules 17.1(1) and 17.1(3).

b. A minimum of 9 semester hours of required coursework in the following:

(1) Coursework in the growth and development of the middle school age child, specifically addressing the social, emotional, physical and cognitive characteristics and needs of middle school age children in addition to related studies completed as part of the professional education core in subrule 13.18(4).

(2) Coursework in middle school design, curriculum, instruction, and assessment including, but not limited to, interdisciplinary instruction, teaming, and differentiated instruction in addition to related studies completed as part of the professional education core in subrule 13.18(4).

(3) Coursework to prepare middle school teachers in literacy (reading, writing, listening and speaking) strategies for students in grades five through eight and in methods to include these strategies throughout the curriculum.

c. Thirty hours of middle school field experiences included in the coursework requirements listed in 13.27(2)*"b"*(1) to (3).

13.27(3) *Concentration areas.* To obtain this endorsement, the applicant must complete the coursework requirements in two of the following content areas:

a. *Social studies concentration.* The social studies concentration requires 12 semester hours of coursework in social studies to include coursework in United States history, world history, government and geography.

b. *Mathematics concentration.* The mathematics concentration requires 12 semester hours in mathematics to include coursework in algebra.

c. *Science concentration.* The science concentration requires 12 semester hours in science to include coursework in life science, earth science, and physical science.

d. *Language arts concentration.* The language arts concentration requires 12 semester hours in language arts to include coursework in composition, language usage, speech, young adult literature, and literature across cultures.

282—13.28(272) Minimum content requirements for teaching endorsements.

13.28(1) *Agriculture.* 5-12. Completion of 24 semester credit hours in agriculture and agriculture education to include:

a. Foundations of vocational and career education.

b. Planning and implementing courses and curriculum.

c. Methods and techniques of instruction to include evaluation of programs and students.

d. Coordination of cooperative education programs.

e. Coursework in each of the following areas and at least three semester credit hours in five of the following areas:

(1) Agribusiness systems.

(2) Power, structural, and technical systems.

(3) Plant systems.

(4) Animal systems.

(5) Natural resources systems.

(6) Environmental service systems.

(7) Food products and processing systems.

13.28(2) *Art.* K-8 or 5-12. Completion of 24 semester hours in art to include coursework in art history, studio art, and two- and three-dimensional art.

13.28(3) *Business—all.* 5-12. Completion of 30 semester hours in business to include 6 semester hours in accounting, 3 semester hours in business law to include contract law, 3 semester hours in computer and technical applications in business, 6 semester hours in marketing to include consumer studies, 3 semester hours in management, 6 semester hours in economics, and 3 semester hours in business communications to include formatting, language usage, and oral presentation. Coursework in entrepreneurship and in financial literacy may be a part of, or in addition to, the coursework listed above. Individuals who were licensed in Iowa prior to October 1, 1988, and were allowed to teach marketing without completing the endorsement requirements must complete the endorsement requirements by July 1, 2010, in order to teach or continue to teach marketing. A waiver provision is available through the board of educational examiners for individuals who have been successfully teaching marketing.

13.28(4) *Driver education.* 5-12. Completion of 9 semester hours in driver education to include coursework in accident prevention that includes drug and alcohol abuse; vehicle safety; and behind-the-wheel driving.

13.28(5) *English/language arts.*

a. *K-8.* Completion of 24 semester hours in English and language arts to include coursework in oral communication, written communication, language development, reading, children's literature, creative drama or oral interpretation of literature, and American literature.

b. *5-12.* Completion of 24 semester hours in English to include coursework in oral communication, written communication, language development, reading, American literature, English literature and adolescent literature.

13.28(6) *Language arts.* 5-12. Completion of 40 semester hours in language arts to include coursework in the following areas:

a. *Written communication.*

(1) Develops a wide range of strategies and appropriately uses writing process elements (e.g., brainstorming, free-writing, first draft, group response, continued drafting, editing, and self-reflection) to communicate with different audiences for a variety of purposes.

(2) Develops knowledge of language structure (e.g., grammar), language conventions (e.g., spelling and punctuation), media techniques, figurative language and genre to create, critique, and discuss print and nonprint texts.

b. *Oral communication.*

(1) Understands oral language, listening, and nonverbal communication skills; knows how to analyze communication interactions; and applies related knowledge and skills to teach students to become competent communicators in varied contexts.

(2) Understands the communication process and related theories, knows the purpose and function of communication and understands how to apply this knowledge to teach students to make appropriate and effective choices as senders and receivers of messages in varied contexts.

c. Language development.

(1) Understands inclusive and appropriate language, patterns and dialects across cultures, ethnic groups, geographic regions and social roles.

(2) Develops strategies to improve competency in the English language arts and understanding of content across the curriculum for students whose first language is not English.

d. Young adult literature, American literature, and world literature.

(1) Reads, comprehends, and analyzes a wide range of texts to build an understanding of self as well as the cultures of the United States and the world in order to acquire new information, to respond to the needs and demands of society and the workplace, and for personal fulfillment. Among these texts are fiction and nonfiction, graphic novels, classic and contemporary works, young adult literature, and nonprint texts.

(2) Reads a wide range of literature from many periods in many genres to build an understanding of the many dimensions (e.g., philosophical, ethical, aesthetic) of human experience.

(3) Applies a wide range of strategies to comprehend, interpret, evaluate, and appreciate texts. Draws on prior experience, interactions with other readers and writers, knowledge of word meaning and of other texts, word identification strategies, and an understanding of textual features (e.g., sound-letter correspondence, sentence structure, context, graphics).

(4) Participates as a knowledgeable, reflective, creative, and critical member of a variety of literacy communities.

e. Creative voice.

(1) Understands the art of oral interpretation and how to provide opportunities for students to develop and apply oral interpretation skills in individual and group performances for a variety of audiences, purposes and occasions.

(2) Understands the basic skills of theatre production including acting, stage movement, and basic stage design.

f. Argumentation/debate.

(1) Understands concepts and principles of classical and contemporary rhetoric and is able to plan, prepare, organize, deliver and evaluate speeches and presentations.

(2) Understands argumentation and debate and how to provide students with opportunities to apply skills and strategies for argumentation and debate in a variety of formats and contexts.

g. Journalism.

(1) Understands ethical standards and major legal issues including First Amendment rights and responsibilities relevant to varied communication content. Utilizes strategies to teach students about the importance of freedom of speech in a democratic society and the rights and responsibilities of communicators.

(2) Understands the writing process as it relates to journalism (e.g., brainstorming, questioning, reporting, gathering and synthesizing information, writing, editing, and evaluating the final media product).

(3) Understands a variety of forms of journalistic writing (e.g., news, sports, features, opinion, Web-based) and the appropriate styles (e.g., Associated Press, multiple sources with attribution, punctuation) and additional forms unique to journalism (e.g., headlines, cutlines, and/or visual presentations).

h. Mass media production.

(1) Understands the role of the media in a democracy and the importance of preserving that role.

(2) Understands how to interpret and analyze various types of mass media messages in order for students to become critical consumers.

(3) Develops the technological skills needed to package media products effectively using various forms of journalistic design with a range of visual and auditory methods.

i. Reading strategies (if not completed as part of the professional education core requirements).

(1) Uses a variety of skills and strategies to comprehend and interpret complex fiction, nonfiction and informational text.

(2) Reads for a variety of purposes and across content areas.

13.28(7) *Foreign language.* K-8 and 5-12. Completion of 24 semester hours in each foreign language for which endorsement is sought.

13.28(8) *Health.* K-8 and 5-12. Completion of 24 semester hours in health to include coursework in public or community health, consumer health, substance abuse, family life education, mental/emotional health, and human nutrition.

13.28(9) *Family and consumer sciences—general.* 5-12. Completion of 24 semester hours in family and consumer sciences to include coursework in human development, parenthood education, family studies, consumer resource management, textiles and apparel, housing, and foods and nutrition.

13.28(10) *Industrial technology.* 5-12. Completion of 24 semester hours in industrial technology to include coursework in manufacturing, construction, energy and power, graphic communications and transportation. The coursework is to include at least 6 semester hours in three different areas.

13.28(11) *Journalism.* 5-12. Completion of 15 semester hours in journalism to include coursework in writing, editing, production and visual communications.

13.28(12) *Mathematics.*

a. K-8. Completion of 24 semester hours in mathematics to include coursework in algebra, geometry, number theory, measurement, computer programming, and probability and statistics.

b. 5-12. Completion of 24 semester hours in mathematics to include a linear algebra or an abstract (modern) algebra course, a geometry course, a two-course sequence in calculus, a computer programming course, a probability and statistics course, and coursework in discrete mathematics.

13.28(13) *Music.*

a. K-8. Completion of 24 semester hours in music to include coursework in music theory (at least two courses), music history, and applied music.

b. 5-12. Completion of 24 semester hours in music to include coursework in music theory (at least two courses), music history (at least two courses), applied music, and conducting.

13.28(14) *Physical education.*

a. K-8. Completion of 24 semester hours in physical education to include coursework in human anatomy, human physiology, movement education, adapted physical education, physical education in the elementary school, human growth and development of children related to physical education, and first aid and emergency care.

b. 5-12. Completion of 24 semester hours in physical education to include coursework in human anatomy, kinesiology, human physiology, human growth and development related to maturational and motor learning, adapted physical education, curriculum and administration of physical education, assessment processes in physical education, and first aid and emergency care.

13.28(15) *Reading.*

a. K-8 requirements. Completion of 24 semester hours in reading to include all of the following requirements:

(1) Foundations of reading. This requirement includes the following competencies:

1. The practitioner demonstrates knowledge of the psychological, sociocultural, and linguistic foundations of reading and writing processes and instruction.

2. The practitioner demonstrates knowledge of a range of research pertaining to reading, writing, and learning, including scientifically based reading research, and knowledge of histories of reading. The range of research encompasses research traditions from the fields of the social sciences and other paradigms appropriate for informing practice.

3. The practitioner demonstrates knowledge of the major components of reading, such as phonemic awareness, word identification, phonics, vocabulary, fluency, and comprehension, and effectively integrates curricular standards with student interests, motivation, and background knowledge.

(2) Reading in the content areas. This requirement includes the following competencies:

1. The practitioner demonstrates knowledge of text structure and the dimensions of content area vocabulary and comprehension, including literal, interpretive, critical, and evaluative.

2. The practitioner provides content area instruction in reading and writing that effectively uses a variety of research-based strategies and practices.

(3) Practicum. This requirement includes the following competencies:

1. The practitioner works with licensed professionals who observe, evaluate, and provide feedback on the practitioner's knowledge, dispositions, and performance of the teaching of reading and writing.

2. The practitioner effectively uses reading and writing strategies, materials, and assessments based upon appropriate reading and writing research and works with colleagues and families in the support of children's reading and writing development.

(4) Language development. This requirement includes the following competency: The practitioner uses knowledge of language development and acquisition of reading skills (birth through sixth grade), and the variations related to cultural and linguistic diversity to provide effective instruction in reading and writing.

(5) Oral communication. This requirement includes the following competencies:

1. The practitioner has knowledge of the unique needs and backgrounds of students with language differences and delays.

2. The practitioner uses effective strategies for facilitating the learning of Standard English by all learners.

(6) Written communication. This requirement includes the following competency: The practitioner uses knowledge of reading-writing-speaking connections; the writing process; the stages of spelling development; the different types of writing, such as narrative, expressive, persuasive, informational and descriptive; and the connections between oral and written language development to effectively teach writing as communication.

(7) Reading assessment, diagnosis and evaluation. This requirement includes the following competencies:

1. The practitioner uses knowledge of a variety of instruments, procedures, and practices that range from individual to group and from formal to informal to alternative for the identification of students' reading proficiencies and needs, for planning and revising instruction for all students, and for communicating the results of ongoing assessments to all stakeholders.

2. The practitioner demonstrates awareness of policies and procedures related to special programs, including Title I.

(8) Children's nonfiction and fiction. This requirement includes the following competency: The practitioner uses knowledge of children's literature for:

1. Modeling the reading and writing of varied genres, including fiction and nonfiction; technology- and media-based information; and nonprint materials;

2. Motivating through the use of texts at multiple levels, representing broad interests, and reflecting varied cultures, linguistic backgrounds, and perspectives; and

3. Matching text complexities to the proficiencies and needs of readers.

(9) Reading instructional strategies. This requirement includes the following competency: The practitioner uses knowledge of a range of research-based strategies and instructional technology for designing and delivering effective instruction across the curriculum, for grouping students, and for selecting materials appropriate for learners at various stages of reading and writing development and from varied cultural and linguistic backgrounds.

b. 5-12 requirements. Completion of 24 semester hours in reading to include all of the following requirements:

(1) Foundations of reading. This requirement includes the following competencies:

1. The practitioner demonstrates knowledge of the psychological, sociocultural, and linguistic foundations of reading and writing processes and instruction.

2. The practitioner demonstrates knowledge of a range of research pertaining to reading, writing, and learning, including scientifically based reading research, and knowledge of histories of reading. The range of research encompasses research traditions from the fields of the social sciences and other paradigms appropriate for informing practice.

3. The practitioner demonstrates knowledge of the major components of reading such as phonemic awareness, word identification, phonics, vocabulary, fluency, and comprehension, and integrates curricular standards with student interests, motivation, and background knowledge.

(2) Reading in the content areas. This requirement includes the following competencies:

1. The practitioner demonstrates knowledge of text structure and the dimensions of content area vocabulary and comprehension, including literal, interpretive, critical, and evaluative.

2. The practitioner provides content area instruction in reading and writing that effectively uses a variety of research-based strategies and practices.

(3) Practicum. This requirement includes the following competencies:

1. The practitioner works with licensed professionals who observe, evaluate, and provide feedback on the practitioner's knowledge, dispositions, and performance of the teaching of reading and writing.

2. The practitioner effectively uses reading and writing strategies, materials, and assessments based upon appropriate reading and writing research, and works with colleagues and families in the support of students' reading and writing development.

(4) Language development. This requirement includes the following competency: The practitioner uses knowledge of the relationship of language acquisition and language development with the acquisition and development of reading skills, and the variations related to cultural and linguistic diversity to provide effective instruction in reading and writing.

(5) Oral communication. This requirement includes the following competency: The practitioner demonstrates knowledge of the unique needs and backgrounds of students with language differences and uses effective strategies for facilitating the learning of Standard English by all learners.

(6) Written communication. This requirement includes the following competency: The practitioner uses knowledge of reading-writing-speaking connections to teach the skills and processes necessary for writing narrative, expressive, persuasive, informational, and descriptive texts, including text structures and mechanics such as grammar, usage, and spelling.

(7) Reading assessment, diagnosis and evaluation. This requirement includes the following competencies:

1. The practitioner uses knowledge of a variety of instruments, procedures, and practices that range from individual to group and from formal to informal to alternative for the identification of students' reading proficiencies and needs, for planning and revising instruction for all students, and for communicating the results of ongoing assessments to all stakeholders.

2. The practitioner demonstrates awareness of policies and procedures related to special programs.

(8) Adolescent or young adult nonfiction and fiction. This requirement includes the following competency: The practitioner uses knowledge of adolescent or young adult literature for:

1. Modeling the reading and writing of varied genres, including fiction and nonfiction; technology and media-based information; and nonprint materials;

2. Motivating through the use of texts at multiple levels, representing broad interests, and reflecting varied cultures, linguistic backgrounds and perspectives; and

3. Matching text complexities to the proficiencies and needs of readers.

(9) Reading instructional strategies. This requirement includes the following competency: The practitioner uses knowledge of a range of research-based strategies and instructional technology for designing and delivering instruction across the curriculum, for grouping students, and for selecting materials appropriate for learners at various stages of reading and writing development and from varied cultural and linguistic backgrounds.

13.28(16) *Reading specialist.* K-12. The applicant must have met the requirements for the standard license and a teaching endorsement, and present evidence of at least one year of experience which included the teaching of reading as a significant part of the responsibility.

a. Authorization. The holder of this endorsement is authorized to serve as a reading specialist in kindergarten and grades one through twelve.

b. Program requirements. Degree—master's.

c. *Content.* Completion of a sequence of courses and experiences which may have been a part of, or in addition to, the degree requirements. This sequence is to be at least 27 semester hours to include the following:

(1) Educational psychology/human growth and development.

(2) Educational measurement and evaluation.

(3) Foundations of reading.

(4) Diagnosis of reading problems.

(5) Remedial reading.

(6) Psychology of reading.

(7) Language learning and reading disabilities.

(8) Practicum in reading.

(9) Administration and supervision of reading programs at the elementary and secondary levels.

13.28(17) *Science.*

a. *Science—basic.* K-8.

(1) Required coursework. Completion of at least 24 semester hours in science to include 12 hours in physical sciences, 6 hours in biology, and 6 hours in earth/space sciences.

(2) Competencies.

1. Understand the nature of scientific inquiry, its central role in science, and how to use the skills and processes of scientific inquiry.

2. Understand the fundamental facts and concepts in major science disciplines.

3. Be able to make conceptual connections within and across science disciplines, as well as to mathematics, technology, and other school subjects.

4. Be able to use scientific understanding when dealing with personal and societal issues.

b. *Biological science.* 5-12. Completion of 24 semester hours in biological science or 30 semester hours in the broad area of science to include 15 semester hours in biological science.

c. *Chemistry.* 5-12. Completion of 24 semester hours in chemistry or 30 semester hours in the broad area of science to include 15 semester hours in chemistry.

d. *Earth science.* 5-12. Completion of 24 semester hours in earth science or 30 semester hours in the broad area of science to include 15 semester hours in earth science.

e. *General science.* 5-12. Completion of 24 semester hours in science to include coursework in biological science, chemistry, and physics.

f. *Physical science.* 5-12. Completion of 24 semester hours in physical sciences to include coursework in physics, chemistry, and earth science.

g. *Physics.* 5-12. Completion of 24 semester hours in physics or 30 semester hours in the broad area of science to include 15 semester hours in physics.

h. *All science I.* 5-8. The holder of this endorsement must also hold the middle school endorsement listed under rule 282—13.27(272).

(1) Required coursework. Completion of at least 24 semester hours in science to include 6 hours in chemistry, 6 hours in physics or physical sciences, 6 hours in biology, and 6 hours in the earth/space sciences.

(2) Competencies.

1. Understand the nature of scientific inquiry, its central role in science, and how to use the skills and processes of scientific inquiry.

2. Understand the fundamental facts and concepts in major science disciplines.

3. Be able to make conceptual connections within and across science disciplines, as well as to mathematics, technology, and other school subjects.

4. Be able to use scientific understanding when dealing with personal and societal issues.

i. *All science II.* 9-12.

(1) Required coursework.

1. Completion of one of the following endorsement areas listed under subrule 13.28(17): biological science 5-12 or chemistry 5-12 or earth science 5-12 or physics 5-12.

2. Completion of at least 12 hours in each of the other three endorsement areas.

(2) Competencies.

1. Understand the nature of scientific inquiry, its central role in science, and how to use the skills and processes of scientific inquiry.

2. Understand the fundamental facts and concepts in major science disciplines.

3. Be able to make conceptual connections within and across science disciplines, as well as to mathematics, technology, and other school subjects.

4. Be able to use scientific understanding when dealing with personal and societal issues.

13.28(18) *Social sciences.*

a. American government. 5-12. Completion of 24 semester hours in American government or 30 semester hours in the broad area of social sciences to include 15 semester hours in American government.

b. American history. 5-12. Completion of 24 semester hours in American history or 30 semester hours in the broad area of social sciences to include 15 semester hours in American history.

c. Anthropology. 5-12. Completion of 24 semester hours in anthropology or 30 semester hours in the broad area of social sciences to include 15 semester hours in anthropology.

d. Economics. 5-12. Completion of 24 semester hours in economics or 30 semester hours in the broad area of social sciences to include 15 semester hours in economics, or 30 semester hours in the broad area of business to include 15 semester hours in economics.

e. Geography. 5-12. Completion of 24 semester hours in geography or 30 semester hours in the broad area of social sciences to include 15 semester hours in geography.

f. History. K-8. Completion of 24 semester hours in history to include at least 9 semester hours in American history and 9 semester hours in world history.

g. Psychology. 5-12. Completion of 24 semester hours in psychology or 30 semester hours in the broad area of social sciences to include 15 semester hours in psychology.

h. Social studies. K-8. Completion of 24 semester hours in social studies, to include coursework from at least three of these areas: history, sociology, economics, American government, psychology and geography.

i. Sociology. 5-12. Completion of 24 semester hours in sociology or 30 semester hours in the broad area of social sciences to include 15 semester hours in sociology.

j. World history. 5-12. Completion of 24 semester hours in world history or 30 semester hours in the broad area of social sciences to include 15 semester hours in world history.

k. All social sciences. 5-12. Completion of 51 semester hours in the social sciences to include 9 semester hours in each of American and world history, 9 semester hours in government, 6 semester hours in sociology, 6 semester hours in psychology other than educational psychology, 6 semester hours in geography, and 6 semester hours in economics.

13.28(19) *Speech communication/theatre.*

a. K-8. Completion of 20 semester hours in speech communication/theatre to include coursework in speech communication, creative drama or theatre, and oral interpretation.

b. 5-12. Completion of 24 semester hours in speech communication/theatre to include coursework in speech communication, oral interpretation, creative drama or theatre, argumentation and debate, and mass media communication.

13.28(20) *English as a second language (ESL).* K-12.

a. Authorization. The holder of this endorsement is authorized to teach English as a second language in kindergarten and grades one through twelve.

b. Program requirements.

(1) Degree—baccalaureate, and

(2) Completion of an approved human relations program, and

(3) Completion of the professional education core. See subrules 13.18(3) and 13.18(4).

c. Content. Completion of 18 semester hours of coursework in English as a second language to include the following:

(1) Knowledge of pedagogy to include the following:

1. Methods and curriculum to include the following:

- Bilingual and ESL methods.

- Literacy in native and second language.
- Methods for subject matter content.
- Adaptation and modification of curriculum.

2. Assessment to include language proficiency and academic content.

(2) Knowledge of linguistics to include the following:

1. Psycholinguistics and sociolinguistics.
2. Language acquisition and proficiency to include the following:

- Knowledge of first and second language proficiency.
- Knowledge of first and second language acquisition.
- Language to include structure and grammar of English.

(3) Knowledge of cultural and linguistic diversity to include the following:

1. History.
2. Theory, models, and research.
3. Policy and legislation.

(4) Current issues with transient populations.

d. *Other.* Individuals who were licensed in Iowa prior to October 1, 1988, and were allowed to teach English as a second language without completing the endorsement requirements must complete the endorsement requirements by July 1, 2012, in order to teach or continue to teach English as a second language. A waiver provision is available through the board of educational examiners for individuals who have been successfully teaching English as a second language.

13.28(21) *Elementary school teacher librarian.*

a. *Authorization.* The holder of this endorsement is authorized to serve as a teacher librarian in kindergarten and grades one through eight.

b. *Program requirements.*

(1) Degree—baccalaureate.

(2) Completion of an approved human relations program.

(3) Completion of the professional education core. See subrules 13.18(3) and 13.18(4).

c. *Content.* Completion of 24 semester hours in school library coursework to include the following:

(1) Knowledge of materials and literature in all formats for elementary children.

(2) Selection, utilization and evaluation of library resources and equipment.

(3) Design and production of instructional materials.

(4) Acquisition, cataloging and classification of library materials.

(5) Information literacy, reference services and networking.

(6) Planning, evaluation and administration of school library programs.

(7) Practicum in an elementary school media center/library.

13.28(22) *Secondary school teacher librarian.*

a. *Authorization.* The holder of this endorsement is authorized to serve as a teacher librarian in grades five through twelve.

b. *Program requirements.*

(1) Degree—baccalaureate.

(2) Completion of an approved human relations program.

(3) Completion of the professional education core. See subrules 13.18(3) and 13.18(4).

c. *Content.* Completion of 24 semester hours in school library coursework to include the following:

(1) Knowledge of materials and literature in all formats for adolescents.

(2) Selection, utilization and evaluation of library resources and equipment.

(3) Design and production of instructional materials.

(4) Acquisition, cataloging and classification of library materials.

(5) Information literacy, reference services and networking.

(6) Planning, evaluation and administration of school library programs.

(7) Practicum in a secondary school media center/library.

13.28(23) *School teacher librarian.* K-12.

a. Authorization. The holder of this endorsement is authorized to serve as a teacher librarian in kindergarten and grades one through twelve. The applicant must be the holder of or eligible for the initial license.

b. Program requirements. Degree—master's.

c. Content. Completion of a sequence of courses and experiences which may have been part of, or in addition to, the degree requirements. This sequence is to be at least 30 semester hours in school library coursework, to include the following:

(1) Planning, evaluation and administration of school library programs.
(2) Curriculum development and teaching and learning strategies.
(3) Instructional development and communication theory.
(4) Selection, evaluation and utilization of library resources and equipment.
(5) Acquisition, cataloging and classification of library materials.
(6) Design and production of instructional materials.
(7) Methods for instruction and integration of information literacy skills into the school curriculum.
(8) Information literacy, reference services and networking.
(9) Knowledge of materials and literature in all formats for elementary children and adolescents.
(10) Reading, listening and viewing guidance.
(11) Utilization and application of computer technology.
(12) Practicum at both the elementary and secondary levels.
(13) Research in library and information science.

13.28(24) *Talented and gifted teacher.*

a. Authorization. The holder of this endorsement is authorized to serve as a teacher or a coordinator of programs for the talented and gifted from the prekindergarten level through grade twelve. This authorization does not permit general classroom teaching at any level except that level or area for which the holder is eligible or holds the specific endorsement.

b. Program requirements—content. Completion of 12 undergraduate or graduate semester hours of coursework in the area of the talented and gifted to include the following:

(1) Psychology of the gifted.
1. Social needs.
2. Emotional needs.
(2) Programming for the gifted.
1. Prekindergarten-12 identification.
2. Differentiation strategies.
3. Collaborative teaching skills.
4. Program goals and performance measures.
5. Program evaluation.
(3) Practicum experience in gifted programs.

NOTE: Teachers in specific subject areas will not be required to hold this endorsement if they teach gifted students in their respective endorsement areas.

c. Other. Individuals who were licensed in Iowa prior to August 31, 1995, and were allowed to teach talented and gifted classes without completing the endorsement requirements must complete the endorsement requirements by July 1, 2012, in order to teach or continue to teach talented and gifted classes. A waiver provision is provided through the board of educational examiners for individuals who have been successfully teaching students who are talented and gifted.

13.28(25) *American Sign Language endorsement.*

a. Authorization. The holder of this endorsement is authorized to teach American Sign Language in kindergarten and grades one through twelve.

b. Program requirements.

(1) Degree—baccalaureate.
(2) Completion of an approved human relations program.
(3) Completion of the professional education core.

c. Content. Completion of 18 semester hours of coursework in American Sign Language to include the following:

(1) Second language acquisition.

(2) Sociology of the deaf community.

(3) Linguistic structure of American Sign Language.

(4) Language teaching methodology specific to American Sign Language.

(5) Teaching the culture of deaf people.

(6) Assessment of students in an American Sign Language program.

d. Other. Be the holder of or be eligible for one other teaching endorsement listed in rules 282—13.26(272) and 282—13.27(272) and this rule.

13.28(26) *Elementary counselor.* Rescinded IAB 7/29/09, effective 9/2/09.

13.28(27) *Secondary counselor.* Rescinded IAB 7/29/09, effective 9/2/09.

13.28(28) *School nurse endorsement.* The school nurse endorsement does not authorize general classroom teaching, although it does authorize the holder to teach health at all grade levels. Alternatively, a nurse may obtain a statement of professional recognition (SPR) from the board of educational examiners, in accordance with the provisions set out in 282—Chapter 16, Statements of Professional Recognition (SPR).

a. Authorization. The holder of this endorsement is authorized to provide service as a school nurse at the prekindergarten and kindergarten levels and in grades one through twelve.

b. Program requirements.

(1) Degree—baccalaureate, and

(2) Completion of an approved human relations program, and

(3) Completion of the professional education core. See subrules 13.18(3) and 13.18(4).

c. Content.

(1) Organization and administration of school nurse services including the appraisal of the health needs of children and youth.

(2) School-community relationships and resources/coordination of school and community resources to serve the health needs of children and youth.

(3) Knowledge and understanding of the health needs of exceptional children.

(4) Health education.

d. Other. Hold a license as a registered nurse issued by the Iowa board of nursing.

13.28(29) *Athletic coach.* K-12. An applicant for the coaching endorsement must hold a teacher's license with one of the teaching endorsements.

a. Authorization. The holder of this endorsement may serve as a head coach or an assistant coach in kindergarten and grades one through twelve.

b. Program requirements.

(1) One semester hour college or university course in the structure and function of the human body in relation to physical activity, and

(2) One semester hour college or university course in human growth and development of children and youth as related to physical activity, and

(3) Two semester hour college or university course in athletic conditioning, care and prevention of injuries and first aid as related to physical activity, and

(4) One semester hour college or university course in the theory of coaching interscholastic athletics.

[**ARC 7986B**, IAB 7/29/09, effective 9/2/09; **ARC 8248B**, IAB 11/4/09, effective 10/12/09; **ARC 8403B**, IAB 12/16/09, effective 1/20/10]

282—13.29(272) Adding, removing or reinstating a teaching endorsement.

13.29(1) *Adding an endorsement.* After the issuance of a teaching license, an individual may add other endorsements to that license upon proper application, provided current requirements for that endorsement have been met. An updated license with expiration date unchanged from the original or renewed license will be prepared.

a. Options. To add an endorsement, the applicant must follow one of these options:

(1) Option 1. Receive the Iowa teacher education institution's recommendation that the current approved program requirements for the endorsement have been met.

(2) Option 2. Receive verification from the Iowa teacher education institution that the minimum state requirements for the endorsement have been met in lieu of the institution's approved program.

(3) Option 3. Receive verification from a state-approved and regionally accredited institution that the Iowa minimum requirements for the endorsement have been met.

(4) Option 4. Apply for a review of the transcripts by the board of educational examiners' staff to determine if all Iowa requirements have been met. The applicant must submit documentation that all of the Iowa requirements have been met by filing transcripts and supporting documentation for review. The fee for the transcript evaluation is in 282—Chapter 12. This fee shall be in addition to the fee for adding the endorsement.

b. Additional requirements for adding an endorsement.

(1) In addition to meeting the requirements listed in rules 282—13.18(272) and 282—13.28(272), applicants for endorsements shall have completed a methods class appropriate for teaching the general subject area of the endorsement added.

(2) Practitioners who are adding an elementary or early childhood endorsement and have not student taught on the elementary or early childhood level shall complete a teaching practicum appropriate for teaching at the level of the new endorsement.

(3) Practitioners who are adding a secondary teaching endorsement and have not student taught on the secondary level shall complete a teaching practicum appropriate for teaching at the level of the new endorsement.

(4) Practitioners holding the K-8 endorsement in the content area of the 5-12 endorsement being added may satisfy the requirement for the secondary methods class and the teaching practicum by completing all required coursework and presenting verification of competence. This verification of competence shall be signed by a licensed evaluator who has observed and formally evaluated the performance of the applicant at the secondary level. This verification of competence may be submitted at any time during the term of the Class B license. The practitioner must obtain a Class B license while practicing with the 5-12 endorsement.

13.29(2) *Removal of an endorsement; reinstatement of removed endorsement.*

a. Removal of an endorsement. A practitioner may remove an endorsement from the practitioner's license as follows:

(1) To remove an endorsement, the practitioner shall meet the following conditions:

1. A practitioner who holds a standard or master educator license is eligible to request removal of an endorsement from the license if the practitioner has not taught in the subject or assignment area of the endorsement in the five years prior to the request for removal of the endorsement, and

2. The practitioner must submit a notarized written application form furnished by the board of educational examiners to remove an endorsement at the time of licensure renewal (licensure renewal is limited to one calendar year prior to the expiration date of the current license), and

3. The application must be signed by the superintendent or designee in the district in which the practitioner is under contract. The superintendent's signature shall serve as notification and acknowledgment of the practitioner's intent to remove an endorsement from the practitioner's license. The absence of the superintendent's or designee's signature does not impede the removal process.

(2) The endorsement shall be removed from the license at the time of application.

(3) If a practitioner is not employed and submits an application, the provisions of 13.29(2)*"a"*(1)"3" shall not be required.

(4) If a practitioner submits an application that does not meet the criteria listed in 13.29(2)*"a"*(1)"1" to "3," the application will be rendered void and the practitioner will forfeit the processing fee.

(5) The executive director has the authority to approve or deny the request for removal. Any denial is subject to the appeal process set forth in rule 282—11.35(272).

b. Reinstatement of a removed endorsement.

(1) If the practitioner wants to add the removed endorsement at a future date, all coursework for the endorsement must be completed within the five years preceding the application to add the endorsement.

(2) The practitioner must meet the current endorsement requirements when making application.

[**ARC 8248B**, IAB 11/4/09, effective 10/12/09]

282—13.30(272) Licenses—issue dates, corrections, duplicates, and fraud.

13.30(1) *Issue date on original license.* A license is valid only from and after the date of issuance.

13.30(2) *Correcting licenses.* If a licensee notifies board staff of a typographical or clerical error on the license within 30 days of the date of the board's mailing of a license, a corrected license shall be issued without charge to the licensee. If notification of a typographical or clerical error is made more than 30 days after the date of the board's mailing of a license, a corrected license shall be issued upon receipt of the fee for issuance of a duplicate license. For purposes of this rule, typographical or clerical errors include misspellings, errors in the expiration date of a license, errors in the type of license issued, and the omission or misidentification of the endorsements for which application was made. A licensee requesting the addition of an endorsement not included on the initial application must submit a new application and the appropriate application fee.

13.30(3) *Duplicate licenses.* Upon application and payment of the fee set out in 282—Chapter 12, a duplicate license shall be issued.

13.30(4) *Fraud in procurement or renewal of licenses.* Fraud in procurement or renewal of a license or falsifying records for licensure purposes will constitute grounds for filing a complaint with the board of educational examiners.

These rules are intended to implement Iowa Code chapter 272.

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HUMAN SERVICES DEPARTMENT[441]

Rules transferred from Social Services Department[770] to Human Services Department[498], see 1983 Iowa Acts, Senate File 464, effective July 1, 1983.
Rules transferred from agency number [498] to [441] to conform with the reorganization numbering scheme in general, IAC Supp. 2/11/87.

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EMERGENCY ASSISTANCE

DIVISION I
IOWA DISASTER AID INDIVIDUAL ASSISTANCE GRANT PROGRAM

PREAMBLE

This division implements a state program of financial assistance to meet disaster-related expenses, food-related costs, or serious needs of individuals or families who are adversely affected by a state-declared disaster emergency. The program is intended to meet needs that cannot be met by other means of financial assistance.

441—58.1(29C) Definitions.

"Emergency management coordinator" means the person appointed by the local emergency management commission pursuant to Iowa Code sections 29C.9 and 29C.10 to be responsible for development of the countywide emergency operations plan and for coordination and assistance to government officials when an emergency or disaster occurs.

"Household" means all adults and children who lived in the pre-disaster residence who request assistance, as well as any persons, such as infants, spouses, or part-time residents, who were not present at the time of the disaster but who are expected to return during the assistance period.

"Necessary expense" means the cost associated with acquiring an item or items, obtaining a service, or paying for any other activity that meets a serious need.

"Safe, sanitary, and secure" means free from disaster-related health hazards.

"Serious need" means the item or service is essential to the household to prevent, mitigate, or overcome a disaster-related hardship, injury, or adverse condition.

441—58.2(29C) Program implementation. The Iowa individual assistance grant program (IIAGP) shall be implemented when the governor issues a declaration of a state of disaster emergency and shall be in effect only in those counties named in the declaration. Assistance shall be provided for a period not to exceed 120 days from the date of declaration.

441—58.3(29C) Application for assistance. To request reimbursement for disaster-related expenses, the household shall complete Form 470-4448, Individual Disaster Assistance Application, and submit it within 45 days of the disaster declaration to the county emergency management coordinator along with receipts for the claimed expenses.

58.3(1) Application forms are available from county emergency management coordinators and local offices of the department of human services, as well as the Internet Web site of the department at www.dhs.iowa.gov.

58.3(2) The application shall include:

a. A declaration of the household's annual income, accompanied by:

(1) A current pay stub, W-2 form, or income tax return, or

(2) Documentation of current enrollment in an assistance program administered by the department of human services, the Special Supplemental Nutrition Program for Women, Infants and Children (WIC), or other subsidy program.

b. A release of confidential information to personnel involved in administering the program.

c. A certification of the accuracy of the information provided.

d. An assurance that the household had no insurance coverage for claimed items.

e. A commitment to refund any part of a grant awarded that is duplicated by insurance or by any other assistance program, such as but not limited to local community development groups and charities, the Small Business Administration, or the Federal Emergency Management Administration.

f. A short, handwritten narrative of the disaster event and how the disaster caused the loss being claimed.

g. A copy of a picture identification document for each adult applicant.

h. When vehicle damage is claimed, current copies of the vehicle registration and liability insurance card.

441—58.4(29C) Eligibility criteria. To be eligible for assistance, an applicant household must meet all of the following conditions:

58.4(1) The household's residence was located in the area identified in the disaster declaration during the designated incident period and the household verifies occupancy at that residence.

58.4(2) Household members are citizens of the United States or are legally residing in the United States.

58.4(3) The household's self-declared annual income is at or less than 200 percent of the federal poverty level for a household of that size.

a. Poverty guidelines are updated annually.

b. All income available to the household is counted, including wages, child support, interest from investments or bank accounts, social security benefits, and retirement income.

58.4(4) The household has disaster-related expenses or serious needs that are not covered by insurance or the claim is less than the deductible amount. This program will not reimburse the amount of the insurance deductible when the claim exceeds the deductible amount.

58.4(5) The household has not previously received assistance from this program or another program for the same loss.

441—58.5(29C) Eligible categories of assistance. The maximum assistance available to a household in a single disaster is $5,000. Reimbursement is available under the program for the following disaster-related expenses:

58.5(1) Reimbursement may be issued for personal property, including repair or replacement of the following items, based on the item's condition:

a. Kitchen items, up to a maximum of $560, including:

(1) Equipment and furnishings, up to a maximum of $560.

(2) Food, up to a maximum of $50 for one person plus $25 for each additional person in the household.

b. Personal hygiene items, up to a maximum of $30 per person and $150 per household.

c. Clothing and bedroom furnishings, up to a maximum of $875, including:

(1) Mattress, box spring, frame, and storage containers, up to a maximum of $250 per person.

(2) Clothing, up to a maximum of $145 per person.

d. Other items, including:

(1) Infant car seat, up to a maximum of $40.

(2) Dehumidifier, up to a maximum of $150.

(3) Sump pump (in a flood event only), up to a maximum of $200 installed.

(4) Electrical or mechanical repairs, up to a maximum of $1,000.

(5) Water heater, up to a maximum of $425 installed.

(6) Vehicle repair, up to a maximum of $500.

(7) Heating and air-conditioning systems, up to a maximum of $2,100 installed. Air conditioning is covered only with proof of medical necessity.

58.5(2) Reimbursement may be issued for home repair as needed to make the home safe, sanitary, and secure, up to a maximum of $5,000.

a. Assistance will be denied if preexisting conditions are the cause of the damage.

b. Reimbursement may be authorized for:

(1) The repair of structural components, such as the foundation and roof.

(2) The repair of floors, walls, ceilings, doors, windows, and carpeting of essential interior living space that was occupied at the time of the disaster.

(3) Debris removal, including trees, up to a maximum of $1,000.

c. Repairs to rental property are excluded under this program.

58.5(3) Reimbursement may be issued for temporary housing assistance, up to a limit of $50 per day, for lodging at a licensed establishment, such as a hotel or motel, if the household's home is destroyed, uninhabitable, inaccessible, or unavailable to the household.

441—58.6(29C) Eligibility determination and payment.

58.6(1) The county emergency management coordinator or designee shall:

a. Confirm that:

(1) The address provided on the application is a valid address and is reasonably believed to be in the disaster-affected area, and

(2) Disaster-related expenses were possible as a result of the current disaster.

b. Submit the household's application form to the Homeland Security and Emergency Management Division, Camp Dodge, Building W-4, 7105 NW 70th Avenue, Johnston, Iowa 50131. The envelope shall be marked "IIAGP application."

58.6(2) The homeland security and emergency management division of the department of public defense shall:

a. Review the application.

b. Submit the household's application form to the DHS Division of Results-Based Accountability, 1305 East Walnut Street, Des Moines, Iowa 50319-0114. The envelope shall be marked "IIAGP application."

58.6(3) Designated disaster staff in the department of human services shall:

a. Determine eligibility and the amount of payment.

b. Notify the applicant household of the eligibility decision.

c. Authorize payment to an eligible household.

d. Process appeals.

441—58.7(29C) Contested cases.

58.7(1) *Reconsideration.* The household may request reconsideration of the department's decisions regarding eligibility and the amount of reimbursement awarded.

a. To request reconsideration, the household shall submit a written request to the DHS Division of Results-Based Accountability, 1305 East Walnut Street, Des Moines, Iowa 50319-0114, within 15 days of the date of the department's letter notifying the household of its decision.

b. The department shall review any additional evidence or documentation submitted and issue a reconsideration decision within 15 days of receipt of the request.

58.7(2) *Appeal.* The household may appeal the department's reconsideration decision according to procedures in 441—Chapter 7.

a. Appeals must be submitted in writing, either on Form 470-0487 or 470-0487(S), Appeal and Request for Hearing, or in any form that provides comparable information, to the DHS Appeals Section, 1305 East Walnut Street, Des Moines, Iowa 50319-0114, within 15 days of the date of the reconsideration decision.

b. A written appeal is filed on the date the envelope sent to the department is postmarked or, when the postmarked envelope is not available, on the date the appeal is stamped received by the agency.

441—58.8(29C) Discontinuance of program.

58.8(1) *Deferral to federal assistance.* Upon declaration of a disaster by the President of the United States under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. Sections 5121 to 5206, the Iowa individual assistance grant program administered under this chapter shall be discontinued in the geographic area included in the presidential declaration. Upon issuance of the presidential declaration:

a. No more applications shall be accepted.

b. Any applications that are in process but are not yet approved shall be denied.

c. Persons seeking assistance under this program shall be advised to apply for federal disaster assistance.

58.8(2) *Exhaustion of funds.* The program shall be discontinued when funds available for the program have been exhausted. To ensure equitable treatment, applications for assistance shall be approved on a first-come, first-served basis until all funds have been depleted. "First-come, first-served" is determined by the date the application is approved for payment.

a. *Partial payment.* Because funds are limited, applications may be approved for less than the amount requested. Payment cannot be approved beyond the amount of funds available.

b. *Reserved funds.* A portion of allocated funds shall be reserved for final appeal decisions reversing the department's denial that are received after funds for the program have been awarded.

c. *Untimely applications.* Applications received after the program is discontinued shall be denied.

These rules are intended to implement Iowa Code chapter 29C as amended by 2007 Iowa Acts, House File 896.

441—58.9 to **58.20** Reserved.

DIVISION II
FAMILY INVESTMENT PROGRAM—EMERGENCY ASSISTANCE
[Prior to 10/13/93, 441—58.1 to 58.11]
Rescinded IAB 4/7/10, effective 5/12/10

441—58.21 to **58.40** Reserved.

DIVISION III
TEMPORARY MEASURES RELATED TO DISASTERS

441—58.41(217) Purpose. The rules in this division are intended to allow the department to deliver services more effectively during or following a disaster emergency declared by state or federal officials. These rules temporarily supersede departmental rules that would otherwise apply, with the primary purpose of reducing barriers to accessing and receiving services that may result from the emergency. The rules shall be tailored to meet special circumstances that arise from a specific disaster emergency and shall be time-limited.

This rule is intended to implement Iowa Code section 217.6.
[**ARC 7577B**, IAB 2/25/09, effective 4/1/09]

441—58.42(234,237A,239B,249,249A,249J,514I) Extension of scheduled reporting and review requirements. Normal scheduled reporting, review, recertification, redetermination, or similar requirements related to continued eligibility are amended as follows:

58.42(1) *Scheduled actions due in June 2008.* For the month of June 2008, no quarterly report, six-month or 12-month review, or similar recertification or redetermination normally required under the following chapters shall be required of households residing in the most affected counties during the month. For all programs except food assistance, the designated counties are Black Hawk, Bremer, Butler, Johnson, and Linn.

1. 441—Chapter 40 (family investment program);
2. 441—Chapter 50 (state supplementary assistance);
3. 441—Chapter 65 (food assistance);
4. 441—Chapter 75, 76, or 83 (medical assistance and family planning waiver);
5. 441—Chapter 86 (HAWK-I);
6. 441—Chapter 92 (IowaCare); or
7. 441—Chapter 170 (child care assistance).

58.42(2) *Scheduled actions due in July and August 2008.* For the months of July and August 2008, no quarterly report, six-month or 12-month review, or similar recertification or redetermination normally required under the following chapters shall be required of households residing in any county of the state:

1. 441—Chapter 40 (family investment program);
2. 441—Chapter 50 (state supplementary assistance);
3. 441—Chapter 65 (food assistance);

4. 441—Chapter 75, 76, or 83 (medical assistance and family planning waiver);
5. 441—Chapter 86 (HAWK-I);
6. 441—Chapter 92 (IowaCare); or
7. 441—Chapter 170 (child care assistance).

58.42(3) *Next scheduled action due.* For those households affected under subrules 58.42(1) and 58.42(2), the next report, review, recertification, or redetermination shall be scheduled as if the action due in June, July, or August 2008 had occurred. For example, if a six-month review was to have occurred in June 2008, the next review will be due in December 2008. Likewise, if a 12-month recertification was due in July 2008, the next recertification will be due in July 2009.

58.42(4) *Continuing to report and act on changes.* Other than as provided by this rule, households shall continue to comply with program requirements for reporting changes in circumstances. Good cause provisions for not reporting changes timely shall apply as provided by existing rules. The department shall continue to act on all changes reported or otherwise known to the department that may affect eligibility or benefits during the extended reporting, review, recertification and redetermination periods provided under this rule.

This rule is intended to implement Iowa Code chapters 234, 237A, 239B, 249, 249A, 249J, and 514I.
[**ARC 7577B**, IAB 2/25/09, effective 4/1/09]

441—58.43(237A) Need for child care services. State child care assistance eligibility requirements concerning need for service in rule 441—170.2(237A,239B) shall be held in abeyance for households residing in governor-declared disaster counties during the months of June, July, and August 2008. Households in those counties that previously met the requirement shall be considered to continue to meet the requirement for those three months if the disaster and ensuing recovery temporarily prevent the household from otherwise meeting this requirement.

This rule is intended to implement Iowa Code section 237A.13.
[**ARC 7577B**, IAB 2/25/09, effective 4/1/09]

441—58.44(249A,249J,514I) Premium payments. Individuals residing in any Iowa county declared by the governor to be a disaster area who would otherwise have their assistance under 441—Chapter 75 (medical assistance), 441—Chapter 86 (HAWK-I), or 441—Chapter 92 (IowaCare) canceled for failure to make a premium payment in the months of June or July 2008 shall not have their assistance canceled for this reason.

This rule is intended to implement Iowa Code chapters 249A, 249J, and 514I.
[**ARC 7577B**, IAB 2/25/09, effective 4/1/09]

441—58.45(249A) Citizenship and identity. Citizenship and identity requirements under 441—Chapter 75 for medical assistance applicants shall be held in abeyance for the months of June, July, and August 2008, for individuals residing in counties declared disaster areas by the governor as provided in this rule.

58.45(1) An affidavit may be used to establish both citizenship and identity when other forms of verification are not available and the department is unable to obtain verification through a match with vital records maintained by the department of public health.

58.45(2) An individual approved for medical assistance under this rule shall be granted a certification period of only three months. At the end of the three-month period, the individual shall be required to provide documentation of citizenship and identity as otherwise required under 441—Chapter 75 to continue eligibility.

This rule is intended to implement Iowa Code chapter 249A.
[**ARC 7577B**, IAB 2/25/09, effective 4/1/09]

441—58.46 to **58.50** Reserved.

DIVISION IV
IOWA UNMET NEEDS DISASTER GRANT PROGRAM

PREAMBLE

This division implements a new program of state assistance to address unmet disaster-related expenses that cannot be met by other financial assistance, as authorized by 2009 Iowa Acts, Senate File 64. The rules provide for reimbursement for repair or replacement of personal property, home repair, mental health services, food assistance, child care, and temporary housing to households whose income is less than 300 percent of the federal poverty guidelines. The amount of assistance available to a household is capped at $2,500.

The program is administered by the department of human services in coordination with the recovery Iowa office and local long-term recovery committees established in affected areas. The long-term recovery committees shall receive applications from affected households, certify the households' residence and unmet disaster-related expenses, and determine eligibility for assistance. Department staff shall issue payments and process any appeals.
[**ARC 7603B**, IAB 3/11/09, effective 2/11/09; **ARC 8007B**, IAB 7/29/09, effective 9/2/09]

441—58.51(83GA,HF64) Definitions.

"Department" means the Iowa department of human services.

"Household" means all adults and children who lived in the pre-disaster residence who request individual assistance (not including landlords or other businesses), as well as any persons, such as infants, spouses, or part-time residents, who were not present at the time of the disaster but who are expected to return during the assistance period.

"Iowa disaster recovery case management" means the entity that oversees the operation of local long-term recovery committees, including ensuring that each county declared a presidential disaster area on and after May 24, 2008, and before August 14, 2008, has a long-term recovery committee.

"Long-term recovery committee" means a county-based committee that performs direct work with households seeking assistance for unmet needs and certifies the assistance that each household may receive. The committee operates the voucher system for certified goods and submits documented claims to the department for reimbursement of voucher-related expenses.

"Unmet need" means an item or service needed to overcome a disaster-related hardship, injury, or adverse condition due to an eligible federally declared disaster resulting in costs or damages related to personal property, home repair, food assistance, mental health assistance, child care, or temporary housing for which the household has not received adequate assistance from any federal, state, nonprofit, or faith-based agency.
[**ARC 7603B**, IAB 3/11/09, effective 2/11/09; **ARC 8007B**, IAB 7/29/09, effective 9/2/09]

441—58.52(83GA,HF64) Program implementation. The Iowa unmet needs disaster grant program (IUNDGP) shall be in effect upon enactment on February 2, 2009, and shall be retroactively applicable to May 24, 2008. Within the funds appropriated, this program is available for households affected by natural disasters in areas that the President of the United States declared a disaster area after May 24, 2008, and before August 14, 2008.
[**ARC 7603B**, IAB 3/11/09, effective 2/11/09; **ARC 8007B**, IAB 7/29/09, effective 9/2/09]

441—58.53(83GA,HF64) Application for assistance. To request financial assistance for unmet disaster needs expenses, the household shall complete Form 470-4689, Iowa Unmet Needs Disaster Grant Application, and submit the application to the local long-term recovery committee.

58.53(1) Application forms are available from the local long-term recovery committee or the rebuild Iowa office. Individuals can find their local long-term recovery committee by calling the rebuild Iowa office toll-free at (866)849-0323.

58.53(2) The application shall include:

a. A declaration of the household's annual gross income.

b. A release of confidential information to personnel involved in administering the program.

c. An assurance that the household had no insurance coverage for claimed items.

d. A commitment to refund any part of a grant awarded that is duplicated by insurance or by any other assistance program, such as but not limited to other state assistance, local community development groups, charities or faith-based agencies, the Small Business Administration, or the Federal Emergency Management Administration.

e. A short, written narrative of the disaster event and how the disaster caused the loss being claimed.

f. A copy of a photo identification document for each adult applicant.

g. When vehicle damage is claimed, current copies of the vehicle registration and liability insurance card.

[**ARC 7603B**, IAB 3/11/09, effective 2/11/09; **ARC 8007B**, IAB 7/29/09, effective 9/2/09]

441—58.54(83GA,HF64) Eligibility criteria. To be eligible for assistance, an applicant household must meet all of the following conditions:

58.54(1) The household's residence was located in the area identified by a presidential disaster declaration occurring on or after May 24, 2008, and before August 14, 2008, and the household verifies occupancy at that residence.

58.54(2) Household members are citizens of the United States or are legally residing in the United States.

58.54(3) The household's self-declared annual income is at or less than 300 percent of the federal poverty level for a household of that size.

a. Poverty guidelines are updated annually.

b. All income available to the household is counted, including wages, child support, interest from investments or bank accounts, social security benefits, and retirement income.

58.54(4) The household has disaster-related expenses not covered by insurance, or the claim is less than or equal to the deductible amount. This program will not reimburse the amount of the insurance deductible when the claim exceeds the deductible amount.

58.54(5) The household has not previously received assistance from this program or another program, such as but not limited to other state assistance, local community development groups, charities or faith-based agencies, the Small Business Administration, or the Federal Emergency Management Administration, for the same loss.

[**ARC 7603B**, IAB 3/11/09, effective 2/11/09; **ARC 8007B**, IAB 7/29/09, effective 9/2/09]

441—58.55(83GA,HF64) Eligible categories of assistance. The maximum assistance available to a household for a single disaster is $2,500. Reimbursement is available under the program for the following disaster-related expenses:

1. Personal property.
2. Home repair.
3. Food assistance.
4. Mental health assistance.
5. Child care.
6. Temporary housing.

[**ARC 7603B**, IAB 3/11/09, effective 2/11/09; **ARC 8007B**, IAB 7/29/09, effective 9/2/09]

441—58.56(83GA,HF64,SF478) Eligibility determination and payment.

58.56(1) *Committee duties.* The long-term recovery committee shall enter into an agreement with the department. The committee shall perform the following duties, including specifying who is approved to certify eligibility for unmet needs grants on behalf of the long-term recovery committee.

a. Accept the household's application.

b. Certify that:

(1) The address provided on the application is a valid address in the disaster-affected area,

(2) Disaster-related expenses were a result of the covered disaster,

(3) The household has presented reasonable documentation or receipts for expenses incurred, or has reasonable estimates for eligible costs for issuance of a voucher to secure specific eligible goods or services to be obtained, and

(4) Funds remain available.

c. Determine the amount of assistance the household is eligible to receive by category of assistance and provide the rationale for that amount.

d. Provide the signature of long-term recovery committee staff making the certification and the date of certification.

e. Notify the applicant household of the certification decision.

f. Submit a copy of the household's Form 470-4689, Iowa Unmet Needs Disaster Grant Application, to:

(1) The Rebuild Iowa Disaster Recovery Case Management, Wallace State Office Building, 502 East Ninth Street, Des Moines, Iowa 50319, and

(2) The Department of Human Services, Division of Results-Based Accountability, 1305 East Walnut Street, Des Moines, Iowa 50319-0114.

58.56(2) *Committee administrative expenses.* Rescinded IAB 7/29/09, effective 9/2/09.

58.56(3) *Duties of disaster case management office.* Designated disaster staff in the rebuild Iowa disaster case management office shall:

a. Ensure that a long-term recovery committee is available in each county affected.

b. Coordinate contact between applicants and their long-term recovery committee.

c. Support the first-level reconsideration process.

58.56(4) *Duties of the department.* Designated disaster staff in the department of human services shall:

a. Process grant payments to the household or vendor or to the long-term recovery committee.

b. Support the second-level reconsideration process.

c. Process appeals.

[**ARC 7603B**, IAB 3/11/09, effective 2/11/09; **ARC 8007B**, IAB 7/29/09, effective 9/2/09]

441—58.57(83GA,HF64) Contested cases.

58.57(1) *First-level reconsideration.* The household may request reconsideration of the long-term recovery committee decision regarding certification of eligible unmet needs and the amount of reimbursement awarded.

a. To request reconsideration, the household shall submit a written request to the Rebuild Iowa Disaster Recovery Case Management, Wallace State Office Building, 502 East Ninth Street, Des Moines, Iowa 50319, within 15 days of the date of the long-term recovery committee's notification to the household of its certification decision.

b. The rebuild Iowa disaster recovery case management shall review any additional evidence or documentation submitted, issue a reconsideration decision within 15 days of receipt of the request, and notify the household of the reconsideration decision.

58.57(2) *Second-level reconsideration.* The household may request reconsideration of the rebuild Iowa disaster recovery case management decision regarding certification of eligible unmet needs and the amount of reimbursement awarded.

a. To request reconsideration, the household shall submit a written request to the Iowa Department of Human Services, Division of Results-Based Accountability, 1305 East Walnut Street, Des Moines, Iowa 50319-0114, within 15 days of the date of the notification to the household of the first-level reconsideration decision from rebuild Iowa disaster recovery case management.

b. The department shall:

(1) Review any additional evidence or documentation submitted,

(2) Issue a reconsideration decision within 15 days of receipt of the request, and

(3) Notify the household of the reconsideration decision and of the household's appeal rights under 441—Chapter 7.

58.57(3) *Appeal.* The household may appeal the department reconsideration decision according to procedures in 441—Chapter 7.

a. Appeals must be submitted in writing, either on Form 470-0487 or 470-0487(S), Appeal and Request for Hearing, or in any form that provides comparable information, to the DHS Appeals Section, 1305 East Walnut Street, Des Moines, Iowa 50319-0114, within 15 days of the date of the second-level reconsideration decision.

b. A written appeal is filed on the date the envelope sent to the department is postmarked or, when the postmarked envelope is not available, on the date the appeal is stamped received by the department.
[**ARC 7603B**, IAB 3/11/09, effective 2/11/09; **ARC 8007B**, IAB 7/29/09, effective 9/2/09]

441—58.58(83GA,HF64) Discontinuance of program. The Iowa unmet needs disaster grant program administered under this chapter shall be discontinued upon exhaustion of allocated funds or on June 30, 2010, whichever occurs first.
[**ARC 7603B**, IAB 3/11/09, effective 2/11/09; **ARC 8007B**, IAB 7/29/09, effective 9/2/09]

These rules are intended to implement 2009 Iowa Acts, House File 64, section 4, as amended by 2009 Iowa Acts, Senate File 478, section 176.

441—58.59 and **58.60** Reserved.

DIVISION V
TICKET TO HOPE PROGRAM

PREAMBLE

This division implements the ticket to hope program, a mental health counseling program funded through a social services emergency disaster relief grant that was authorized by Public Law 110-329, the Consolidated Security, Disaster Assistance, and Continuing Appropriations Act of 2009. The program pays for professional mental health evaluation and treatment services for individuals and families who have been affected by the weather-related disasters of 2008.
[**ARC 7641B**, IAB 3/25/09, effective 3/1/09; **ARC 7830B**, IAB 6/3/09, effective 7/8/09]

441—58.61(234) Definitions.

"Department" means the Iowa department of human services.

"Ticket to hope" means the mental health counseling program for individuals and families who have been directly affected by the weather-related disasters of 2008.
[**ARC 7641B**, IAB 3/25/09, effective 3/1/09; **ARC 7830B**, IAB 6/3/09, effective 7/8/09]

441—58.62(234) Application process. The process for obtaining assistance from the ticket to hope program is as follows:

58.62(1) A person requesting assistance shall contact the Iowa concern hotline by telephone at 1-800-447-1985.

58.62(2) The Iowa concern hotline shall gather information and determine eligibility for ticket to hope services based on criteria established in this division.

58.62(3) The Iowa concern hotline shall send to each eligible applicant a packet of information that includes:

a. An introductory cover letter;

b. A list of participating providers;

c. An authorization form for one 45- to 50-minute session (valid for 30 days); and

d. A demographic data form that includes a unique numeric client identifier.

58.62(4) The eligible applicant shall:

a. Make an appointment with an approved provider; and

b. Give the authorization and demographic data forms to the provider at the time of the appointment.

58.62(5) After the eligible applicant meets with the provider, the applicant may call the Iowa concern hotline and receive authorization for up to seven additional sessions. A new authorization form shall be issued for each session.
[**ARC 7641B**, IAB 3/25/09, effective 3/1/09; **ARC 7830B**, IAB 6/3/09, effective 7/8/09]

441—58.63(234) Eligibility criteria. To be eligible for assistance, a person living in Iowa must report:

1. That the impact of the 2008 disaster has impaired the person's ability to carry out normal daily functions to some extent; and
2. That the person has no insurance coverage for mental health services, or has insurance with a high deductible that will deter the person from accessing necessary mental health services.

[**ARC 7641B**, IAB 3/25/09, effective 3/1/09; **ARC 7830B**, IAB 6/3/09, effective 7/8/09]

441—58.64(234) Provider participation. A mental health professional with an active professional license issued by the Iowa department of public health who is qualified to provide individual psychotherapy (i.e., Current Procedural Terminology code 90806, "individual psychotherapy, insight-oriented behavior modification or support, provided face to face with the patient in an office or outpatient setting") according to the Iowa Plan vendor requirements shall be allowed to participate as a ticket to hope provider.

58.64(1) A mental health professional applying to participate in the program shall submit a copy of the professional license to the Iowa concern hotline.

58.64(2) The mental health professional shall agree to the terms of participation in the ticket to hope program by:

a. Signing a professional services agreement with the department; and

b. Returning the signed agreement to the Iowa concern hotline.

[**ARC 7641B**, IAB 3/25/09, effective 3/1/09; **ARC 7830B**, IAB 6/3/09, effective 7/8/09]

441—58.65(234) Provider reimbursement. A provider approved to participate shall be reimbursed as follows:

58.65(1) The provider shall submit a completed demographic data form and the authorization form to the Iowa concern hotline within 30 days after each completed session with an approved applicant.

58.65(2) The provider shall be reimbursed at the lower of:

a. A rate of $93 per assessment or counseling session, or

b. The prevailing Iowa Medicaid rate.

[**ARC 7641B**, IAB 3/25/09, effective 3/1/09; **ARC 7830B**, IAB 6/3/09, effective 7/8/09]

441—58.66(234) Reconsideration. An applicant may request reconsideration of a denial of access to services. A mental health professional may request reconsideration of a denial to be a part of the professional provider panel.

58.66(1) To request reconsideration, the person shall submit a written request to the DHS Division of Mental Health and Disability Services, 1305 East Walnut Street, Des Moines, Iowa 50319-0114.

58.66(2) The department shall review any additional evidence or documentation submitted and issue a reconsideration decision within 15 days from receipt of the request.
[**ARC 7641B**, IAB 3/25/09, effective 3/1/09; **ARC 7830B**, IAB 6/3/09, effective 7/8/09]

441—58.67(234) Appeal. The person may appeal the department's reconsideration decision according to procedures in 441—Chapter 7.

58.67(1) Appeals must be submitted in writing, either on Form 470-0487 or 470-0487(S), Appeal and Request for Hearing, or in any form that provides comparable information, to the DHS Appeals Section, 1305 East Walnut Street, Des Moines, Iowa 50319-0114, within 15 days of the date of the reconsideration decision.

58.67(2) A written appeal is filed on the date the envelope sent to the department is postmarked or, when the postmarked envelope is not available, on the date the appeal is stamped received by the department.
[**ARC 7641B**, IAB 3/25/09, effective 3/1/09; **ARC 7830B**, IAB 6/3/09, effective 7/8/09]

441—58.68(234) Discontinuance of program. The program shall end on June 30, 2010, or when the funds are expended, whichever occurs first.

[**ARC 7641B**, IAB 3/25/09, effective 3/1/09; **ARC 7830B**, IAB 6/3/09, effective 7/8/09]

These rules are intended to implement Iowa Code section 234.6.

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TITLE VIII
MEDICAL ASSISTANCE

CHAPTER 75
CONDITIONS OF ELIGIBILITY

[Ch 75, 1973 IDR, renumbered as Ch 90]
[Prior to 7/1/83, Social Services[770] Ch 75]
[Prior to 2/11/87, Human Services[498]]

DIVISION I
GENERAL CONDITIONS OF ELIGIBILITY, COVERAGE GROUPS, AND SSI-RELATED PROGRAMS

441—75.1(249A) Persons covered.

75.1(1) *Persons receiving refugee cash assistance.* Medical assistance shall be available to all recipients of refugee cash assistance. Recipient means a person for whom a refugee cash assistance (RCA) payment is received and includes persons deemed to be receiving RCA. Persons deemed to be receiving RCA are:

a. Persons denied RCA because the amount of payment would be less than $10.

b. Rescinded IAB 7/30/08, effective 10/1/08.

c. Persons who are eligible in every respect for refugee cash assistance (RCA) as provided in 441—Chapter 60, but who do not receive RCA because they did not make application for the assistance.

75.1(2) Rescinded IAB 10/8/97, effective 12/1/97.

75.1(3) *Persons who are ineligible for Supplemental Security Income (SSI) because of requirements that do not apply under Title XIX of the Social Security Act.* Medicaid shall be available to persons who would be eligible for SSI except for an eligibility requirement used in that program which is specifically prohibited under Title XIX.

75.1(4) *Beneficiaries of Title XVI of the Social Security Act (supplemental security income for the aged, blind and disabled) and mandatory state supplementation.* Medical assistance will be available to all beneficiaries of the Title XVI program and those receiving mandatory state supplementation.

75.1(5) *Persons receiving care in a medical institution who were eligible for Medicaid as of December 31, 1973.* Medicaid shall be available to all persons receiving care in a medical institution who were Medicaid members as of December 31, 1973. Eligibility of these persons will continue as long as they continue to meet the eligibility requirements for the applicable assistance programs (old-age assistance, aid to the blind or aid to the disabled) in effect on December 31, 1973.

75.1(6) *Persons who would be eligible for supplemental security income (SSI), state supplementary assistance (SSA), or the family medical assistance program (FMAP) except for their institutional status.* Medicaid shall be available to persons receiving care in a medical institution who would be eligible for SSI, SSA, or FMAP if they were not institutionalized.

75.1(7) *Persons receiving care in a medical facility who would be eligible under a special income standard.*

a. Subject to paragraphs *"b"* and *"c"* below, Medicaid shall be available to persons who:

(1) Meet level of care requirements as set forth in rules 441—78.3(249A), 441—81.3(249A), and 441—82.7(249A).

(2) Receive care in a hospital, nursing facility, psychiatric medical institution, intermediate care facility for the mentally retarded, or Medicare-certified skilled nursing facility.

(3) Have gross countable monthly income that does not exceed 300 percent of the federal supplemental security income benefits for one.

(4) Either meet all supplemental security income (SSI) eligibility requirements except for income or are under age 21. FMAP policies regarding income and age do not apply when determining eligibility for persons under the age of 21.

b. For all persons in this coverage group, income shall be considered as provided for SSI-related coverage groups under subrule 75.13(2). In establishing eligibility for persons aged 21 or older for this coverage group, resources shall be considered as provided for SSI-related coverage groups under subrule 75.13(2).

c. Eligibility for persons in this group shall not exist until the person has been institutionalized for a period of 30 consecutive days and shall be effective no earlier than the first day of the month in which the 30-day period begins. A "period of 30 days" is defined as being from 12 a.m. of the day of admission to the medical institution, and ending no earlier than 12 midnight of the thirtieth day following the beginning of the period.

(1) A person who enters a medical institution and who dies prior to completion of the 30-day period shall be considered to meet the 30-day period provision.

(2) Only one 30-day period is required to establish eligibility during a continuous stay in a medical institution. Discharge during a subsequent month, creating a partial month of care, does not affect eligibility for that partial month regardless of whether the eligibility determination was completed prior to discharge.

(3) A temporary absence of not more than 14 full consecutive days during which the person remains under the jurisdiction of the institution does not interrupt the 30-day period. In order to remain "under the jurisdiction of the institution" a person must first have been physically admitted to the institution.

75.1(8) *Certain persons essential to the welfare of Title XVI beneficiaries.* Medical assistance will be available to the person living with and essential to the welfare of a Title XIX beneficiary provided the essential person was eligible for medical assistance as of December 31, 1973. The person will continue to be eligible for medical assistance as long as the person continues to meet the definition of "essential person" in effect in the public assistance program on December 31, 1973.

75.1(9) *Individuals receiving state supplemental assistance.* Medical assistance shall be available to all recipients of state supplemental assistance as authorized by Iowa Code chapter 249. Medical assistance shall also be available to the individual's dependent relative as defined in 441—subrule 51.4(4).

75.1(10) *Individuals under age 21 living in a licensed foster care facility or in a private home pursuant to a subsidized adoption arrangement for whom the department has financial responsibility in whole or in part.* When Iowa is responsible for foster care payment for a child pursuant to Iowa Code section 234.35 and rule 441—156.20(234) or has negotiated an adoption assistance agreement for a child pursuant to rule 441—201.5(600), medical assistance shall be available to the child if:

a. The child lives in Iowa and is not otherwise eligible under a category for which federal financial participation is available; or

b. The child lives in another state and is not eligible for benefits from the other state pursuant to a program funded under Title XIX of the federal Social Security Act, notwithstanding the residency requirements of 441—75.10(249A) and 441—75.53(249A).

75.1(11) *Individuals living in a court-approved subsidized guardianship home for whom the department has financial responsibility in whole or in part.* When Iowa is responsible for a subsidized guardianship payment for a child pursuant to 441—Chapter 204, medical assistance will be available to the child under this subrule if the child is living in a court-approved subsidized guardianship home and either:

a. The child lives in Iowa and is not eligible for medical assistance under a category for which federal financial participation is available due to reasons other than:

(1) Failure to provide information, or

(2) Failure to comply with other procedural requirements; or

b. Notwithstanding the residency requirements of 441—75.10(249A) and 441—75.53(249A), the child lives in another state and is not eligible for benefits from the other state pursuant to a program funded under Title XIX of the federal Social Security Act due to reasons other than:

(1) Failure to provide information, or

(2) Failure to comply with other procedural requirements.

75.1(12) *Persons ineligible due to October 1, 1972, social security increase.* Medical assistance will be available to individuals and families whose assistance grants were canceled as a result of the increase in social security benefits October 1, 1972, as long as these individuals and families would be eligible for an assistance grant if the increase were not considered.

75.1(13) *Persons who would be eligible for supplemental security income or state supplementary assistance but for social security cost-of-living increases received.* Medical assistance shall be available to all current social security recipients who meet the following conditions:

a. They were entitled to and received concurrently in any month after April 1977 supplemental security income and social security or state supplementary assistance and social security, and

b. They subsequently lost eligibility for supplemental security income or state supplementary assistance, and

c. They would be eligible for supplemental security income or state supplementary assistance if all of the social security cost-of-living increases which they and their financially responsible spouses, parents, and dependent children received since they were last eligible for and received social security and supplemental security income (or state supplementary assistance) concurrently were deducted from their income. Spouses, parents, and dependent children are considered financially responsible if their income would be considered in determining the applicant's eligibility.

75.1(14) *Family medical assistance program (FMAP).* Medicaid shall be available to children who meet the provisions of rule 441—75.54(249A) and to the children's specified relatives who meet the provisions of subrule 75.54(2) and rule 441—75.55(249A) if the following criteria are met.

a. In establishing eligibility of specified relatives for this coverage group, resources are considered in accordance with the provisions of rule 441—75.56(249A) and shall not exceed $2,000 for applicant households or $5,000 for member households. In establishing eligibility for children for this coverage group, resources of all persons in the eligible group, regardless of age, shall be disregarded.

b. Income is considered in accordance with rule 441—75.57(249A) and does not exceed needs standards established in rule 441—75.58(249A).

c. Rescinded IAB 11/1/00, effective 1/1/01.

75.1(15) *Child medical assistance program (CMAP).* Medicaid shall be available to persons under the age of 21 if the following criteria are met:

a. Financial eligibility shall be determined for the family size of which the child is a member using the income standards in effect for the family medical assistance program (FMAP) unless otherwise specified. Income shall be considered as provided in rule 441—75.57(249A). Additionally, the earned income disregards as provided in paragraphs 75.57(2)*"a," "b," "c,"* and *"d"* shall be allowed for those persons whose income is considered in establishing eligibility for the persons under the age of 21 and whose needs must be included in accordance with paragraph 75.58(1)*"a"* but who are not eligible for Medicaid. Resources of all persons in the eligible group, regardless of age, shall be disregarded. Unless a family member is voluntarily excluded in accordance with the provisions of rule 441—75.59(249A), family size shall be determined as follows:

(1) If the person under the age of 21 is pregnant and the pregnancy has been verified in accordance with rule 441—75.17(249A), the unborn child (or children if more than one) is considered a member of the family for purposes of establishing the number of persons in the family.

(2) A "man-in-the-house" who is not married to the mother of the unborn child is not considered a member of the unborn child's family for the purpose of establishing the number of persons in the family. His income and resources are not automatically considered, regardless of whether or not he is the legal or natural father of the unborn child. However, income and resources made available to the mother of the unborn child by the "man-in-the-house" shall be considered in determining eligibility for the pregnant individual.

(3) Unless otherwise specified, when the person under the age of 21 is living with a parent(s), the family size shall consist of all family members as defined by the family medical assistance program in accordance with paragraph 75.57(8)*"c"* and subrule 75.58(1).

Application for Medicaid shall be made by the parent(s) when the person is residing with them. A person shall be considered to be living with the parent(s) when the person is temporarily absent from the parent's(s') home as defined in subrule 75.53(4). If the person under the age of 21 is married or has been married, the needs, income and resources of the person's parent(s) and any siblings in the home shall not be considered in the eligibility determination unless the marriage was annulled.

(4) When a person is living with a spouse the family size shall consist of that person, the spouse and any of their children, including any unborn children.

(5) Siblings under the age of 21 who live together shall be considered in the same filing unit for the purpose of establishing eligibility under this rule unless one sibling is married or has been married, in which case, the married sibling shall be considered separately unless the marriage was annulled.

(6) When a person is residing in a household in which some members are receiving FMAP under the provisions of subrule 75.1(14) or MAC under the provisions of subrule 75.1(28), and when the person is not included in the FMAP or MAC eligible group, the family size shall consist of the person and all other family members as defined above except those in the FMAP or MAC eligible group.

b. Rescinded IAB 9/6/89, effective 11/1/89.

c. Rescinded IAB 11/1/89, effective 1/1/90.

d. A person is eligible for the entire month in which the person's twenty-first birthday occurs unless the birthday falls on the first day of the month.

e. Living with a specified relative as provided in subrule 75.54(2) shall not be considered when determining eligibility for persons under this coverage group.

75.1(16) *Children receiving subsidized adoption payments from states providing reciprocal medical assistance benefits.* Medical assistance shall be available to children under the age of 21 for whom an adoption assistance agreement with another state is in effect if all of the following conditions are met:

a. The child is residing in Iowa in a private home with the child's adoptive parent or parents.

b. Benefits funded under Title IV-E of the Social Security Act are not being paid for the child by any state.

c. Another state currently has an adoption assistance agreement in effect for the child.

d. The state with the adoption assistance agreement:

(1) Is a member of the interstate compact on adoption and medical assistance (ICAMA); and

(2) Provides medical assistance benefits pursuant to a program funded under Title XIX of the Social Security Act, under the optional group at Section 1902(a)(10)(A)(ii)(VIII) of the Act, to children residing in that state (at least until age 18) for whom there is a state adoption assistance agreement in effect with the state of Iowa other than under Title IV-E of the Social Security Act.

75.1(17) *Persons who meet the income and resource requirements of the cash assistance programs.* Medicaid shall be available to the following persons who meet the income and resource guidelines of supplemental security income or refugee cash assistance, but who are not receiving cash assistance:

a. Aged and blind persons, as defined at subrule 75.13(2).

b. Disabled persons, as defined at rule 441—75.20(249A).

In establishing eligibility for children for this coverage group based on eligibility for SSI, resources of all persons in the eligible group, regardless of age, shall be disregarded. In establishing eligibility for adults for this coverage group, resources shall be considered as provided for SSI-related coverage groups under subrule 75.13(2) or as under refugee cash assistance.

75.1(18) *Persons eligible for waiver services.* Medicaid shall be available to recipients of waiver services as defined in 441—Chapter 83.

75.1(19) *Persons and families terminated from aid to dependent children (ADC) prior to April 1, 1990, due to discontinuance of the $30 or the $30 and one-third earned income disregards.* Rescinded IAB 6/12/91, effective 8/1/91.

75.1(20) *Newborn children.* Medicaid shall be available without an application to newborn children of women who are determined eligible for Medicaid for the month of the child's birth or for three-day emergency services for labor and delivery for the child's birth. Effective April 1, 2009, eligibility begins with the month of the birth and continues through the month of the first birthday as long as the child remains an Iowa resident.

a. The department shall accept any written or verbal statement as verification of the newborn's birth date unless the birth date is questionable.

b. In order for Medicaid to continue after the month of the first birthday, a redetermination of eligibility shall be completed.

75.1(21) *Persons and families ineligible for the family medical assistance program (FMAP) in whole or in part because of child or spousal support.* Medicaid shall be available for an additional four months to persons and families who become ineligible for FMAP because of income from child support, alimony, or contributions from a spouse if the person or family member received FMAP in at least three of the six months immediately preceding the month of cancellation.

a. The four months of extended Medicaid coverage begin the day following termination of FMAP eligibility.

b. When ineligibility is determined to occur retroactively, the extended Medicaid coverage begins with the first month in which FMAP eligibility was erroneously granted.

c. Rescinded IAB 10/11/95, effective 10/1/95.

75.1(22) *Refugee spenddown participants.* Rescinded IAB 10/11/95, effective 10/1/95.

75.1(23) *Persons who would be eligible for supplemental security income or state supplementary assistance but for increases in social security benefits because of elimination of the actuarial reduction formula and cost-of-living increases received.* Medical assistance shall be available to all current social security recipients who meet the following conditions. They:

a. Were eligible for a social security benefit in December of 1983.

b. Were eligible for and received a widow's or widower's disability benefit and supplemental security income or state supplementary assistance for January of 1984.

c. Became ineligible for supplemental security income or state supplementary assistance because of an increase in their widow's or widower's benefit which resulted from the elimination of the reduction factor in the first month in which the increase was paid and in which a retroactive payment of that increase for prior months was not made.

d. Have been continuously eligible for a widow's or widower's benefit from the first month the increase was received.

e. Would be eligible for supplemental security income or state supplementary assistance benefits if the amount of the increase from elimination of the reduction factor and any subsequent cost-of-living adjustments were disregarded.

f. Submit an application prior to July 1, 1988, on Form 470-0442, Application for Medical Assistance or State Supplementary Assistance.

75.1(24) *Postpartum eligibility for pregnant women.* Medicaid shall continue to be available, without an application, for 60 days beginning with the last day of pregnancy and throughout the remaining days of the month in which the 60-day period ends, to a woman who had applied for Medicaid prior to the end of her pregnancy and was subsequently determined eligible for Medicaid for the month in which the pregnancy ended.

a. Postpartum Medicaid shall only be available to a woman who is not eligible for another coverage group after the pregnancy ends.

b. The woman shall not be required to meet any income or resource criteria during the postpartum period.

c. When the sixtieth day is not on the last day of the month the woman shall be eligible for Medicaid for the entire month.

75.1(25) *Persons who would be eligible for supplemental security income or state supplementary assistance except that they receive child's social security benefits based on disability.* Medical assistance shall be available to persons who receive supplemental security income (SSI) or state supplementary assistance (SSA) after their eighteenth birthday because of a disability or blindness which began before age 22 and who would continue to receive SSI or SSA except that they become entitled to or receive an increase in social security benefits from a parent's account.

75.1(26) Rescinded IAB 10/8/97, effective 12/1/97.

75.1(27) *Widows and widowers who are no longer eligible for supplemental security income or state supplementary assistance because of the receipt of social security benefits.* Medicaid shall be available to widows and widowers who meet the following conditions:

a. They have applied for and received or were considered recipients of supplemental security income or state supplementary assistance.

b. They apply for and receive Title II widow's or widower's insurance benefits or any other Title II old age or survivor's benefits, if eligible for widow's or widower's benefits.

c. Rescinded IAB 5/1/91, effective 4/11/91.

d. They were not entitled to Part A Medicare hospital insurance benefits at the time of application and receipt of Title II old age or survivor's benefits. They are not currently entitled to Part A Medicare hospital insurance benefits.

e. They are no longer eligible for supplemental security income or state supplementary assistance solely because of the receipt of their social security benefits.

75.1(28) *Pregnant women, infants and children (Mothers and Children (MAC)).* Medicaid shall be available to all pregnant women, infants (under one year of age) and children who have not attained the age of 19 if the following criteria are met:

a. Income.

(1) Family income shall not exceed 300 percent of the federal poverty level for pregnant women and for infants (under one year of age). Family income shall not exceed 133 percent of the federal poverty level for children who have attained one year of age but who have not attained 19 years of age. Income to be considered in determining eligibility for pregnant women, infants, and children shall be determined according to family medical assistance program (FMAP) methodologies except that the three-step process for determining initial eligibility and the two-step process for determining ongoing eligibility, as described at rule 441—75.57(249A), shall not apply. "Family income" is the income remaining after disregards and deductions have been applied as provided in rule 441—75.57(249A).

(2) Moneys received as a lump sum, except as specified in subrules 75.56(4) and 75.56(7) and paragraphs 75.57(8)*"b"* and *"c,"* shall be treated in accordance with paragraphs 75.57(9)*"b"* and *"c."*

(3) Unless otherwise specified, when the person under the age of 19 is living with a parent or parents, the family size shall consist of all family members as defined by the family medical assistance program.

Application for Medicaid shall be made by the parents when the person is residing with them. A person shall be considered to be living with the parents when the person is temporarily absent from the parent's home as defined in subrule 75.53(4). If the person under the age of 19 is married or has been married, the needs, income and resources of the person's parents and any siblings in the home shall not be considered in the eligibility determination unless the marriage was annulled.

(4) When a person under the age of 19 is living with a spouse, the family size shall consist of that person, the spouse, and any of their children.

(5) Siblings under the age of 19 who live together shall be considered in the same filing unit for the purpose of establishing eligibility under this subrule unless one sibling is married or has been married, in which case the married sibling shall be considered separately unless the marriage was annulled.

b. For pregnant women, resources shall not exceed $10,000 per household. In establishing eligibility for infants and children for this coverage group, resources of all persons in the eligible group, regardless of age, shall be disregarded. In establishing eligibility for pregnant women for this coverage group, resources shall be considered in accordance with department of public health 641—subrule 75.4(2).

c. Rescinded IAB 9/6/89, effective 11/1/89.

d. Eligibility for pregnant women under this rule shall begin no earlier than the first day of the month in which conception occurred and in accordance with 441—76.5(249A).

e. The unborn child (children if more than one fetus exists) shall be considered when determining the number of persons in the household.

f. An infant shall be eligible through the month of the first birthday unless the birthday falls on the first day of the month. A child shall be eligible through the month of the nineteenth birthday unless the birthday falls on the first day of the month.

g. Rescinded IAB 11/1/89, effective 1/1/90.

h. When determining eligibility under this coverage group, living with a specified relative as specified at subrule 75.54(2) and the student provisions specified in subrule 75.54(1) do not apply.

i. A woman who had applied for Medicaid prior to the end of her pregnancy and was subsequently determined eligible for assistance under this coverage group for the month in which her pregnancy ended shall be entitled to receive Medicaid through the postpartum period in accordance with subrule 75.1(24).

j. If an infant loses eligibility under this coverage group at the time of the first birthday due to an inability to meet the income limit for children or if a child loses eligibility at the time of the nineteenth birthday, but the infant or child is receiving inpatient services in a medical institution, Medicaid shall continue under this coverage group for the duration of the time continuous inpatient services are provided.

75.1(29) *Persons who are entitled to hospital insurance benefits under Part A of Medicare (Qualified Medicare Beneficiary program).* Medicaid shall be available to persons who are entitled to hospital insurance under Part A of Medicare to cover the cost of the Medicare Part A and B premiums, coinsurance and deductibles, providing the following conditions are met:

a. The person's monthly income does not exceed 100 percent of the federal poverty level (as defined by the United States Office of Management and Budget and revised annually in accordance with Section 673(2) of the Omnibus Budget Reconciliation Act of 1981) applicable to a family of the size involved.

(1) The amount of income shall be determined as under the federal Supplemental Security Income (SSI) program.

(2) Income shall not include any amount of social security income attributable to the cost-of-living increase through the month following the month in which the annual revision of the official poverty line is published.

b. The person's resources do not exceed the maximum amount of resources that a person may have to obtain the full low-income subsidy for Medicare Part D drug benefits. The amount of resources shall be determined as under the SSI program unless the person lives and is expected to live at least 30 consecutive days in a medical institution and has a spouse at home. Then the resource determination shall be made according to subrules 75.5(3) and 75.5(4).

c. The effective date of eligibility is the first of the month after the month of decision.

75.1(30) *Presumptive eligibility for pregnant women.* A pregnant woman who is determined by a qualified provider to be presumptively eligible for Medicaid, based only on her statements regarding family income, shall be eligible for ambulatory prenatal care. Eligibility shall continue until the last day of the month following the month of the presumptive eligibility determination unless the pregnant woman is determined to be ineligible for Medicaid during this period based on a Medicaid application filed either before the presumptive eligibility determination or during this period. In this case, presumptive eligibility shall end on the date Medicaid ineligibility is determined. A pregnant woman who files a Medicaid application but withdraws that application before eligibility is determined has not been determined ineligible for Medicaid. The pregnant woman shall complete Form 470-2927 or 470-2927(S), Health Services Application, in order for the qualified provider to make the presumptive eligibility determination. The qualified provider shall complete Form 470-2629, Presumptive Medicaid Income Calculation, in order to establish that the pregnant woman's family income is within the prescribed limits of the Medicaid program.

If the pregnant woman files a Medicaid application in accordance with rule 441—76.1(249A) by the last day of the month following the month of the presumptive eligibility determination, Medicaid shall continue until a decision of ineligibility is made on the application. Payment of claims for ambulatory prenatal care services provided to a pregnant woman under this subrule is not dependent upon a finding of Medicaid eligibility for the pregnant woman.

a. A qualified provider is defined as a provider who is eligible for payment under the Medicaid program and who meets all of the following criteria:

(1) Provides one or more of the following services:

1. Outpatient hospital services.
2. Rural health clinic services (if contained in the state plan).
3. Clinic services furnished by or under the direction of a physician, without regard to whether the clinic itself is administered by a physician.

(2) Has been specifically designated by the department in writing as a qualified provider for the purposes of determining presumptive eligibility on the basis of the department's determination that the provider is capable of making a presumptive eligibility determination based on family income.

(3) Meets one of the following:

1. Receives funds under the Migrant Health Centers or Community Health Centers (subsection 329 or subsection 330 of the Public Health Service Act) or the Maternal and Child Health Services Block Grant Programs (Title V of the Social Security Act) or the Health Services for Urban Indians Program (Title V of the Indian Health Care Improvement Act).

2. Participates in the program established under the Special Supplemental Food Program for Women, Infants, and Children (subsection 17 of the Child Nutrition Act of 1966) or the Commodity Supplemental Food Program (subsection 4(a) of the Agriculture and Consumer Protection Act of 1973).

3. Participates in a state perinatal program.

4. Is an Indian health service office or a health program or facility operated by a tribe or tribal organization under the Indian Self-Determination Act.

b. The provider shall complete Form 470-2579, Application for Authorization to Make Presumptive Medicaid Eligibility Determinations, and submit it to the department for approval in order to become certified as a provider qualified to make presumptive eligibility determinations. Once the provider has been approved as a provider qualified to make presumptive Medicaid eligibility determinations, Form 470-2582, Memorandum of Understanding Between the Iowa Department of Human Services and a Qualified Provider, shall be signed by the provider and the department.

c. Once the qualified provider has made a presumptive eligibility determination for a pregnant woman, the provider shall:

(1) Contact the department to obtain a state identification number for the pregnant woman who has been determined presumptively eligible.

(2) Notify the department in writing of the determination within five working days after the date the presumptive determination is made. A copy of the Presumptive Medicaid Eligibility Notice of Decision, Form 470-2580 or 470-2580(S), shall be used for this purpose.

(3) Inform the pregnant woman in writing, at the time the determination is made, that if she chose not to apply for Medicaid on the Health Services Application, Form 470-2927 or 470-2927(S), she has until the last day of the month following the month of the preliminary determination to file an application with the department. A Presumptive Medicaid Eligibility Notice of Decision, Form 470-2580, shall be issued by the qualified provider for this purpose.

(4) Forward copies of the Health Services Application, Form 470-2927 or 470-2927(S), to the appropriate offices for eligibility determinations if the pregnant woman indicated on the application that she was applying for any of the other programs listed on the application. These copies shall be forwarded within two working days from the date of the presumptive determination.

d. In the event that a pregnant woman needing prenatal care does not appear to be presumptively eligible, the qualified provider shall inform the pregnant woman that she may file an application at the local department office if she wishes to have a formal determination made.

e. Presumptive eligibility shall end under any of the following conditions:

(1) The woman fails to file an application for Medicaid in accordance with rule 441—76.1(249A) by the last day of the month following the month of the presumptive eligibility determination.

(2) The woman files a Medicaid application by the last day of the month following the month of the presumptive eligibility determination and has been found ineligible for Medicaid.

(3) Rescinded IAB 5/1/91, effective 7/1/91.

f. The adequate and timely notice requirements and appeal rights associated with an application that is filed pursuant to rule 441—76.1(249A) shall apply to an eligibility determination made on the Medicaid application. However, notice requirements and appeal rights of the Medicaid program shall not apply to a woman who is:

(1) Issued a presumptive eligibility decision by a qualified provider.

(2) Determined to be presumptively eligible by a qualified provider and whose presumptive eligibility ends because the woman fails to file an application by the last day of the month following the month of the initial presumptive eligibility determination.

(3) Rescinded IAB 5/1/91, effective 7/1/91.

g. A woman shall not be determined to be presumptively eligible for Medicaid more than once per pregnancy.

75.1(31) *Persons and families canceled from the family medical assistance program (FMAP) due to the increased earnings of the specified relative in the eligible group.* Medicaid shall be available for a period of up to 12 additional months to families who are canceled from FMAP as provided in subrule 75.1(14) because the specified relative of a dependent child receives increased income from employment.

For the purposes of this subrule, "family" shall mean individuals living in the household whose needs and income were included in determining the FMAP eligibility of the household members at the time that the FMAP benefits were terminated. "Family" also includes those individuals whose needs and income would be taken into account in determining the FMAP eligibility of household members if the household were applying in the current month.

a. Increased income from employment includes:

(1) Beginning employment.

(2) Increased rate of pay.

(3) Increased hours of employment.

b. In order to receive transitional Medicaid coverage under these provisions, an FMAP family must have received FMAP during at least three of the six months immediately preceding the month in which ineligibility occurred.

c. The 12 months' Medicaid transitional coverage begins the day following termination of FMAP eligibility.

d. When ineligibility is determined to occur retroactively, the transitional Medicaid coverage begins with the first month in which FMAP eligibility was erroneously granted, unless the provisions of paragraph *"f"* below apply.

e. Rescinded IAB 8/12/98, effective 10/1/98.

f. Transitional Medicaid shall not be allowed under these provisions when it has been determined that the member received FMAP in any of the six months immediately preceding the month of cancellation as the result of fraud. Fraud shall be defined in accordance with Iowa Code Supplement section 239B.14.

g. During the transitional Medicaid period, assistance shall be terminated at the end of the first month in which the eligible group ceases to include a child, as defined by the family medical assistance program.

h. If the family receives transitional Medicaid coverage during the entire initial six-month period and the department has received, by the twenty-first day of the fourth month, a complete Notice of Decision/Quarterly Income Report, Form 470-2663 or 470-2663(S), Medicaid shall continue for an additional six months, subject to paragraphs *"g"* and *"i"* of this subrule.

(1) If the department does not receive a completed form by the twenty-first day of the fourth month, assistance shall be canceled.

(2) A completed form is one that has all items answered, is signed, is dated, and is accompanied by verification as required in paragraphs 75.57(1)*"f"* and 75.57(2)*"l."*

i. Medicaid shall end at the close of the first or fourth month of the additional six-month period if any of the following conditions exists:

(1) The department does not receive a complete Notice of Decision/Quarterly Income Report, Form 470-2663 or 470-2663(S), by the twenty-first day of the first month or the fourth month of the additional six-month period as required in paragraph 75.1(31)*"h,"* unless the family establishes good cause for failure to report on a timely basis. Good cause shall be established when the family demonstrates that one or more of the following conditions exist:

1. There was a serious illness or death of someone in the family.

2. There was a family emergency or household disaster, such as a fire, flood, or tornado.

3. The family offers a good cause beyond the family's control.

4. There was a failure to receive the department's notification for a reason not attributable to the family. Lack of a forwarding address is attributable to the family.

(2) The specified relative had no earnings in one or more of the previous three months, unless the lack of earnings was due to an involuntary loss of employment, illness, or there were instances when problems could negatively impact the client's achievement of self-sufficiency as described at 441—subrule 93.133(4).

(3) It is determined that the family's average gross earned income, minus child care expenses for the children in the eligible group necessary for the employment of the specified relative, during the immediately preceding three-month period exceeds 185 percent of the federal poverty level as defined by the United States Office of Management and Budget and revised annually in accordance with Section 673(2) of the Omnibus Budget Reconciliation Act of 1981.

j. These provisions apply to specified relatives defined at paragraph 75.55(1)*"a,"* including:

(1) Any parent who is in the home. This includes parents who are included in the eligible group as well as those who are not.

(2) A stepparent who is included in the eligible group and who has assumed the role of the caretaker relative due to the absence or incapacity of the parent.

(3) A needy specified relative who is included in the eligible group.

k. The timely notice requirements as provided in 441—subrule 76.4(1) shall not apply when it is determined that the family failed to meet the eligibility criteria specified in paragraph *"g"* or *"i"* above. Transitional Medicaid shall be terminated beginning with the first month following the month in which the family no longer met the eligibility criteria. An adequate notice shall be provided to the family when any adverse action is taken.

75.1(32) *Persons and families terminated from refugee cash assistance (RCA) because of income earned from employment.* Refugee medical assistance (RMA) shall be available as long as the eight-month limit for the refugee program is not exceeded to persons who are receiving RMA and who are canceled from the RCA program solely because a member of the eligible group receives income from employment.

a. An RCA recipient shall not be required to meet any minimum program participation time frames in order to receive RMA coverage under these provisions.

b. A person who returns to the home after the family became ineligible for RCA may be included in the eligible group for RMA coverage if the person was included on the assistance grant the month the family became ineligible for RCA.

75.1(33) *Qualified disabled and working persons.* Medicaid shall be available to cover the cost of the premium for Part A of Medicare (hospital insurance benefits) for qualified disabled and working persons.

a. Qualified disabled and working persons are persons who meet the following requirements:

(1) The person's monthly income does not exceed 200 percent of the federal poverty level applicable to the family size involved.

(2) The person's resources do not exceed twice the maximum amount allowed under the supplemental security income (SSI) program.

(3) The person is not eligible for any other Medicaid benefits.

(4) The person is entitled to enroll in Medicare Part A of Title XVIII under Section 1818A of the Social Security Act (as added by Section 6012 of OBRA 1989).

b. The amount of the person's income and resources shall be determined as under the SSI program.

75.1(34) *Specified low-income Medicare beneficiaries.* Medicaid shall be available to persons who are entitled to hospital insurance under Part A of Medicare to cover the cost of the Medicare Part B premium, provided the following conditions are met:

a. The person's monthly income exceeds 100 percent of the federal poverty level but is less than 120 percent of the federal poverty level (as defined by the United States Office of Management and Budget and revised annually in accordance with Section 673(2) of the Omnibus Budget Reconciliation Act of 1981) applicable to a family of the size involved.

b. The person's resources do not exceed the maximum amount of resources that a person may have to obtain the full low-income subsidy for Medicare Part D drug benefits.

c. The amount of income and resources shall be determined as under the SSI program unless the person lives and is expected to live at least 30 consecutive days in a medical institution and has a spouse at home. Then the resource determination shall be made according to subrules 75.5(3) and 75.5(4). Income shall not include any amount of social security income attributable to the cost-of-living increase through the month following the month in which the annual revision of the official poverty level is published.

d. The effective date of eligibility shall be as set forth in rule 441—76.5(249A).

75.1(35) *Medically needy persons.*

a. *Coverage groups.* Subject to other requirements of this chapter, Medicaid shall be available to the following persons:

(1) Pregnant women. Pregnant women who would be eligible for FMAP-related coverage groups except for excess income or resources. For FMAP-related programs, pregnant women shall have the unborn child or children counted in the household size as if the child or children were born and living with them.

(2) FMAP-related persons under the age of 19. Persons under the age of 19 who would be eligible for an FMAP-related coverage group except for excess income.

(3) CMAP-related persons under the age of 21. Persons under the age of 21 who would be eligible in accordance with subrule 75.1(15) except for excess income.

(4) SSI-related persons. Persons who would be eligible for SSI except for excess income or resources.

(5) FMAP-specified relatives. Persons whose income or resources exceed the family medical assistance program's limit and who are a specified relative as defined at subrule 75.55(1) living with a child who is determined dependent.

b. *Resources and income of all persons considered.*

(1) Resources of all specified relatives and of all potentially eligible individuals living together, except as specified at subparagraph 75.1(35)*"b"*(2) or who are excluded in accordance with the provisions of rule 441—75.59(249A), shall be considered in determining eligibility of adults. Resources of all specified relatives and of all potentially eligible individuals living together shall be disregarded in determining eligibility of children. Income of all specified relatives and of all potentially eligible individuals living together, except as specified at subparagraph 75.1(35)*"b"*(2) or who are excluded in accordance with the provisions of rule 441—75.59(249A), shall be considered in determining eligibility.

(2) The amount of income of the responsible relative that has been counted as available to an FMAP household or SSI individual shall not be considered in determining the countable income for the medically needy eligible group.

(3) The resource determination shall be according to subrules 75.5(3) and 75.5(4) when one spouse is expected to reside at least 30 consecutive days in a medical institution.

c. *Resources.*

(1) The resource limit for adults in SSI-related households shall be $10,000 per household.

(2) Disposal of resources for less than fair market value by SSI-related applicants or members shall be treated according to policies specified in rule 441—75.23(249A).

(3) The resource limit for FMAP- or CMAP-related adults shall be $10,000 per household. In establishing eligibility for children for this coverage group, resources of all persons in the eligible group, regardless of age, shall be disregarded. In establishing eligibility for adults for this coverage group, resources shall be considered according to department of public health 641—subrule 75.4(2).

(4) The resources of SSI-related persons shall be treated according to SSI policies.

(5) When a resource is jointly owned by SSI-related persons and FMAP-related persons, the resource shall be treated according to SSI policies for the SSI-related person and according to FMAP policies for the FMAP-related persons.

d. *Income.* All unearned and earned income, unless specifically exempted, disregarded, deducted for work expenses, or diverted shall be considered in determining initial and continuing eligibility.

(1) Income policies specified in subrules 75.57(1) through 75.57(8) and paragraphs 75.57(9)*"b," "c," "g," "h,"* and *"i"* regarding treatment of earned and unearned income are applied to FMAP-related and CMAP-related persons when determining initial eligibility and for determining continuing eligibility unless otherwise specified. The three-step process for determining initial eligibility and the two-step process for determining ongoing eligibility, as described at rule 441—75.57(249A), shall not apply to medically needy persons.

(2) Income policies as specified in federal SSI regulations regarding treatment of earned and unearned income are applied to SSI-related persons when determining initial and continuing eligibility.

(3) The monthly income shall be determined prospectively unless actual income is available.

(4) The income for the certification period shall be determined by adding both months' net income together to arrive at a total.

(5) The income for the retroactive certification period shall be determined by adding each month of the retroactive period to arrive at a total.

e. Medically needy income level (MNIL).

(1) The MNIL is based on 133 1/3 percent of the schedule of basic needs, as provided in subrule 75.58(2), with households of one treated as households of two, as follows:

Number of Persons	1	2	3	4	5	6	7	8	9	10
MNIL	$483	$483	$566	$666	$733	$816	$891	$975	$1058	$1158

Each additional person $116

(2) When determining household size for the MNIL, all potential eligibles and all individuals whose income is considered as specified in paragraph 75.1(35)*"b"* shall be included unless the person has been excluded according to the provisions of rule 441—75.59(249A).

(3) The MNIL for the certification period shall be determined by adding both months' MNIL to arrive at a total.

The MNIL for the retroactive certification period shall be determined by adding each month of the retroactive period to arrive at a total.

(4) The total net countable income for the certification period shall be compared to the total MNIL for the certification period based on family size as specified in subparagraph (2).

If the total countable net income is equal to or less than the total MNIL, the medically needy individuals shall be eligible for Medicaid.

If the total countable net income exceeds the total MNIL, the medically needy individuals shall not be eligible for Medicaid unless incurred medical expenses equal or exceed the difference between the net income and the MNIL.

(5) Effective date of approval. Eligibility during the certification period or the retroactive certification period shall be effective as of the first day of the first month of the certification period or the retroactive certification period when the medically needy income level (MNIL) is met.

f. Verification of medical expenses to be used in spenddown calculation. The applicant or member shall submit evidence of medical expenses that are for noncovered Medicaid services and for covered services incurred prior to the certification period to the department on a claim form, which shall be completed by the medical provider. In cases where the provider is uncooperative or where returning to the provider would constitute an unreasonable requirement on the applicant or member, the form shall be completed by the worker. Verification of medical expenses for the applicant or member that are covered Medicaid services and occurred during the certification period shall be submitted by the provider to the Iowa Medicaid enterprise on a claim form. The applicant or member shall inform the provider of the applicant's or member's spenddown obligation at the time services are rendered or at the time the applicant or member receives notification of a spenddown obligation. Verification of allowable expenses incurred for transportation to receive medical care as specified in rule 441—78.13(249A) shall be verified on Form 470-0394, Medical Transportation Claim.

Applicants who have not established that they met spenddown in the current certification period shall be allowed 12 months following the end of the certification period to submit medical expenses for that

period or 12 months following the date of the notice of decision when the certification period had ended prior to the notice of decision.

g. Spenddown calculation.

(1) Medical expenses that are incurred during the certification period may be used to meet spenddown. Medical expenses incurred prior to a certification period shall be used to meet spenddown if not already used to meet spenddown in a previous certification period and if all of the following requirements are met. The expenses:

1. Remain unpaid as of the first day of the certification period.

2. Are not Medicaid-payable in a previous certification period or the retroactive certification period.

3. Are not incurred during any prior certification period with the exception of the retroactive period in which the person was conditionally eligible but did not meet spenddown.

Notwithstanding numbered paragraphs "1" through "3" above, paid medical expenses from the retroactive period can be used to meet spenddown in the retroactive period or in the certification period for the two months immediately following the retroactive period.

(2) Order of deduction. Spenddown shall be adjusted when a bill for a Medicaid-covered service incurred during the certification period has been applied to meet spenddown if a bill for a covered service incurred prior to the certification period is subsequently received. Spenddown shall also be adjusted when a bill for a noncovered Medicaid service is subsequently received with a service date prior to the Medicaid-covered service. Spenddown shall be adjusted when an unpaid bill for a Medicaid-covered service incurred during the certification period has been applied to meet spenddown if a paid bill for a covered service incurred in the certification period is subsequently received with a service date prior to the date of the notice of spenddown status.

If spenddown has been met and a bill is received with a service date after spenddown has been met, the bill shall not be deducted to meet spenddown.

Incurred medical expenses, including those reimbursed by a state or political subdivision program other than Medicaid, but excluding those otherwise subject to payment by a third party, shall be deducted in the following order:

1. Medicare and other health insurance premiums, deductibles, or coinsurance charges.

EXCEPTION: When some of the household members are eligible for full Medicaid benefits under the Health Insurance Premium Payment Program (HIPP), as provided in rule 441—75.21(249A), the health insurance premium shall not be allowed as a deduction to meet the spenddown obligation of those persons in the household in the medically needy coverage group.

2. An average statewide monthly standard deduction for the cost of medically necessary personal care services provided in a licensed residential care facility shall be allowed as a deduction for spenddown. These personal care services include assistance with activities of daily living such as preparation of a special diet, personal hygiene and bathing, dressing, ambulation, toilet use, transferring, eating, and managing medication.

The average statewide monthly standard deduction for personal care services shall be based on the average per day rate of health care costs associated with residential care facilities participating in the state supplementary assistance program for a 30.4-day month as computed in the Compilation of Various Costs and Statistical Data (Category: All; Type of Care: Residential Care Facility; Location: All; Type of Control: All). The average statewide standard deduction for personal care services used in the medically needy program shall be updated and effective the first day of the first month beginning two full months after the release of the Compilation of Various Costs and Statistical Data for the previous fiscal year.

3. Medical expenses for necessary medical and remedial services that are recognized under state law but not covered by Medicaid, chronologically by date of submission.

4. Medical expenses for acupuncture, chronologically by date of submission.

5. Medical expenses for necessary medical and remedial services that are covered by Medicaid, chronologically by date of submission.

(3) When incurred medical expenses have reduced income to the applicable MNIL, the individuals shall be eligible for Medicaid.

(4) Medical expenses reimbursed by a public program other than Medicaid prior to the certification period shall not be considered a medical deduction.

h. *Medicaid services.* Persons eligible for Medicaid as medically needy will be eligible for all services covered by Medicaid except:

(1) Care in a nursing facility or an intermediate care facility for the mentally retarded.

(2) Care in an institution for mental disease.

(3) Care in a Medicare-certified skilled nursing facility.

i. *Reviews.* Reviews of eligibility shall be made for SSI-related, CMAP-related, and FMAP-related medically needy members with a zero spenddown as often as circumstances indicate but in no instance shall the period of time between reviews exceed 12 months.

SSI-related, CMAP-related, and FMAP-related medically needy persons shall complete Form 470-3118 or 470-3118(S), Medicaid Review, as part of the review process when requested to do so by the department.

j. *Redetermination.* When an SSI-related, CMAP-related, or FMAP-related member who has had ongoing eligibility because of a zero spenddown has income that exceeds the MNIL, a redetermination of eligibility shall be completed to change the member's eligibility to a two-month certification with spenddown. This redetermination shall be effective the month the income exceeds the MNIL or the first month following timely notice.

(1) The Health Services Application, Form 470-2927 or 470-2927(S), or the Health and Financial Support Application, Form 470-0462 or Form 470-0466(Spanish), shall be used to determine eligibility for SSI-related medically needy when an SSI recipient has been determined to be ineligible for SSI due to excess income or resources in one or more of the months after the effective date of the SSI eligibility decision.

(2) All eligibility factors shall be reviewed on redeterminations of eligibility.

k. *Recertifications.* A new application shall be made when the certification period has expired and there has been a break in assistance as defined at rule 441—75.25(249A). When the certification period has expired and there has not been a break in assistance, the person shall use the Medicaid Review, Form 470-3118 or 470-3118(S), to be recertified.

l. *Disability determinations.* An applicant receiving social security disability benefits under Title II of the Social Security Act or railroad retirement benefits based on the Social Security Act definition of disability by the Railroad Retirement Board shall be deemed disabled without any further determination. In other cases under the medically needy program, the department shall conduct an independent determination of disability unless the applicant has been denied supplemental security income benefits based on lack of disability and does not allege either (1) a disabling condition different from or in addition to that considered by the Social Security Administration, or (2) that the applicant's condition has changed or deteriorated since the most recent Social Security Administration determination.

(1) In conducting an independent determination of disability, the department shall use the same criteria required by federal law to be used by the Social Security Administration of the United States Department of Health and Human Services in determining disability for purposes of Supplemental Security Income under Title XVI of the Social Security Act. The disability determination services bureau of the division of vocational rehabilitation shall make the initial disability determination on behalf of the department.

(2) For an independent determination of disability, the applicant or the applicant's authorized representative shall complete, sign and submit Form 470-4459 or 470-4459(S), Authorization to Disclose Information to the Department of Human Services, and either:

1. Form 470-2465, Disability Report for Adults, if the applicant is aged 18 or over; or

2. Form 470-3912, Disability Report for Children, if the applicant is under the age of 18.

(3) In connection with any independent determination of disability, the department shall determine whether reexamination of the person's medical condition will be necessary for periodic redeterminations of eligibility. When reexamination is required, the member or the member's authorized representative shall complete and submit the same forms as required in subparagraph (2).

75.1(36) *Expanded specified low-income Medicare beneficiaries.* As long as 100 percent federal funding is available under the federal Qualified Individuals (QI) Program, Medicaid benefits to cover the cost of the Medicare Part B premium shall be available to persons who are entitled to Medicare Part A provided the following conditions are met:

a. The person is not otherwise eligible for Medicaid.

b. The person's monthly income is at least 120 percent of the federal poverty level but is less than 135 percent of the federal poverty level (as defined by the United States Office of Management and Budget and revised annually in accordance with Section 673(2) of the Omnibus Budget Reconciliation Act of 1981) applicable to a family of the size involved.

c. The person's resources do not exceed the maximum amount of resources that a person may have to obtain the full low-income subsidy for Medicare Part D drug benefits.

d. The amount of the income and resources shall be determined the same as under the SSI program unless the person lives and is expected to live at least 30 consecutive days in a medical institution and has a spouse at home. Then the resource determination shall be made according to subrules 75.5(3) and 75.5(4). Income shall not include any amount of social security income attributable to the cost-of-living increase through the month following the month in which the annual revision of the official poverty level is published.

e. The effective date of eligibility shall be as set forth in rule 441—76.5(249A).

75.1(37) *Home health specified low-income Medicare beneficiaries.* Rescinded IAB 10/30/02, effective 1/1/03.

75.1(38) *Continued Medicaid for disabled children from August 22, 1996.* Medical assistance shall be available to persons who were receiving SSI as of August 22, 1996, and who would continue to be eligible for SSI but for Section 211(a) of the Personal Responsibility and Work Opportunity Act of 1996 (P.L. 104-193).

75.1(39) *Working persons with disabilities.*

a. Medical assistance shall be available to all persons who meet all of the following conditions:

(1) They are disabled as determined pursuant to rule 441—75.20(249A), except that being engaged in substantial gainful activity will not preclude a determination of disability.

(2) They are less than 65 years of age.

(3) They are members of families (including families of one) whose income is less than 250 percent of the most recently revised official federal poverty level for the family. Family income shall include gross income of all family members, less supplemental security income program disregards, exemptions, and exclusions, including the earned income disregards.

(4) They receive earned income from employment or self-employment or are eligible under paragraph *"c."*

(5) They would be eligible for medical assistance under another coverage group set out in this rule (other than the medically needy coverage groups at subrule 75.1(35)), disregarding all income, up to $10,000 of available resources, and any additional resources held by the disabled individual in a retirement account, a medical savings account, or an assistive technology account. For this purpose, disability shall be determined as under subparagraph (1) above.

(6) They have paid any premium assessed under paragraph *"b"* below.

b. Eligibility for a person whose gross income is greater than 150 percent of the federal poverty level for an individual is conditional upon payment of a premium. Gross income includes all earned and unearned income of the conditionally eligible person. A monthly premium shall be assessed at the time of application and at the annual review. The premium amounts and the federal poverty level increments above 150 percent of the federal poverty level used to assess premiums will be adjusted annually on August 1.

(1) Beginning with the month of application, the monthly premium amount shall be established for a 12-month period based on projected average monthly income for the 12-month period. The monthly premium established shall not be increased for any reason during the 12-month period. The premium shall not be reduced due to a change in the federal poverty level but may be reduced or eliminated prospectively during the 12-month period if a reduction in projected average monthly income is verified.

(2) Eligible persons are required to complete and return Form 470-3118 or 470-3118(S), Medicaid Review, with income information during the twelfth month of the annual enrollment period to determine the premium to be assessed for the next 12-month enrollment period.

(3) Premiums shall be assessed as follows:

IF THE INCOME OF THE APPLICANT IS ABOVE:	THE MONTHLY PREMIUM IS:
150% of Federal Poverty Level	$25
180% of Federal Poverty Level	$40
220% of Federal Poverty Level	$55
250% of Federal Poverty Level	$70
280% of Federal Poverty Level	$85
310% of Federal Poverty Level	$100
340% of Federal Poverty Level	$120
370% of Federal Poverty Level	$140
400% of Federal Poverty Level	$165
430% of Federal Poverty Level	$190
460% of Federal Poverty Level	$220
490% of Federal Poverty Level	$255
530% of Federal Poverty Level	$295
575% of Federal Poverty Level	$340
620% of Federal Poverty Level	$390
670% of Federal Poverty Level	$452

(4) Eligibility is contingent upon the payment of any assessed premiums. Medical assistance eligibility shall not be made effective for a month until the premium assessed for the month is paid. The premium must be paid within three months of the month of coverage or of the month of initial billing, whichever is later, for the person to be eligible for the month.

(5) When the department notifies the applicant of the amount of the premiums, the applicant shall pay any premiums due as follows:

1. The premium for each month is due the fourteenth day of the month the premium is to cover. EXCEPTIONS: The premium for the month of initial billing is due the fourteenth day of the following month; premiums for any months prior to the month of initial billing are due on the fourteenth day of the third month following the month of billing.

2. If the fourteenth day falls on a weekend or a state holiday, payment is due the first working day following the holiday or weekend.

3. When any premium payment due in the month it is to cover is not received by the due date, Medicaid eligibility shall be canceled.

(6) Payments received shall be applied in the following order:

1. To the month in which the payment is received if the premium for the current calendar month is unpaid.

2. To the following month when the payment is received after a billing statement has been issued for the following month.

3. To prior months when a full payment has not been received. Payments shall be applied beginning with the most recent unpaid month before the current calendar month, then the oldest unpaid prior month and forward until all prior months have been paid.

4. When premiums for all months above have been paid, any excess shall be held and applied to any months for which eligibility is subsequently established, as specified in numbered paragraphs “1,” “2,” and “3” above, and then to future months when a premium becomes due.

5. Any excess on an inactive account shall be refunded to the client after two calendar months of inactivity or of a zero premium or upon request from the client.

(7) An individual's case may be reopened when Medicaid eligibility is canceled for nonpayment of premium. However, the premium must be paid in full within the calendar month following the month the payment was due for reopening.

(8) Premiums may be submitted in the form of cash, money orders, or personal checks to the department at the following address: Department of Human Services, Supply Unit A-Level, Room 77, Hoover State Office Building, 1305 East Walnut, Des Moines, Iowa 50319.

(9) Once an individual is canceled from Medicaid due to nonpayment of premiums, the individual must reapply to establish Medicaid eligibility unless the reopening provisions of this subrule apply.

(10) When a premium due in the month it is to cover is not received by the due date, a notice of decision will be issued to cancel Medicaid. The notice will include reopening provisions that apply if payment is received and appeal rights.

(11) Form 470-3694, Billing Statement, shall be used for billing and collection.

c. Persons receiving assistance under this coverage group who become unable to work due to a change in their medical condition or who lose employment shall remain eligible for a period of six months from the month of the change in their medical condition or loss of employment as long as they intend to return to work and continue to meet all other eligibility criteria under this subrule.

d. For purposes of this subrule, the following definitions apply:

"Assistive technology" is the systematic application of technologies, engineering, methodologies, or scientific principles to meet the needs of and address the barriers confronted by individuals with disabilities in areas that include education, rehabilitation, technology devices and assistive technology services.

"Assistive technology accounts" include funds in contracts, savings, trust or other financial accounts, financial instruments or other arrangements with a definite cash value set aside and designated for the purchase, lease or acquisition of assistive technology, assistive technology devices or assistive technology services. Assistive technology accounts must be held separate from other accounts and funds and must be used to purchase, lease or otherwise acquire assistive technology, assistive technology services or assistive technology devices for the working person with a disability when a physician, certified vocational rehabilitation counselor, licensed physical therapist, licensed speech therapist, or licensed occupational therapist has established the medical necessity of the device, technology, or service and determined the technology, device, or service can reasonably be expected to enhance the individual's employment.

"Assistive technology device" is any item, piece of equipment, product system or component part, whether acquired commercially, modified or customized, that is used to increase, maintain, or improve functional capabilities or address or eliminate architectural, communication, or other barriers confronted by persons with disabilities.

"Assistive technology service" means any service that directly assists an individual with a disability in the selection, acquisition, or use of an assistive technology device or other assistive technology. It includes, but is not limited to, services referred to or described in the Assistive Technology Act of 1998, 29 U.S.C. 3002(4).

"Family," if the individual is under 18 and unmarried, includes parents living with the individual, siblings under 18 and unmarried living with the individual, and children of the individual who live with the individual. If the individual is 18 years of age or older, or married, "family" includes the individual's spouse living with the individual and any children living with the individual who are under 18 and unmarried. No other persons shall be considered members of an individual's family. An individual living alone or with others not listed above shall be considered to be a family of one.

"Medical savings account" means an account exempt from federal income taxation pursuant to Section 220 of the United States Internal Revenue Code (26 U.S.C. § 220).

"Retirement account" means any retirement or pension fund or account, listed in Iowa Code section 627.6(8)*"f"* as exempt from execution, regardless of the amount of contribution, the interest generated, or the total amount in the fund or account.

75.1(40) *People who have been screened and found to need treatment for breast or cervical cancer.*

a. Medical assistance shall be available to people who:

(1) Have been screened for breast or cervical cancer under the Centers for Disease Control and Prevention Breast and Cervical Cancer Early Detection Program established under Title XV of the Public Health Service Act and have been found to need treatment for either breast or cervical cancer (including a precancerous condition);

(2) Do not otherwise have creditable coverage, as that term is defined by the Health Insurance Portability and Accountability Act (HIPAA) (42 U.S.C. Section 300gg(c)(1)), and are not eligible for medical assistance under Iowa Code section 249A.3(1); and

(3) Are under the age of 65.

b. Eligibility established under paragraph *"a"* continues until the person is:

(1) No longer receiving treatment for breast or cervical cancer;

(2) No longer under the age of 65; or

(3) Covered by creditable coverage or eligible for medical assistance under Iowa Code section 249A.3(1).

c. Presumptive eligibility. A person who has been screened for breast or cervical cancer under the Centers for Disease Control and Prevention Breast and Cervical Cancer Early Detection Program established under Title XV of the Public Health Service Act, who has been found to need treatment for either breast or cervical cancer (including a precancerous condition), and who is determined by a qualified provider to be presumptively eligible for medical assistance under paragraph *"a"* shall be eligible for medical assistance until the last day of the month following the month of the presumptive eligibility determination if no Medicaid application is filed in accordance with rule 441—76.1(249A) by that day or until the date of a decision on a Medicaid application filed in accordance with rule 441—76.1(249A) by the last day of the month following the month of the presumptive eligibility determination, whichever is earlier.

The person shall complete Form 470-2927 or 470-2927(S), Health Services Application, in order for the qualified provider to make the presumptive eligibility determination. Presumptive eligibility shall begin no earlier than the date the qualified Medicaid provider determines eligibility.

Payment of claims for services provided to a person under this paragraph is not dependent upon a finding of Medicaid eligibility for the person.

(1) A provider who is qualified to determine presumptive eligibility is defined as a provider who:

1. Is eligible for payment under the Medicaid program; and

2. Either:

- Has been named lead agency for a county or regional local breast and cervical cancer early detection program under a contract with the department of public health; or
- Has a cooperative agreement with the department of public health under the Centers for Disease Control and Prevention Breast and Cervical Cancer Early Detection Program established under Title XV of the Public Health Service Act to receive reimbursement for providing breast or cervical cancer screening or diagnostic services to participants in the Care for Yourself Breast and Cervical Cancer Early Detection Program; and

3. Has made application and has been specifically designated by the department in writing as a qualified provider for the purpose of determining presumptive eligibility under this rule.

(2) The provider shall complete Form 470-3864, Application for Authorization to Make Presumptive Medicaid Eligibility Determinations (BCCT), and submit it to the department for approval in order to be designated as a provider qualified to make presumptive eligibility determinations. Once the department has approved the provider's application, the provider and the department shall sign Form 470-3865, Memorandum of Understanding with a Qualified Provider for People with Breast or Cervical Cancer Treatment. When both parties have signed the memorandum, the department shall designate the provider as a qualified provider and notify the provider.

(3) When a qualified provider has made a presumptive eligibility determination for a person, the provider shall:

1. Contact the department to obtain a state identification number for the person who has been determined presumptively eligible.

2. Notify the department in writing of the determination within five working days after the date the presumptive eligibility determination is made. The provider shall use a copy of Form 470-2580 or 470-2580(S), Presumptive Medicaid Eligibility Notice of Decision, for this purpose.

3. Inform the person in writing, at the time the determination is made, that if the person has not applied for Medicaid on Form 470-2927 or 470-2927(S), Health Services Application, the person has until the last day of the month following the month of the preliminary determination to file the application with the department. The qualified provider shall use Form 470-2580 or 470-2580(S), Presumptive Medicaid Eligibility Notice of Decision, for this purpose.

4. Forward copies of Form 470-2927 or 470-2927(S), Health Services Application, to the appropriate department office for eligibility determination if the person indicated on the application that the person was applying for any of the other programs. The provider shall forward these copies and proof of screening for breast or cervical cancer under the Centers for Disease Control and Prevention Breast and Cervical Cancer Early Detection Program within two working days from the date of the presumptive eligibility determination.

(4) In the event that a person needing care does not appear to be presumptively eligible, the qualified provider shall inform the person that the person may file an application at the county department office if the person wishes to have an eligibility determination made by the department.

(5) Presumptive eligibility shall end under either of the following conditions:

1. The person fails to file an application for Medicaid in accordance with rule 441—76.1(249A) by the last day of the month following the month of the presumptive eligibility determination.

2. The person files a Medicaid application by the last day of the month following the month of the presumptive eligibility determination and is found ineligible for Medicaid.

(6) Adequate and timely notice requirements and appeal rights shall apply to an eligibility determination made on a Medicaid application filed pursuant to rule 441—76.1(249A). However, notice requirements and appeal rights of the Medicaid program shall not apply to a person who is:

1. Denied presumptive eligibility by a qualified provider.

2. Determined to be presumptively eligible by a qualified provider and whose presumptive eligibility ends because the person fails to file an application by the last day of the month following the month of the presumptive eligibility determination.

(7) A new period of presumptive eligibility shall begin each time a person is screened for breast or cervical cancer under the Centers for Disease Control and Prevention Breast and Cervical Cancer Early Detection Program established under Title XV of the Public Health Service Act, is found to need treatment for breast or cervical cancer, and files Form 470-2927 or 470-2927(S), Health Services Application, with a qualified provider.

75.1(41) *Women eligible for family planning services under demonstration waiver.* Medical assistance for family planning services only shall be available to women as provided in this subrule.

a. Eligibility. The following are eligible for assistance under this coverage group:

(1) Women who were Medicaid members when their pregnancy ended and who are capable of bearing children but are not pregnant. Eligibility for these women extends for 12 consecutive months after the month when their 60-day postpartum period ends.

(2) Women who are of childbearing age, are capable of bearing children but are not pregnant, and have income that does not exceed 200 percent of the federal poverty level, as determined according to paragraph 75.1(41)*"c."*

b. Application.

(1) Women eligible under subparagraph 75.1(41)*"a"*(1) are not required to file an application for assistance under this coverage group. The department will automatically redetermine eligibility pursuant to rule 441—76.11(249A) upon loss of other Medicaid eligibility within 12 months after the month when the 60-day postpartum period ends.

(2) Women requesting assistance based on subparagraph 75.1(41)*"a"*(2) shall file an application as required in rule 441—76.1(249A).

c. Determining income eligibility. The department shall determine the countable income of a woman applying under subparagraph 75.1(41)*"a"*(2) as follows:

(1) Household size. The household size shall include the applicant or member, any dependent children as defined in 441—subrule 75.54(1) living in the same home as the applicant or member, and any spouse living in the same home as the applicant or member, except when a dependent child or spouse has elected to receive supplemental security income under Title XVI of the Social Security Act.

(2) Earned income. All earned income as defined in 441—subrule 75.57(2) that is received by a member of the household shall be counted except for the earnings of a child who is a full-time student as defined in 441—paragraph 75.54(1)*"b."*

(3) Unearned income. The following unearned income of all household members shall be counted:

1. Unemployment compensation.
2. Child support.
3. Alimony.
4. Social security and railroad retirement benefits.
5. Worker's compensation and disability payments.
6. Benefits paid by the Department of Veterans Affairs to disabled members of the armed forces or survivors of deceased veterans.

(4) Deductions. Deductions from income shall be made for any payments made by household members for court-ordered child support, alimony, or spousal support to non-household members and as provided in 441—subrule 75.57(2).

(5) Disregard of changes. A woman found to be income-eligible upon application or annual redetermination of eligibility shall remain income-eligible for 12 months regardless of any change in income or household size.

d. Effective date. Assistance for family planning services under this coverage group shall be effective on the first day of the month of application or the first day of the month all eligibility requirements are met, whichever is later. Notwithstanding 441—subrule 76.5(1), assistance shall not be available under this coverage group for any months preceding the month of application.

75.1(42) *Medicaid for independent young adults.* Medical assistance shall be available, as assistance related to the family medical assistance program, to a person who left a foster care placement on or after May 1, 2006, and meets all of the following conditions:

a. The person is at least 18 years of age and under 21 years of age.

b. On the person's eighteenth birthday, the person resided in foster care and Iowa was responsible for the foster care payment pursuant to Iowa Code section 234.35.

c. The person is not a mandatory household member or receiving Medicaid benefits under another coverage group.

d. The person has income below 200 percent of the most recently revised federal poverty level for the person's household size.

(1) "Household" shall mean the person and any of the following people who are living with the person and are not active on another Medicaid case:

1. The person's own children;
2. The person's spouse; and
3. Any children of the person's spouse who are under the age of 18 and unmarried.

No one else shall be considered a member of the person's household. A person who lives alone or with others not listed above, including the person's parents, shall be considered a household of one.

(2) The department shall determine the household's countable income pursuant to rule 75.57(249A). Twenty percent of earned income shall be disregarded.

(3) A person found to be income-eligible upon application or upon annual redetermination of eligibility shall remain income-eligible for 12 months regardless of any change in income or household size.

75.1(43) *Medicaid for children with disabilities.* Medical assistance shall be available to children who meet all of the following conditions on or after January 1, 2009:

a. The child is under 19 years of age.

b. The child is disabled as determined pursuant to rule 441—75.20(249A) based on the disability standards for children used for Supplemental Security Income (SSI) benefits under Title XVI of the Social Security Act, but without regard to any income or asset eligibility requirements of the SSI program.

c. The child is enrolled in any group health plan available through the employer of a parent living in the same household as the child if the employer contributes at least 50 percent of the total cost of annual premiums for that coverage. The parent shall enroll the child and pay any employee premium required to maintain coverage for the child.

d. The child's household has income at or below 300 percent of the federal poverty level applicable to a family of that size.

(1) For this purpose, the child's household shall include any of the following persons who are living with the child and are not receiving Medicaid on another case:

1. The child's parents.
2. The child's siblings under the age of 19.
3. The child's spouse.
4. The child's children.
5. The children of the child's spouse.

(2) Only those persons identified in subparagraph (1) shall be considered a member of the child's household. A person who receives medically needy coverage with a spenddown or limited benefits such as Medicare savings programs or family planning services only is not considered to be "receiving Medicaid" for the purposes of subparagraph (1). A child who lives alone or with persons not identified in subparagraph (1) shall be considered as having a household of one.

(3) For this purpose, the income of all persons included in the child's household shall be determined as provided for SSI-related groups under subrule 75.13(2).

(4) The federal poverty levels used to determine eligibility shall be revised annually on April 1.

75.1(44) *Presumptive eligibility for children.* Medical assistance shall be available to children under the age of 19 who are determined by a qualified entity to be presumptively eligible for medical assistance pursuant to this subrule.

a. *Qualified entity.* A "qualified entity" is an entity described in paragraphs (1) through (10) of the definition of the term at 42 CFR 435.1101, as amended to October 1, 2008, that:

(1) Has been determined by the department to be capable of making presumptive determinations of eligibility, and

(2) Has signed an agreement with the department as a qualified entity.

b. *Application process.* Families requesting assistance for children under this subrule shall apply with a qualified entity using the form specified in 441—paragraph 76.1(1)*"f."* The qualified entity shall use the department's Web-based system to make the presumptive eligibility determination, based on the information provided in the application.

(1) All presumptive eligibility applications shall be forwarded to the department for a full Medicaid or HAWK-I eligibility determination, regardless of the child's presumptive eligibility status.

(2) The date a valid application was received by the qualified entity establishes the date of application for purposes of determining the effective date of Medicaid or HAWK-I eligibility unless the qualified entity received the application on a weekend or state holiday. Applications received by the qualified entity on a weekend or a state holiday shall be considered to be received on the first business day following the weekend or state holiday.

(3) The qualified entity shall issue Form 470-2580 or 470-2580(S), Presumptive Medicaid Eligibility Notice of Decision, to inform the applicant of the decision on the application as soon as possible but no later than within two working days after the date the determination is made.

(4) Timely and adequate notice requirements and appeal rights of the Medicaid program shall not apply to presumptive eligibility decisions made by a qualified entity.

c. *Eligibility requirements.* To be determined presumptively eligible for medical assistance, a child shall meet the following eligibility requirements.

(1) Age. The child must be under the age of 19.

(2) Household income. Household income must be less than 300 percent of the federal poverty level for a household of the same size. For this purpose, the household shall include the applicant child and any sibling (of whole or half blood, or adoptive), spouse, parent, or stepparent living with the applicant child. This determination shall be based on the household's gross income, with no deductions, diversions, or disregards.

(3) Citizenship or qualified alien status. The child must be a citizen of the United States or a qualified alien as defined in subrule 75.11(2).

(4) Iowa residency. The child must be a resident of Iowa.

(5) Prior presumptive eligibility. A child shall not be determined presumptively eligible more than once in a 12-month period. The first month of the 12-month period begins with the month the application is received by the qualified entity.

d. Period of presumptive eligibility. Presumptive eligibility shall begin with the date that presumptive eligibility is determined and shall continue until the earliest of the following dates:

(1) The last day of the next calendar month;

(2) The day the child is determined eligible for Medicaid;

(3) The last day of the month that the child is determined eligible for HAWK-I; or

(4) The day the child is determined ineligible for Medicaid and HAWK-I. Withdrawal of the Medicaid or HAWK-I application before eligibility is determined shall not affect the child's eligibility during the presumptive period.

e. Services covered. Children determined presumptively eligible under this subrule shall be entitled to all Medicaid-covered services, including early and periodic screening, diagnosis, and treatment (EPSDT) services. Payment of claims for Medicaid services provided to a child during the presumptive eligibility period, including EPSDT services, is not dependent upon a determination of Medicaid or HAWK-I eligibility by the department.

This rule is intended to implement Iowa Code sections 249A.3, 249A.4 and 249A.6.

[**ARC 7741B**, IAB 5/6/09, effective 7/1/09; **ARC 7833B**, IAB 6/3/09, effective 8/1/09; **ARC 7929B**, IAB 7/1/09, effective 7/1/09; **ARC 7931B**, IAB 7/1/09, effective 7/1/09; **ARC 8095B**, IAB 9/9/09, effective 10/14/09; **ARC 8260B**, IAB 11/4/09, effective 1/1/10; **ARC 8261B**, IAB 11/4/09, effective 10/15/09; **ARC 8439B**, IAB 1/13/10, effective 3/1/10; **ARC 8503B**, IAB 2/10/10, effective 1/13/10]

441—75.2(249A) Medical resources. Medical resources include health and accident insurance, eligibility for care through the Department of Veterans Affairs, specialized child health services, Title XVIII of the Social Security Act (Medicare), and other resources for meeting the cost of medical care which may be available to the member. These resources must be used when reasonably available.

75.2(1) The department shall approve payment only for those services or that part of the cost of a given service for which no medical resources exist unless pay and chase provisions as defined in rule 441—75.25(249A) are applicable.

a. Persons who have been approved by the Social Security Administration for Supplemental Security Income shall complete Form 470-0364, 470-0364(M), 470-0364(MS), or 470-0364(S), SSI Medicaid Information, and return it to the department.

b. Persons eligible for Part B of the Medicare program shall make assignment to the department on Form 470-0364, 470-0364(M), 470-0364(MS), or 470-0364(S), SSI Medicaid Information.

75.2(2) As a condition of eligibility for medical assistance, a person who has the legal capacity to execute an assignment shall do all of the following:

a. Assign to the department any rights to payments of medical care from any third party to the extent that payment has been made under the medical assistance program. The applicant's signature on any form listed in 441—subrule 76.1(1) shall constitute agreement to the assignment. The assignment shall be effective for the entire period for which medical assistance is paid.

b. Cooperate with the department in obtaining third-party payments. The member or one acting on the member's behalf shall:

(1) File a claim or submit an application for any reasonably available medical resource, and

(2) Cooperate in the processing of the claim or application.

c. Cooperate with the department in identifying and providing information to assist the department in pursuing any third party who may be liable to pay for medical care and services available under the medical assistance program.

75.2(3) Good cause for failure to cooperate in the filing or processing of a claim or application shall be considered to exist when the member, or one acting on behalf of a minor, or of a legally incompetent adult member, is physically or mentally incapable of cooperation. Good cause shall be considered to exist when cooperation is reasonably anticipated to result in:

a. Physical or emotional harm to the member for whom medical resources are being sought.

b. Physical or emotional harm to the parent or payee, acting on the behalf of a minor, or of a legally incompetent adult member, for whom medical resources are being sought.

75.2(4) Failure to cooperate as required in subrule 75.2(2) without good cause as defined in subrule 75.2(3) shall result in the termination of medical assistance benefits. The department shall make the determination of good cause based on information and evidence provided by the member or by one acting on the member's behalf.

a. The medical assistance benefits of a minor or a legally incompetent adult member shall not be terminated for failure to cooperate in reporting medical resources.

b. When a parent or payee acting on behalf of a minor or legally incompetent adult member fails to file a claim or application for reasonably available medical resources or fails to cooperate in the processing of a claim or application without good cause, the medical assistance benefits of the parent or payee shall be terminated.

75.2(5) When the department receives information through a cross-match with Iowa workforce development department and child support recovery files which indicates the absent parent of a Medicaid-eligible child is employed, the department shall send Form 470-0413, Obligor Insurance Questionnaire, to the absent parent in order to obtain health insurance coverage information. If the absent parent does not respond within 15 days from the date Form 470-0413 is sent, the department shall send Form 470-2240, Employer Insurance Questionnaire, to the employer in order to obtain the health insurance coverage information.

This rule is intended to implement Iowa Code sections 249A.4, 249A.5 and 249A.6.

[**ARC 7546B**, IAB 2/11/09, effective 4/1/09; **ARC 8503B**, IAB 2/10/10, effective 1/13/10]

441—75.3(249A) Acceptance of other financial benefits. An applicant or member shall take all steps necessary to apply for and, if entitled, accept any income or resources for which the applicant or member may qualify, unless the applicant or member can show an incapacity to do so. Sources of benefits may be, but are not limited to, annuities, pensions, retirement or disability benefits, veterans' compensation and pensions, old-age, survivors, and disability insurance, railroad retirement benefits, black lung benefits, or unemployment compensation.

75.3(1) When it is determined that the supplemental security income (SSI)-related applicant or member may be entitled to other cash benefits, the department shall send a Notice Regarding Acceptance of Other Benefits, Form 470-0383, to the applicant or member.

75.3(2) The SSI-related applicant or member must express an intent to apply or refuse to apply for other benefits within ten calendar days from the date the notice is issued. A signed refusal to apply or failure to return the form shall result in denial of the application or cancellation of Medicaid unless the applicant or member is mentally or physically incapable of filing the claim for other cash benefits.

75.3(3) When the SSI-related applicant or member is physically or mentally incapable of filing the claim for other cash benefits, the department shall request the person acting on behalf of the member to pursue the potential benefits.

75.3(4) The SSI-related applicant or member shall cooperate in applying for the other benefits. Failure to timely secure the other benefits shall result in cancellation of Medicaid.

EXCEPTION: An applicant or member shall not be required to apply for supplementary security income to receive Medicaid under subrule 75.1(17).

This rule is intended to implement Iowa Code sections 249A.3 and 249A.4.

441—75.4(249A) Medical assistance lien.

75.4(1) When payment is made by the department for medical care or expenses through the medical assistance program on behalf of a member, the department shall have a lien, to the extent of those payments, to all monetary claims which the member may have against third parties.

a. A lien is not effective unless the department files a notice of lien with the clerk of the district court in the county where the member resides and with the member's attorney when the member's eligibility for medical assistance is established. The notice of lien shall be filed before the third party has concluded a final settlement with the member, the member's attorney, or other representative.

b. The third party shall obtain a written determination from the department concerning the amount of the lien before a settlement is deemed final.

(1) A compromise, including, but not limited to, notification, settlement, waiver or release of a claim, does not defeat the department's lien except pursuant to the written agreement of the director or the director's designee under which the department would receive less than full reimbursement of the amounts it expended.

(2) A settlement, award, or judgment structured in any manner not to include medical expenses or an action brought by a member or on behalf of a member which fails to state a claim for recovery of medical expenses does not defeat the department's lien if there is any recovery on the member's claim.

c. All notifications to the department required by law shall be directed to the Iowa Medicaid Enterprise, Revenue Collection Unit, P.O. Box 36475, Des Moines, Iowa 50315. Notification shall be considered made as of the time the notification is deposited so addressed, postage prepaid, in the United States Postal Service system.

75.4(2) The department may pursue its rights to recover either directly from any third party or from any recovery obtained by or on behalf of any member. If a member incurs the obligation to pay attorney fees and court costs for the purpose of enforcing a monetary claim to which the department has a lien under this section, upon the receipt of the judgment or settlement of the total claim, of which the lien for medical assistance payments is a part, the court costs and reasonable attorney fees shall first be deducted from this total judgment or settlement. One-third of the remaining balance shall then be deducted and paid to the member. From the remaining balance, the lien of the department shall be paid. Any amount remaining shall be paid to the member. An attorney acting on behalf of a member for the purpose of enforcing a claim to which the department has a lien shall not collect from the member any amount as attorney fees which is in excess of the amount which the attorney customarily would collect on claims not subject to this rule. The department will provide computer-generated documents or claim forms describing the services for which it has paid upon request of any affected member or the member's attorney. The documents may also be provided to a third party where necessary to establish the extent of the department's claim.

75.4(3) In those cases where appropriate notification is not given to the department or where the department's recovery rights are otherwise adversely affected by an action of the member or one acting on the member's behalf, medical assistance benefits shall be terminated. The medical assistance benefits of a minor child or a legally incompetent adult member shall not be terminated. Subsequent eligibility for medical assistance benefits shall be denied until an amount equal to the unrecovered claim has been reimbursed to the department or the individual produces documentation of incurred medical expense equal to the amount of the unrecovered claim. The incurred medical expense shall not be paid by the medical assistance program.

a. The client, or one acting on the client's behalf, shall provide information and verification as required to establish the availability of medical or third-party resources.

b. Rescinded IAB 9/4/91, effective 11/1/91.

c. The client or person acting on the client's behalf shall complete Form 470-2826, Supplemental Insurance Questionnaire, in a timely manner at the time of application, when any change in medical resources occurs during the application period, and when any changes in medical resources occur after the application is approved.

A report shall be considered timely when made within ten days from:

(1) The date that health insurance begins, changes, or ends.

(2) The date that eligibility begins for care through the Department of Veterans Affairs, specialized child health services, Title XVIII of the Social Security Act (Medicare) and other resources.

(3) The date the client, or one acting on the client's behalf, files an insurance claim against an insured third party, for the payment of medical expenses that otherwise would be paid by Medicaid.

(4) The date the member, or one acting on the member's behalf, retains an attorney with the expectation of seeking restitution for injuries from a possibly liable third party, and the medical expenses resulting from those injuries would otherwise be paid by Medicaid.

(5) The date that the member, or one acting on the member's behalf, receives a partial or total settlement for the payment of medical expenses that would otherwise be paid by Medicaid.

The member may report the change in person, by telephone, by mail or by using the Ten-Day Report of Change, Form 470-0499 or 470-0499(S), which is mailed with the Family Investment Program warrants and is issued to the client when Medicaid applications are approved, when annual reviews are completed, when a completed Ten-Day Report of Change is submitted, and when the client requests a form.

d. The member, or one acting on the member's behalf, shall complete the Priority Leads Letter, Form 470-0398, when the department has reason to believe that the member has sustained an accident-related injury. Failure to cooperate in completing and returning this form, or in giving complete and accurate information, shall result in the termination of Medicaid benefits.

e. When the recovery rights of the department are adversely affected by the actions of a parent or payee acting on behalf of a minor or legally incompetent adult member, the Medicaid benefits of the parent or payee shall be terminated. When a parent or payee fails to cooperate in completing or returning the Priority Leads Letter, Form 470-0398, or the Supplemental Insurance Questionnaire, Form 470-2826, or fails to give complete and accurate information concerning the accident-related injuries of a minor or legally incompetent adult member, the department shall terminate the Medicaid benefits of the parent or payee.

f. The member, or one acting on the member's behalf, shall refund to the department from any settlement or payment received the amount of any medical expenses paid by Medicaid. Failure of the member to do so shall result in the termination of Medicaid benefits. In those instances where a parent or payee, acting on behalf of a minor or legally incompetent adult member, fails to refund a settlement overpayment to the department, the Medicaid benefits of the parent or payee shall be terminated.

75.4(4) Third party and provider responsibilities.

a. The health care services provider shall inform the department by appropriate notation on the Health Insurance Claim, Form CMS-1500, that other coverage exists but did not cover the service being billed or that payment was denied.

b. The health care services provider shall notify the department in writing by mailing copies of any billing information sent to a member, an attorney, an insurer or other third party after a claim has been submitted to or paid by the department.

c. An attorney representing an applicant for medical assistance or a past or present Medicaid member on a claim to which the department has filed a lien under this rule shall notify the department of the claim of which the attorney has actual knowledge, before filing a claim, commencing an action or negotiating a settlement offer. Actual knowledge shall include the notice to the attorney pursuant to subrule 75.4(1). The mailing and deposit in a United States post office or public mailing box of the notice, addressed to the department at its state or local office location, is adequate legal notice of the claim.

75.4(5) Department's lien.

a. The department's liens are valid and binding on an attorney, insurer or other third party only upon notice by the department or unless the attorney, insurer or other third party has actual notice that the member is receiving medical assistance from the department and only to the extent that the attorney, insurer or third party has not made payment to the member or an assignee of the member prior to the notice.

Any information released to an attorney, insurer or other third party, by the health care services provider, that indicates that reimbursement from the state was contemplated or received, shall be

construed as giving the attorney, insurer or other third party actual knowledge of the department's involvement. For example, information supplied by a health care services provider which indicates medical assistance involvement shall be construed as showing involvement by the department under Iowa Code section 249A.6. Payment of benefits by an insurer or third party pursuant to the rights of the lienholder in this rule discharges the attorney, insurer or other third party from liability to the member or the member's assignee to the extent of the payment to the department.

b. When the department has reason to believe that an attorney is representing a member on a claim to which the department filed a lien under this rule, the department shall issue notice to that attorney of the department's lien rights by mailing the Notice of Medical Assistance Lien, Form 470-3030, to the attorney.

c. When the department has reason to believe that an insurer is liable for the costs of a member's medical expenses, the department shall issue notice to the insurer of the department's lien rights by mailing the Notice of Medical Assistance Lien, Form 470-3030, to the insurer.

d. The mailing and deposit in a United States post office or public mailing box of the notice, addressed to the attorney or insurer, is adequate legal notice of the department's subrogation rights.

75.4(6) For purposes of this rule, the term "third party" includes an attorney, individual, institution, corporation, or public or private agency which is or may be liable to pay part or all of the medical costs incurred as a result of injury, disease or disability by or on behalf of an applicant for medical assistance or a past or present Medicaid member.

75.4(7) The department may enforce its lien by a civil action against any liable third party.

This rule is intended to implement Iowa Code sections 249A.4, 249A.5, and 249A.6.

441—75.5(249A) Determination of countable income and resources for persons in a medical institution. In determining eligibility for any coverage group under rule 441—75.1(249A), certain factors must be considered differently for persons who reside in a medical institution. They are:

75.5(1) Determining income from property.

a. *Nontrust property.* Where there is nontrust property, unless the document providing income specifies differently, income paid in the name of one person shall be available only to that person. If payment of income is in the name of two persons, one-half is attributed to each. If payment is in the name of several persons, including a Medicaid client, a client's spouse, or both, the income shall be considered in proportion to the Medicaid client's or spouse's interest. If payment is made jointly to both spouses and no interest is specified, one-half of the couple's joint interest shall be considered available for each spouse. If the client or the client's spouse can establish different ownership by a preponderance of evidence, the income shall be divided in proportion to the ownership.

b. *Trust property.* Where there is trust property, the payment of income shall be considered available as provided in the trust. In the absence of specific provisions in the trust, the income shall be considered as stated above for nontrust property.

75.5(2) Division of income between married people for SSI-related coverage groups.

a. *Institutionalized spouse and community spouse.* If there is a community spouse, only the institutionalized person's income shall be considered in determining eligibility for the institutionalized spouse.

b. *Spouses institutionalized and living together.* Partners in a marriage who are residing in the same room in a medical institution shall be treated as a couple until the first day of the seventh calendar month that they continuously reside in the facility. The couple may continue to be considered as a couple for medical assistance effective the first day of the seventh calendar month of continuous residency if one partner would be ineligible for medical assistance or receive reduced benefits by considering them separate individuals or if they choose to be considered together. When spouses are treated as a couple, the combined income of the couple shall not exceed twice the amount of the income limit established in subrule 75.1(7). Persons treated together as a couple for income must be treated together for resources and persons treated individually for income must be treated individually for resources.

Spouses residing in the same room in a medical institution may be treated as individuals effective the first day of the seventh calendar month. The income of each spouse shall not exceed the income limit established in subrule 75.1(7).

c. Spouses institutionalized and living apart. Partners in a marriage who are both institutionalized, although not residing in the same room of the institution, shall be treated as individuals effective the month after the month the partners cease living together. Their income shall be treated separately for eligibility. If they live in the same facility after six months of continuous residence, they may be considered as a couple for medical assistance effective the first day of the seventh calendar month of continuous residency if one partner would be ineligible for medical assistance or receive reduced benefits by considering them separate individuals or if they choose to be considered together.

In the month of entry into a medical institution, income shall not exceed the amount of the income limit established in subrule 75.1(7).

75.5(3) Attribution of resources to institutionalized spouse and community spouse. The department shall determine the attribution of a couple's resources to the institutionalized spouse and to the community spouse when the institutionalized spouse is expected to remain in a medical institution at least 30 consecutive days on or after September 30, 1989, at the beginning of the first continuous period of institutionalization.

a. When determined. The department shall determine the attribution of resources between spouses at the earlier of the following:

(1) When either spouse requests that the department determine the attribution of resources at the beginning of the person's continuous stay in a medical facility prior to an application for Medicaid benefits. This request must be accompanied by Form 470-2577, Resources Upon Entering a Medical Facility, and necessary documentation.

(2) When the institutionalized spouse or someone acting on that person's behalf applies for Medicaid benefits. If the application is not made in the month of entry, the applicant shall also complete Form 470-2577 and provide necessary documentation.

b. Information required. The couple must provide the social security number of the community spouse. The attribution process shall include a match of the Internal Revenue Service data for both the institutionalized and community spouses.

c. Resources considered. The resources attributed shall include resources owned by both the community spouse and institutionalized spouse except for the following resources:

(1) The home in which the spouse or relatives as defined in 441—paragraph 41.22(3)*"a"* live (including the land that appertains to the home).

(2) Household goods, personal effects, and one automobile.

(3) The value of any burial spaces held for the purpose of providing a place for the burial of either spouse or any other member of the immediate family.

(4) Other property essential to the means of self-support of either spouse as to warrant its exclusion under the SSI program.

(5) Resources of a blind or disabled person who has a plan for achieving self-support as determined by division of vocational rehabilitation or the department of human services.

(6) For natives of Alaska, shares of stock held in a regional or a village corporation, during the period of 20 years in which the stock is inalienable, as provided in Section 7(h) and Section 8(c) of the Alaska Native Claims Settlement Act.

(7) Assistance under the Disaster Relief Act and Emergency Assistance Act or other assistance provided pursuant to federal statute on account of a presidentially declared major disaster and interest earned on these funds for the nine-month period beginning on the date these funds are received or for a longer period where good cause is shown.

(8) Any amount of underpayment of SSI or social security benefit due either spouse for one or more months prior to the month of receipt. This exclusion shall be limited to the first six months following receipt.

(9) A life insurance policy(ies) whose total face value is $1500 or less per spouse.

(10) An amount, not in excess of $1500 for each spouse that is separately identifiable and has been set aside to meet the burial and related expenses of that spouse. The amount of $1500 shall be reduced by an amount equal to the total face value of all insurance policies which are owned by the person or spouse and the total of any amounts in an irrevocable trust or other irrevocable arrangement available to meet the burial and related expenses of that spouse.

(11) Federal assistance paid for housing occupied by the spouse.

(12) Assistance from a fund established by a state to aid victims of crime for nine months from receipt when the client demonstrates that the amount was paid as compensation for expenses incurred or losses suffered as a result of a crime.

(13) Relocation assistance provided by a state or local government to a client comparable to assistance provided under Title II of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 which is subject to the treatment required by Section 216 of the Act.

d. Method of attribution. The resources attributed to the institutionalized spouse shall be one-half of the documented resources of both the institutionalized spouse and the community spouse as of the first moment of the first day of the month of the spouse's first entry to a medical facility. However, if one-half of the resources is less than $24,000, then $24,000 shall be protected for the community spouse. Also, when one-half of the resources attributed to the community spouse exceeds the maximum amount allowed as a community spouse resource allowance by Section 1924(f)(2)(A)(i) of the Social Security Act (42 U.S.C. § 1396r-5(f)(2)(A)(i)), the amount over the maximum shall be attributed to the institutionalized spouse. (The maximum limit is indexed annually according to the consumer price index.)

If the institutionalized spouse has transferred resources to the community spouse under a court order for the support of the community spouse, the amount transferred shall be the amount attributed to the community spouse if it exceeds the specified limits above.

e. Notice and appeal rights. The department shall provide each spouse a notice of the attribution results. The notice shall state that either spouse has a right to appeal the attribution if the spouse believes:

(1) That the attribution is incorrect, or

(2) That the amount of income generated by the resources attributed to the community spouse is inadequate to raise the community spouse's income to the minimum monthly maintenance allowance.

If an attribution has not previously been appealed, either spouse may appeal the attribution upon the denial of an application for Medicaid benefits based on the attribution.

f. Appeals. Hearings on attribution decisions shall be governed by procedures in 441—Chapter 7. If the hearing establishes that the community spouse's resource allowance is inadequate to raise the community spouse's income to the minimum monthly maintenance allowance, there shall be substituted an amount adequate to provide the minimum monthly maintenance needs allowance.

(1) To establish that the resource allowance is inadequate and receive a substituted allowance, the applicant must provide verification of all the income of the community spouse. For an applicant who became an institutionalized spouse on or after February 8, 2006, all income of the institutionalized spouse that could be made available to the community spouse pursuant to 75.16(2)*"d"* shall be treated as countable income of the community spouse when the attribution decision was made on or after February 8, 2006.

(2) The amount of resources adequate to provide the community spouse minimum maintenance needs allowance shall be based on the cost of a single premium lifetime annuity with monthly payments equal to the difference between the monthly maintenance needs allowance and other countable income not generated by either spouse's countable resources.

(3) The resources necessary to provide the minimum maintenance needs allowance shall be based on the maintenance needs allowance as provided by these rules at the time of the filing of the appeal.

(4) To receive the substituted allowance, the applicant shall be required to obtain one estimate of the cost of the annuity.

(5) The estimated cost of an annuity shall be substituted for the amount of resources attributed to the community spouse when the amount of resources previously determined is less than the estimated cost of an annuity. If the amount of resources previously attributed for the community spouse is greater

than the estimated cost of an annuity, there shall be no substitution for the cost of the annuity, and the attribution will remain as previously determined.

(6) The applicant shall not be required to purchase this annuity as a condition of Medicaid eligibility.

(7) If the appellant provides a statement from an insurance company that it will not provide an estimate due to the potential annuitant's age, the amount to be set aside shall be determined using the following calculation: The difference between the community spouse's gross monthly income not generated by countable resources (times 12) and the minimum monthly maintenance needs allowance (times 12) shall be multiplied by the annuity factor for the age of the community spouse in the Table for an Annuity for Life published at the end of Iowa Code chapter 450. This amount shall be substituted for the amount of resources attributed to the community spouse pursuant to subparagraph 75.5(3)*"f"*(5).

75.5(4) Consideration of resources of married people.

a. One spouse in a medical facility who entered the facility on or after September 30, 1989.

(1) Initial month. When the institutionalized spouse is expected to stay in a medical facility less than 30 consecutive days, the resources of both spouses shall be considered in determining initial Medicaid eligibility.

When the institutionalized spouse is expected to be in a medical facility 30 consecutive days or more, only the resources not attributed to the community spouse according to subrule 75.5(3) shall be considered in determining initial eligibility for the institutionalized spouse.

The amount of resources counted for eligibility for the institutionalized spouse shall be the difference between the couple's total resources at the time of application and the amount attributed to the community spouse under this rule.

(2) Ongoing eligibility. After the month in which the institutionalized spouse is determined eligible, no resources of the community spouse shall be deemed available to the institutionalized spouse during the continuous period in which the spouse is in an institution. Resources which are owned wholly or in part by the institutionalized spouse and which are not transferred to the community spouse shall be counted in determining ongoing eligibility. The resources of the institutionalized spouse shall not count for ongoing eligibility to the extent that the institutionalized spouse intends to transfer and does transfer the resources to the community spouse within 90 days unless unable to effect the transfer.

(3) Exception based on estrangement. When it is established by a disinterested third-party source that the institutionalized spouse is estranged from the community spouse, Medicaid eligibility will not be denied on the basis of resources when the applicant can demonstrate hardship.

The applicant can demonstrate hardship when the applicant is unable to obtain information about the community spouse's resources after exploring all legal means.

The applicant can also demonstrate hardship when resources attributed from the community spouse cause the applicant to be ineligible, but the applicant is unable to access these resources after exhausting legal means.

(4) Exception based on assignment of support rights. The institutionalized spouse shall not be ineligible by attribution of resources that are not actually available when:

1. The institutionalized spouse has assigned to the state any rights to support from the community spouse, or

2. The institutionalized spouse lacks the ability to execute an assignment due to physical or mental impairment, but the state has the right to bring a support proceeding against a community spouse without an assignment.

b. One spouse in a medical institution prior to September 30, 1989. When one spouse is in the medical institution prior to September 30, 1989, only the resources of the institutionalized spouse shall count for eligibility according to SSI policies the month after the month of entry. In the month of entry, the resources of both spouses are countable toward the couple resource limit.

c. Spouses institutionalized and living together. The combined resources of both partners in a marriage who are residing in the same room in a medical institution shall be subject to the resource limit for a married couple until the first of the seventh calendar month that they continuously reside in the facility. The couple may continue to be considered as a couple for medical assistance effective with the

seventh month if one partner would be ineligible for medical assistance or would receive reduced benefits by considering them separately or if they choose to be considered together. Persons treated together as a couple for resources must be treated together for income and persons treated individually for resources must be treated individually for income. Effective the first of the seventh calendar month of continuous residence, they may be treated as individuals, with the resource limit for each spouse the limit for a single person.

d. Spouses institutionalized and living apart. Partners in a marriage who are both institutionalized, although not residing in the same room of the institution, shall be treated as individuals effective the month after the month the partners cease living together. If they live in the same facility after six months of continuous residence, they may be considered as a couple for medical assistance effective the first day of the seventh calendar month of continuous residency if one partner would be ineligible for medical assistance or would receive reduced benefits by considering them separately or if they choose to be considered together.

In the month of entry into a medical institution, all resources of both spouses shall be combined and shall be subject to the resource limit for a married couple.

75.5(5) Consideration of resources for persons in a medical institution who have purchased and used a qualified or approved long-term care insurance policy pursuant to department of commerce, division of insurance, rules in 191—Chapter 39 or 72.

a. *Eligibility.* A person may be eligible for medical assistance under this subrule if:

(1) The person is the beneficiary of a qualified long-term care insurance policy or is enrolled in a prepaid health care delivery plan that provides long-term care services pursuant to 191—Chapter 39 or 72; and

(2) The person is eligible for medical assistance under 75.1(6), 75.1(7), or 75.1(18) except for excess resources; and

(3) The excess resources causing ineligibility under the listed coverage groups do not exceed the "asset adjustment" provided in this subrule.

b. *Definition.* "Asset adjustment" shall mean a $1 disregard of resources for each $1 that has been paid out under the person's qualified or approved long-term care insurance policy.

c. *Estate recovery.* An amount equal to the benefits paid out under a member's qualified or approved long-term care insurance policy will be exempt from recovery from the estate of the member or the member's spouse for payments made by the medical assistance program on behalf of the member.

This rule is intended to implement Iowa Code sections 249A.3, 249A.4, and 249A.35and chapter 514H.

[**ARC 8443B**, IAB 1/13/10, effective 3/1/10]

441—75.6(249A) Entrance fee for continuing care retirement community or life care community. When an individual resides in a continuing care retirement community or life care community that collects an entrance fee on admission, the entrance fee paid shall be considered a resource available to the individual for purposes of determining the individual's Medicaid eligibility and the amount of benefits to the extent that:

1. The individual has the ability to use the entrance fee, or the contract between the individual and the community provides that the entrance fee may be used to pay for care should the individual's other resources or income be insufficient to pay for such care;

2. The individual is eligible for a refund of any remaining entrance fee when the individual dies or when the individual terminates the community contract and leaves the community; and

3. The entrance fee does not confer an ownership interest in the community.

This rule is intended to implement Iowa Code section 249A.4.

441—75.7(249A) Furnishing of social security number. As a condition of eligibility, a person for whom Medicaid is being requested or received must furnish a social security account number or must furnish proof of application for the number if the social security number has not been issued or is not known and provide the number upon receipt. This requirement does not apply if the person

refuses to obtain a social security number because of well-established religious objections. The term "well-established religious objections" means that the person is a member of a recognized religious sect or a division of a recognized religious sect and adheres to the tenets or teachings of the sect or division, and for that reason is conscientiously opposed to applying for or using a national identification number.

75.7(1) Assistance shall not be denied, delayed, or discontinued pending the issuance or verification of the numbers when the applicants or recipients are cooperating in providing information necessary for issuance of their social security numbers.

75.7(2) The mother of a newborn child shall have until the second month following the mother's discharge from the hospital to apply for a social security account number for the child.

75.7(3) Social security account numbers may be requested for people in the eligible group for whom Medicaid is not being requested or received, but provision of the number shall not be a condition of eligibility for the people in the eligible group for whom Medicaid is being requested or received.

This rule is intended to implement Iowa Code section 249A.3.

441—75.8(249A) Medical assistance corrective payments. If a decision by the department or the Social Security Administration following an appeal on a denied application for any of the categories of medical assistance eligibility set forth in rule 441—75.1(249A) is favorable to the claimant, reimbursement will be made to the claimant for any medical bills paid by the claimant during the period between the date of the denial on the initial application and the date regular medical assistance coverage began when the bills were for medical services rendered in the period now determined to be an eligible period based on the following conditions:

75.8(1) These bills must be for services covered by the medical assistance program as set forth in 441—Chapter 78.

75.8(2) Reimbursement will be based on Medicaid rates for services in effect at the time the services were provided.

75.8(3) If a county relief agency has paid medical bills on the recipient's behalf and has not received reimbursement through assignment as set forth in 441—Chapter 80, the department will reimburse the county relief agency directly on the same basis as if the reimbursement was made to the recipient.

75.8(4) Recipients and county relief agencies shall file claims for payment under this subrule by submitting Form 470-2224, Verification of Paid Medical Bills, to the department. A supply of these forms is available from the county office. All requests for reimbursement shall be acted upon within 60 days of receipt of all Forms 470-2224 in the county office.

75.8(5) Any adverse action taken by the department with respect to an application for reimbursement is appealable under 441—Chapter 7.

This rule is intended to implement Iowa Code section 249A.4.

441—75.9(249A) Treatment of Medicaid qualifying trusts.

75.9(1) A Medicaid qualifying trust is a trust or similar legal device established, on or before August 10, 1993, other than by will by a person or that person's spouse under which the person may be the beneficiary of payments from the trust and the distribution of these payments is determined by one or more trustees who are permitted to exercise any discretion with respect to the distribution to the person. Trusts or initial trust decrees established prior to April 7, 1986, solely for the benefit of a mentally retarded person who resides in an intermediate care facility for the mentally retarded, are exempt.

75.9(2) The amount of income and principal from a Medicaid qualifying trust that shall be considered available shall be the maximum amount that may be permitted under the terms of the trust assuming the full exercise of discretion by the trustee or trustees for the distribution of the funds.

a. Trust income considered available shall be counted as income.

b. Trust principal (including accumulated income) considered available shall be counted as a resource, except where the trust explicitly limits the amount of principal that can be made available on an annual or less frequent basis. Where the trust limits the amount, the principal considered available over any particular period of time shall be counted as income for that period of time.

c. To the extent that the trust principal and income is available only for medical care, this principal or income shall not be used to determine eligibility. To the extent that the trust is restricted to medical expenses, it shall be used as a third party resource.

This rule is intended to implement Iowa Code section 249A.4.

441—75.10(249A) Residency requirements. Residency in Iowa is a condition of eligibility for medical assistance.

75.10(1) *Definitions.*

"Incapable of expressing intent" shall mean that the person meets one or more of the following conditions:

1. Has an IQ of 49 or less or has a mental age of seven or less.
2. Is judged legally incompetent.
3. Is found incapable of indicating intent based on medical documentation obtained from a physician, psychologist or other person licensed by the state in the field of mental retardation.

"Institution" shall mean an establishment that furnishes (in single or multiple facilities) food, shelter, and some treatment or services to four or more persons unrelated to the proprietor. Foster care facilities are included.

75.10(2) *Determining residency.* Residency is determined according to the following criteria:

a. Persons aged 21 and over.

(1) For any person not residing in an institution the state of residence is the state where the person is:

1. Living with the intention to remain there permanently or for an indefinite period (or, if incapable of expressing intent, where the person is living), or
2. Living and which the person entered with a job commitment or seeking employment (whether or not currently employed).

(2) For any institutionalized person who became incapable of indicating intent before age 21, the person's state of residence is:

1. That of the parent applying for Medicaid on the person's behalf, if the parents reside in separate states. If a legal guardian has been appointed and parental rights are terminated, the state of residence of the guardian is used instead of the parent's.
2. The parent's or legal guardian's state of residence at the time of placement. If a legal guardian has been appointed and parental rights are terminated, the state of residence of the guardian is used instead of the parent's.
3. The current state of residence of the parent or legal guardian who files the application if the person is institutionalized in the state. If a legal guardian has been appointed and parental rights are terminated, the state of residence of the guardian is used instead of the parent's.
4. The state of residence of the person who has been abandoned by the person's parents and does not have a legal guardian is the state in which the person is institutionalized.

(3) For any institutionalized person who became incapable of expressing intent at or after age 21, the state of residence is the state in which the person is physically present, except where another state makes a placement.

(4) For any other institutionalized person the state of residence is the state where the person is living with the intention to remain there permanently or for an indefinite period.

b. Persons under age 21.

(1) For any person who is emancipated from the person's parents or who is married and capable of expressing intent, the state of residence is the state where the person is living with the intention to remain there permanently or for an indefinite period.

(2) For any person not residing in an institution or foster home whose Medicaid eligibility is based on blindness or disability, the state of residence is the state in which the person is living.

(3) For any other person not in an institution or foster home and not subject to subparagraph (1) or (2) above, the state of residence is determined in accordance with rule 441—75.53(249A).

(4) For any person in an institution or foster home who is neither married nor emancipated, the state of residence is:

1. The parent's or legal guardian's state of residence at the time of placement. If a legal guardian has been appointed and parental rights are terminated, the state of residence of the guardian is used instead of the parent's.

2. The current state of residence of the parent or legal guardian who files the application if the person is in institutionalized or in foster care in that state. If a legal guardian has been appointed and parental rights are terminated, the state of residence of the guardian is used instead of the parent's.

3. The state of residence of the person who has been abandoned by the person's parents and does not have a legal guardian is the state in which the person is institutionalized or in foster care.

c. Persons placed by a state in an out-of-state foster home or institution. A state arranging or actually making the placement of a person in an institution or foster home in another state is considered the person's state of residence. However, a Title IV-E eligible child placed out of state by the department is eligible for Medicaid from the other state. Therefore, the Title IV-E eligible child shall only receive Iowa Medicaid until the receiving state provides coverage. A Title IV-E eligible child placed in Iowa by another state shall be considered eligible for Iowa Medicaid.

d. Medicaid-eligible persons receiving Medicaid from another state and gaining Iowa residency. These persons shall be granted Medicaid beginning with the month of residency in Iowa if the person is otherwise eligible and surrenders the other state's medical card. Good cause for not surrendering the other state's medical card shall exist when:

(1) The other state does not issue medical cards.

(2) The other state's medical card is a magnetic stripe or a computer chip card that contains more than Medicaid-related information.

(3) The other state's medical card: was left with Medicaid-eligible members of the person's household in the other state who did not move to Iowa with the person; was lost, mutilated, or destroyed; was not kept by the person upon the person's move to Iowa; or was previously surrendered to the other state.

In addition to surrendering the other state's medical card or establishing good cause, the cancellation of Medicaid in the other state shall be verified.

This rule is intended to implement Iowa Code section 249A.3.

441—75.11(249A) Citizenship or alienage requirements.

75.11(1) *Definitions.*

"Care and services necessary for the treatment of an emergency medical condition" shall mean services provided in a hospital, clinic, office or other facility that is equipped to furnish the required care after the sudden onset of an emergency medical condition, provided the care and services are not related to an organ transplant procedure furnished on or after August 10, 1993. Payment for emergency medical services shall be limited to the day treatment is initiated for the emergency medical condition and the following two days.

"Emergency medical condition" shall mean a medical condition (including labor and delivery) manifesting itself by acute symptoms of sufficient severity (including severe pain) that the absence of immediate medical attention could reasonably be expected to result in one or more of the following:

1. Placing the patient's health in serious jeopardy.

2. Serious impairment to bodily functions.

3. Serious dysfunction of any bodily organ or part.

"Federal means-tested program" means all federal programs that are means-tested with the exception of:

1. Medical assistance for care and services necessary for the treatment of an emergency medical condition not related to an organ transplant procedure furnished on or after August 10, 1993.

2. Short-term, non-cash, in-kind emergency disaster relief.

3. Assistance or benefits under the National School Lunch Act.

4. Assistance or benefits under the Child Nutrition Act of 1966.

5. Public health assistance (not including any assistance under Title XIX of the Social Security Act) for immunizations with respect to immunizable diseases and for testing and treatment of symptoms of communicable diseases whether or not the symptoms are caused by a communicable disease.

6. Payments of foster care and adoption assistance under Parts B and E of Title IV of the Social Security Act for a parent or a child who would, in the absence of numbered paragraph "1," be eligible to have payments made on the child's behalf under such part, but only if the foster or adoptive parent (or parents) of the child is a qualified alien (as defined in Section 431).

7. Programs, services, or assistance (such as soup kitchens, crisis counseling and intervention, and short-term shelter) specified by the attorney general of the United States in the attorney general's sole and unreviewable discretion after consultation with appropriate federal agencies and departments, that:

- Deliver in-kind services at the community level, including through public or private nonprofit agencies;
- Do not condition the provision of assistance, the amount of assistance provided, or the cost of assistance provided on the individual recipient's income or resources; and
- Are necessary for the protection of life or safety.

8. Programs of student assistance under Titles IV, V, IX, and X of the Higher Education Act of 1965, and Titles III, VII, and VIII of the Public Health Services Act.

9. Means-tested programs under the Elementary and Secondary Education Act of 1965.

10. Benefits under the Head Start Act.

11. Benefits funded through an employment and training program of the U.S. Department of Labor.

"Qualified alien" means an alien who is:

1. Lawfully admitted for permanent residence under the Immigration and Nationality Act;
2. Granted asylum under Section 208 of the Immigration and Nationality Act;
3. A refugee and who is admitted to the United States under Section 207 of the Immigration and Nationality Act;
4. Paroled into the United States under Section 212(d)(5) of the Immigration and Nationality Act for a period of at least one year;
5. An alien whose deportation is being withheld under Section 243(h) of the Immigration and Nationality Act; or
6. Granted conditional entry pursuant to Section 203(a)(7) of the Immigration and Nationality Act, as in effect prior to April 1, 1980.

"Qualifying quarters" includes all of the qualifying quarters of coverage as defined under Title II of the Social Security Act worked by a parent of an alien while the alien was under age 18 and all of the qualifying quarters worked by a spouse of the alien during their marriage if the alien remains married to the spouse or the spouse is deceased. No qualifying quarter of coverage that is creditable under Title II of the Social Security Act for any period beginning after December 31, 1996, may be credited to an alien if the parent or spouse of the alien received any federal means-tested public benefit during the period for which the qualifying quarter is so credited.

75.11(2) *Citizenship and alienage.*

a. To be eligible for Medicaid a person must be one of the following:

(1) A citizen or national of the United States.

(2) A qualified alien residing in the United States before August 22, 1996.

(3) An alien child under the age of 19 who is lawfully admitted for permanent residence under the Immigration and Nationality Act.

(4) A refugee who is admitted to the United States under Section 207 of the Immigration and Nationality Act.

(5) An alien who has been granted asylum under Section 208 of the Immigration and Nationality Act.

(6) An alien whose deportation is being withheld under Section 243(h) of the Immigration and Nationality Act.

(7) A qualified alien veteran who has an honorable discharge that is not due to alienage.

(8) A qualified alien who is on active duty in the Armed Forces of the United States other than active duty for training.

(9) A qualified alien who is the spouse or unmarried dependent child of a qualified alien described in subparagraph (7) or (8), including a surviving spouse who has not remarried.

(10) A qualified alien who has resided in the United States for a period of at least five years.

b. As a condition of eligibility, each member shall complete and sign Form 470-2549, Statement of Citizenship Status, attesting to the member's citizenship or alien status. When the member is incompetent or deceased, the form shall be signed by someone acting responsibly on the member's behalf. An adult shall sign the form for dependent children.

(1) As a condition of eligibility, all applicants for Medicaid shall attest to their citizenship or alien status by signing the application form which contains the same declaration.

(2) As a condition of continued eligibility, SSI-related Medicaid members not actually receiving SSI who have been continuous members since August 1, 1988, shall attest to their citizenship or alien status by signing the application form which contains a similar declaration at time of review.

(3) An attestation of citizenship or alien status completed on any one of the following forms shall meet the requirements of subrule 75.11(2) for children under the age of 19 who are otherwise eligible pursuant to 441—subrule 76.1(8):

1. Application for Food Assistance, Form 470-0306 or 470-0307 (Spanish);

2. Health and Financial Support Application, Form 470-0462 or 470-0466 (Spanish);

3. Review/Recertification Eligibility Document, Form 470-2881, 470-2881(S), 470-2881(M), or 470-2881(MS);

c. Except as provided in paragraph *"f,"* applicants or members for whom an attestation of United States citizenship has been made pursuant to paragraph *"b"* shall present satisfactory documentation of citizenship or nationality as defined in paragraph *"d"* or *"e."* An applicant or member shall have a reasonable period to obtain and provide proof of citizenship or nationality.

(1) For the purposes of this requirement, the "reasonable period" begins on the date a written request to obtain and provide proof is issued to an applicant or member and continues to the date when the proof is provided or the date when the department establishes that the applicant or member is no longer making a good-faith effort to obtain the proof, whichever is earlier.

(2) Medicaid eligibility shall continue for members during the reasonable period. Medicaid shall not be approved for applicants until acceptable documentary evidence is provided.

(3) A reference to a form in paragraph *"d"* or *"e"* includes any successor form.

d. Any one of the following documents shall be accepted as satisfactory documentation of citizenship or nationality:

(1) A United States passport.

(2) Form N-550 or N-570 (Certificate of Naturalization) issued by the U.S. Citizenship and Immigration Services.

(3) Form N-560 or N-561 (Certificate of United States Citizenship) issued by the U.S. Citizenship and Immigration Services.

(4) A valid state-issued driver's license or other identity document described in Section 274A(b)(1)(D) of the United States Immigration and Nationality Act, but only if the state issuing the license or document either:

1. Requires proof of United States citizenship before issuance of the license or document; or

2. Obtains a social security number from the applicant and verifies before certification that the number is valid and is assigned to the applicant who is a citizen.

(5) Another document that provides proof of United States citizenship or nationality and provides a reliable means of documentation of personal identity, as the secretary of the U.S. Department of Health and Human Services may specify by regulation pursuant to 42 U.S.C. Section 1396b(x)(3)(B)(v).

e. Satisfactory documentation of citizenship or nationality may also be demonstrated by the combination of:

(1) Any identity document described in Section 274A(b)(1)(D) of the United States Immigration and Nationality Act or any other documentation of personal identity that provides a reliable means of

identification, as the secretary of the U.S. Department of Health and Human Services finds by regulation pursuant to 42 U.S.C. Section 1396b(x)(3)(D)(ii), and

(2) Any one of the following:

1. A certificate of birth in the United States.

2. Form FS-545 or Form DS-1350 (Certification of Birth Abroad) issued by the U.S. Citizenship and Immigration Services.

3. Form I-97 (United States Citizen Identification Card) issued by the U.S. Citizenship and Immigration Services.

4. Form FS-240 (Report of Birth Abroad of a Citizen of the United States) issued by the U.S. Citizenship and Immigration Services.

5. Another document that provides proof of United States citizenship or nationality, as the secretary of the U.S. Department of Health and Human Services may specify pursuant to 42 U.S.C. Section 1396b(x)(3)(C)(v).

f. A person for whom an attestation of United States citizenship has been made pursuant to paragraph *"b"* is not required to present documentation of citizenship or nationality for Medicaid eligibility if any of the following circumstances apply:

(1) The person is entitled to or enrolled for benefits under any part of Title XVIII of the federal Social Security Act (Medicare).

(2) The person is receiving federal social security disability insurance (SSDI) benefits under Title II of the federal Social Security Act, Section 223 or 202, based on disability (as defined in Section 223(d)).

(3) The person is receiving supplemental security income (SSI) benefits under Title XVI of the federal Social Security Act.

(4) The person is a child in foster care who is eligible for child welfare services funded under Part B of Title IV of the federal Social Security Act.

(5) The person is eligible for adoption or foster care assistance funded under Part E of Title IV of the federal Social Security Act; or

(6) The person has previously presented satisfactory documentary evidence of citizenship or nationality, as specified by the United States Secretary of Health and Human Services.

g. If no other identity documentation allowed by subparagraph 75.11(2)*"e"*(1) is available, identity may be documented by affidavit as described in this paragraph. However, affidavits cannot be used to document both identity and citizenship.

(1) For children under the age of 16, identity may be documented using Form 470-4386 or 470-4386(S), Affidavit of Identity, signed by the child's parent, guardian, or caretaker relative under penalty of perjury.

(2) For disabled persons who live in a residential care facility, identity may be documented using Form 470-4386 or 470-4386(S), Affidavit of Identity, signed by a residential care facility director or administrator under penalty of perjury.

h. If no other documentation that provides proof of United States citizenship or nationality allowed by subparagraph 75.11(2)*"e"*(2) is available, United States citizenship or nationality may be documented using Form 470-4373 or 470-4373(S), Affidavit of Citizenship. However, affidavits cannot be used to document both identity and citizenship.

(1) Two affidavits of citizenship are required. The person who signs the affidavit must provide proof of citizenship and identity. A person who is not related to the applicant or member must sign at least one of the affidavits.

(2) When affidavits of citizenship are used, Form 470-4374 or 470-4374(S), Affidavit Concerning Documentation of Citizenship, or an equivalent affidavit explaining why other evidence of citizenship does not exist or cannot be obtained must also be submitted and must be signed by the applicant or member or by another knowledgeable person (guardian or representative).

75.11(3) *Deeming of sponsor's income and resources.*

a. In determining the eligibility and amount of benefits of an alien, the income and resources of the alien shall be deemed to include the following:

(1) The income and resources of any person who executed an affidavit of support pursuant to Section 213A of the Immigration and Nationality Act (as implemented by the Personal Responsibility and Work Reconciliation Act of 1996) on behalf of the alien.

(2) The income and resources of the spouse of the person who executed the affidavit of support.

b. When an alien attains citizenship through naturalization pursuant to Chapter 2 of Title III of the Immigration and Nationality Act or has worked 40 qualifying quarters of coverage as defined in Title II of the Social Security Act or can be credited with qualifying quarters as defined at subrule 75.11(1) and, in the case of any qualifying quarter creditable for any period beginning after December 31, 1996, did not receive any federal means-tested public benefits, as defined in subrule 75.11(1), during any period, deeming of the sponsor's income and resources no longer applies.

75.11(4) *Eligibility for payment of emergency medical services.* Aliens who do not meet the provisions of subrule 75.11(2) and who would otherwise qualify except for their alien status are eligible to receive Medicaid for care and services necessary for the treatment of an emergency medical condition as defined in subrule 75.11(1). To qualify for payment under this provision:

a. The alien must meet all other eligibility criteria, including state residence requirements provided at rules 441—75.10(249A) and 441—75.53(249A), with the exception of rule 441—75.7(249A) and subrules 75.11(2) and 75.11(3).

b. The medical provider who treated the emergency medical condition or the provider's designee must submit verification of the existence of the emergency medical condition on either:

(1) Form 470-4299, Verification of Emergency Health Care Services; or

(2) A signed statement that contains the same information as requested by Form 470-4299.

This rule is intended to implement Iowa Code section 249A.3.

[**ARC 7932B**, IAB 7/1/09, effective 7/1/09; **ARC 8096B**, IAB 9/9/09, effective 10/14/09; **ARC 8642B**, IAB 4/7/10, effective 6/1/10]

441—75.12(249A) Inmates of public institutions. A person is not eligible for medical assistance for any care or services received while the person is an inmate of a public institution. For the purpose of this rule, the phrase "inmate of a public institution" is defined by 42 CFR Section 435.1009, as amended on November 10, 1994.

This rule is intended to implement Iowa Code section 249A.3.

441—75.13(249A) Categorical relatedness.

75.13(1) *FMAP-related Medicaid eligibility.* Medicaid eligibility for persons who are under the age of 21, pregnant women, or specified relatives of dependent children who are not blind or disabled shall be determined using the income criteria in effect for the family medical assistance program (FMAP) as provided in subrule 75.1(14) unless otherwise specified. Income shall be considered prospectively.

75.13(2) *SSI-related Medicaid.* Except as otherwise provided in 441—Chapters 75 and 76, persons who are 65 years of age or older, blind, or disabled are eligible for Medicaid only if eligible for the Supplemental Security Income (SSI) program administered by the United States Social Security Administration.

a. *SSI policy reference.* The statutes, regulations, and policy governing eligibility for SSI are found in Title XVI of the Social Security Act (42 U.S.C. Sections 1381 to 1383f), in the federal regulations promulgated pursuant to Title XVI (20 CFR 416.101 to 416.2227), and in Part 5 of the Program Operations Manual System published by the United States Social Security Administration. The Program Operations Manual System is available at Social Security Administration offices in Ames, Burlington, Carroll, Cedar Rapids, Clinton, Council Bluffs, Creston, Davenport, Decorah, Des Moines, Dubuque, Fort Dodge, Iowa City, Marshalltown, Mason City, Oskaloosa, Ottumwa, Sioux City, Spencer, Storm Lake, and Waterloo, or through the Department of Human Services, Division of Financial, Health, and Work Supports, Hoover State Office Building, 1305 East Walnut, Des Moines, Iowa 50319-0114.

b. *Income considered.* For SSI-related Medicaid eligibility purposes, income shall be considered prospectively.

c. Trust contributions. Income that a person contributes to a trust as specified at 75.24(3)*"b"* shall not be considered for purposes of determining eligibility for SSI-related Medicaid.

d. Conditional eligibility. For purposes of determining eligibility for SSI-related Medicaid, the SSI conditional eligibility process, by which a client may receive SSI benefits while attempting to sell excess resources, found at 20 CFR 416.1240 to 416.1245, is not considered an eligibility methodology.

e. Valuation of life estates and remainder interests. In the absence of other evidence, the value of a life estate or remainder interest in property shall be determined using the following table by multiplying the fair market value of the entire underlying property (including all life estates and all remainder interests) by the life estate or remainder interest decimal corresponding to the age of the life estate holder or other person whose life controls the life estate.

If a Medicaid applicant or recipient disputes the value determined using the following table, the applicant or recipient may submit other evidence and the value of the life estate or remainder interest shall be determined based on the preponderance of all the evidence submitted to or obtained by the department, including the value given by the following table.

Age	Life Estate	Remainder	Age	Life Estate	Remainder	Age	Life Estate	Remainder
0	.97188	.02812	37	.93026	.06974	74	.53862	.46138
1	.98988	.01012	38	.92567	.07433	75	.52149	.47851
2	.99017	.00983	39	.92083	.07917	76	.51441	.49559
3	.99008	.00992	40	.91571	.08429	77	.48742	.51258
4	.98981	.01019	41	.91030	.08970	78	.47049	.52951
5	.98938	.01062	42	.90457	.09543	79	.45357	.54643
6	.98884	.01116	43	.89855	.10145	80	.43569	.56341
7	.98822	.01178	44	.89221	.10779	81	.41967	.58033
8	.98748	.01252	45	.88558	.11442	82	.40295	.59705
9	.98663	.01337	46	.87863	.12137	83	.38642	.61358
10	.98565	.01435	47	.87137	.12863	84	.36998	.63002
11	.98453	.01547	48	.86374	.13626	85	.35359	.64641
12	.98329	.01671	49	.85578	.14422	86	.33764	.66236
13	.98198	.01802	50	.84743	.15257	87	.32262	.67738
14	.98066	.01934	51	.83674	.16126	88	.30859	.69141
15	.97937	.02063	52	.82969	.17031	89	.29526	.70474
16	.97815	.02185	53	.82028	.17972	90	.28221	.71779
17	.97700	.02300	54	.81054	.18946	91	.26955	.73045
18	.97590	.02410	55	.80046	.19954	92	.25771	.74229
19	.97480	.02520	56	.79006	.20994	93	.24692	.75308
20	.97365	.02635	57	.77931	.22069	94	.23728	.76272
21	.97245	.02755	58	.76822	.23178	95	.22887	.77113
22	.97120	.02880	59	.75675	.24325	96	.22181	.77819
23	.96986	.03014	60	.74491	.25509	97	.21550	.78450
24	.96841	.03159	61	.73267	.26733	98	.21000	.79000
25	.96678	.03322	62	.72002	.27998	99	.20486	.79514
26	.96495	.03505	63	.70696	.29304	100	.19975	.80025
27	.96290	.03710	64	.69352	.30648	101	.19532	.80468
28	.96062	.03938	65	.67970	.32030	102	.19054	.80946
29	.95813	.04187	66	.66551	.33449	103	.18437	.81563
30	.95543	.04457	67	.65098	.343902	104	.17856	.82144

Age	Life Estate	Remainder	Age	Life Estate	Remainder	Age	Life Estate	Remainder
31	.95254	.04746	68	.63610	.363690	105	.16962	.83038
32	.94942	.05058	69	.62086	.37914	106	.15488	.84512
33	.94608	.05392	70	.60522	.39478	107	.13409	.86591
34	.94250	.05750	71	.58914	.41086	108	.10068	.89932
35	.93868	.06132	72	.57261	.42739	109	.04545	.95455
36	.93460	.06540	73	.55571	.44429			

75.13(3) *Resource eligibility for SSI-related Medicaid for children.* Resources of all household members shall be disregarded when determining eligibility for children under any SSI-related coverage group except for those groups at subrules 75.1(3), 75.1(4), 75.1(6), 75.1(9), 75.1(10), 75.1(12), 75.1(13), 75.1(23), 75.1(25), 75.1(29), 75.1(33), 75.1(34), 75.1(36), 75.1(37), and 75.1(38).

This rule is intended to implement Iowa Code section 249A.3.

441—75.14(249A) Establishing paternity and obtaining support.

75.14(1) As a condition of eligibility, Medicaid applicants and members in households with an absent parent shall cooperate in obtaining medical support for each applicant or member as well as for any other person in the household for whom Medicaid is requested and for whom the applicant or member can legally assign rights for medical support, except when good cause as defined in subrule 75.14(8) for refusal to cooperate is established.

a. The applicant or member shall cooperate in the following:

(1) Identifying and locating the parent of the child for whom Medicaid is requested.

(2) Establishing the paternity of a child born out of wedlock for whom Medicaid is requested.

(3) Obtaining medical support and payments for medical care for the applicant or member and for a child for whom Medicaid is requested.

(4) Rescinded IAB 2/3/93, effective 4/1/93.

b. Cooperation is defined as including the following actions by the applicant or member:

(1) Appearing at the income maintenance unit or the child support recovery unit to provide verbal or written information or documentary evidence known to, possessed by or reasonably obtainable by the applicant or member that is relevant to achieving the objectives of the child support recovery program.

(2) Appearing as a witness at judicial or other hearings or proceedings.

(3) Providing information, or attesting to the lack of information, under penalty of perjury.

c. The applicant or member shall cooperate with the department in supplying information with respect to the absent parent, the receipt of medical support or payments for medical care, and the establishment of paternity, to the extent necessary to establish eligibility for assistance and permit an appropriate referral to the child support recovery unit.

d. The applicant or member shall cooperate with the child support recovery unit to the extent of supplying all known information and documents pertaining to the location of the absent parent and taking action as may be necessary to secure medical support and payments for medical care or to establish paternity. This includes completing and signing documents determined to be necessary by the state's attorney for any relevant judicial or administrative process.

e. The income maintenance unit shall make the determination of whether or not the applicant or member has cooperated.

75.14(2) Failure of the applicant or member to cooperate shall result in denial or cancellation of the person's Medicaid benefits. In family medical assistance program (FMAP)-related Medicaid cases, all deductions and disregards described at paragraphs 75.57(2)*"a," "b,"* and *"c"* shall be allowed when otherwise applicable.

75.14(3) Each Medicaid applicant or member who is required to cooperate with the child support recovery unit shall have the opportunity to claim good cause for refusing to cooperate in establishing

paternity or securing medical support and payments for medical care. The provisions set forth in subrules 75.14(8) to 75.14(12) shall be used when making a determination of the existence of good cause.

75.14(4) Each Medicaid applicant or member shall assign to the department any rights to medical support and payments for medical care from any other person for which the person can legally make assignment. This shall include rights to medical support and payments for medical care on the applicant's or member's own behalf or on behalf of any other family member for whom the applicant or member is applying. An assignment is effective the same date the eligibility information is entered into the automated benefit calculation system and is effective for the entire period for which eligibility is granted. Support payments not intended for medical support shall not be assigned to the department.

75.14(5) Referrals to the child support recovery unit for Medicaid applicants or members. The department shall provide prompt notice to the child support recovery unit whenever assistance is furnished with respect to a child with a parent who is absent from the home or when any member of the eligible group is entitled to support payments.

a. A referral to the child support recovery unit shall not be made when a parent's absence is occasioned solely by reason of the performance of active duty in the uniformed services of the United States. "Uniformed service" means the Army, Navy, Air Force, Marine Corps, Coast Guard, National Oceanographic and Atmospheric Administration, or Public Health Service of the United States.

b. *"Prompt notice"* means within two working days of the date assistance is approved.

75.14(6) Pregnant women establishing eligibility under the mothers and children (MAC) coverage group as provided at subrule 75.1(28) shall be exempt from the provisions in this rule for any born child for whom the pregnant woman applies for or receives Medicaid. Additionally, any previously pregnant woman eligible for postpartum coverage under the provision of subrule 75.1(24) shall not be subject to the provisions in this rule until after the end of the month in which the 60-day postpartum period expires. Pregnant women establishing eligibility under any other coverage groups except those set forth in subrule 75.1(24) or 75.1(28) shall be subject to the provisions in this rule when establishing eligibility for born children. However, when a pregnant woman who is subject to these provisions fails to cooperate, the woman shall lose eligibility under her current coverage group and her eligibility for Medicaid shall be automatically redetermined under subrule 75.1(28).

75.14(7) Notwithstanding subrule 75.14(6), any pregnant woman or previously pregnant woman establishing eligibility under subrule 75.1(28) or 75.1(24) shall not be exempt from the provisions of 75.14(4) and 75.14(5) which require the applicant or member to assign any rights to medical support and payments for medical care and to be referred to the child support recovery unit.

75.14(8) Good cause for refusal to cooperate. Good cause shall exist when it is determined that cooperation in establishing paternity and securing support is against the best interests of the child.

a. The income maintenance unit shall determine that cooperation is against the child's best interest when the applicant's or member's cooperation in establishing paternity or securing support is reasonably anticipated to result in:

(1) Physical or emotional harm to the child for whom support is to be sought; or

(2) Physical or emotional harm to the parent or specified relative with whom the child is living which reduces the person's capacity to care for the child adequately.

(3) Physical harm to the parent or specified relative with whom the child is living which reduces the person's capacity to care for the child adequately; or

(4) Emotional harm to the parent or specified relative with whom the child is living of a nature or degree that it reduces the person's capacity to care for the child adequately.

b. The income maintenance unit shall determine that cooperation is against the child's best interest when at least one of the following circumstances exists, and the income maintenance unit believes that because of the existence of that circumstance, in the particular case, proceeding to establish paternity or secure support would be detrimental to the child for whom support would be sought.

(1) The child was conceived as the result of incest or forcible rape.

(2) Legal proceedings for the adoption of the child are pending before a court of competent jurisdiction.

(3) The applicant or member is currently being assisted by a public or licensed private social agency to resolve the issue of whether to keep the child or relinquish the child for adoption, and the discussions have not gone on for more than three months.

c. Physical harm and emotional harm shall be of a serious nature in order to justify a finding of good cause. A finding of good cause for emotional harm shall be based only upon a demonstration of an emotional impairment that substantially affects the individual's functioning.

d. When the good cause determination is based in whole or in part upon the anticipation of emotional harm to the child, the parent, or the specified relative, the following shall be considered:

(1) The present emotional state of the individual subject to emotional harm.

(2) The emotional health history of the individual subject to emotional harm.

(3) Intensity and probable duration of the emotional impairment.

(4) The degree of cooperation required.

(5) The extent of involvement of the child in the paternity establishment or support enforcement activity to be undertaken.

75.14(9) Claiming good cause. Each Medicaid applicant or member who is required to cooperate with the child support recovery unit shall have the opportunity to claim good cause for refusing to cooperate in establishing paternity or securing support payments.

a. Before requiring cooperation, the department shall notify the applicant or member using Form 470-0169 or 470-0169(S), Requirements of Support Enforcement, of the right to claim good cause as an exception to the cooperation requirement and of all the requirements applicable to a good cause determination.

b. The initial notice advising of the right to refuse to cooperate for good cause shall:

(1) Advise the applicant or member of the potential benefits the child may derive from the establishment of paternity and securing support.

(2) Advise the applicant or member that by law cooperation in establishing paternity and securing support is a condition of eligibility for the Medicaid program.

(3) Advise the applicant or member of the sanctions provided for refusal to cooperate without good cause.

(4) Advise the applicant or member that good cause for refusal to cooperate may be claimed and that if the income maintenance unit determines, in accordance with these rules, that there is good cause, the applicant or member will be excused from the cooperation requirement.

(5) Advise the applicant or member that upon request, or following a claim of good cause, the income maintenance unit will provide further notice with additional details concerning good cause.

c. When the applicant or member makes a claim of good cause or requests additional information regarding the right to file a claim of good cause, the income maintenance unit shall issue a second notice, Form 470-0170, Requirements of Claiming Good Cause. To claim good cause, the applicant or member shall sign and date Form 470-0170 and return it to the income maintenance unit. This form:

(1) Indicates that the applicant or member must provide corroborative evidence of good cause circumstance and must, when requested, furnish sufficient information to permit the county office to investigate the circumstances.

(2) Informs the applicant or member that, upon request, the income maintenance unit will provide reasonable assistance in obtaining the corroborative evidence.

(3) Informs the applicant or member that on the basis of the corroborative evidence supplied and the agency's investigation when necessary, the income maintenance unit shall determine whether cooperation would be against the best interests of the child for whom support would be sought.

(4) Lists the circumstances under which cooperation may be determined to be against the best interests of the child.

(5) Informs the applicant or member that the child support recovery unit may review the income maintenance unit's findings and basis for a good cause determination and may participate in any hearings concerning the issue of good cause.

(6) Informs the applicant or member that the child support recovery unit may attempt to establish paternity and collect support in those cases where the income maintenance unit determines that this can be done without risk to the applicant or member if done without the applicant's or member's participation.

d. The applicant or member who refuses to cooperate and who claims to have good cause for refusing to cooperate has the burden of establishing the existence of a good cause circumstance. Failure to meet these requirements shall constitute a sufficient basis for the income maintenance unit to determine that good cause does not exist. The applicant or member shall:

(1) Specify the circumstances that the applicant or member believes provide sufficient good cause for not cooperating.

(2) Corroborate the good cause circumstances.

(3) When requested, provide sufficient information to permit an investigation.

75.14(10) Determination of good cause. The income maintenance unit shall determine whether good cause exists for each Medicaid applicant or member who claims to have good cause.

a. The income maintenance unit shall notify the applicant or member of its determination that good cause does or does not exist. The determination shall:

(1) Be in writing.

(2) Contain the income maintenance unit's findings and basis for determination.

(3) Be entered in the case record.

b. The determination of whether or not good cause exists shall be made within 45 days from the day the good cause claim is made. The income maintenance unit may exceed this time standard only when:

(1) The case record documents that the income maintenance unit needs additional time because the information required to verify the claim cannot be obtained within the time standard, or

(2) The case record documents that the claimant did not provide corroborative evidence within the time period set forth in subrule 75.14(11).

c. When the income maintenance unit determines that good cause does not exist:

(1) The applicant or member shall be so notified and be afforded an opportunity to cooperate, withdraw the application for assistance, or have the case closed; and

(2) Continued refusal to cooperate will result in the loss of Medicaid for the person who refuses to cooperate.

d. The income maintenance unit shall make a good cause determination based on the corroborative evidence supplied by the applicant or member only after the income maintenance unit has examined the evidence and found that it actually verifies the good cause claim.

e. Before making a final determination of good cause for refusing to cooperate, the income maintenance unit shall:

(1) Afford the child support recovery unit the opportunity to review and comment on the findings and basis for the proposed determination, and

(2) Consider any recommendation from the child support recovery unit.

f. The child support recovery unit may participate in any appeal hearing that results from an applicant's or member's appeal of an agency action with respect to a decision on a claim of good cause.

g. Assistance shall not be denied, delayed, or discontinued pending a determination of good cause for refusal to cooperate when the applicant or member has specified the circumstances under which good cause can be claimed and provided the corroborative evidence and any additional information needed to establish good cause.

h. The income maintenance unit shall:

(1) Periodically, but not less frequently than every six months, review those cases in which the agency has determined that good cause exists based on a circumstance that is subject to change.

(2) When it determines that circumstances have changed so that good cause no longer exists, rescind its findings and proceed to enforce the requirements pertaining to cooperation in establishing paternity and securing support.

75.14(11) Proof of good cause. The applicant or member who claims good cause shall provide corroborative evidence within 20 days from the day the claim was made. In exceptional cases where the

income maintenance unit determines that the applicant or member requires additional time because of the difficulty in obtaining the corroborative evidence, the income maintenance unit shall allow a reasonable additional period upon approval by the worker's immediate supervisor.

a. A good cause claim may be corroborated with the following types of evidence:

(1) Birth certificates or medical or law enforcement records which indicate that the child was conceived as the result of incest or forcible rape.

(2) Court documents or other records which indicate that legal proceedings for adoption are pending before a court of competent jurisdiction.

(3) Court, medical, criminal, child protective services, social services, psychological, or law enforcement records which indicate that the putative father or absent parent might inflict physical or emotional harm on the child or specified relative.

(4) Medical records which indicate emotional health history and present emotional health status of the specified relative or the children for whom support would be sought; or written statements from a mental health professional indicating a diagnosis or prognosis concerning the emotional health of the specified relative or the child for whom support would be sought.

(5) A written statement from a public or licensed private social agency that the applicant or member is being assisted by the agency to resolve the issue of whether to keep the child or relinquish the child for adoption.

(6) Sworn statements from individuals other than the applicant or member with knowledge of the circumstances which provide the basis for the good cause claim.

b. When, after examining the corroborative evidence submitted by the applicant or member, the income maintenance unit wishes to request additional corroborative evidence which is needed to permit a good cause determination, the income maintenance unit shall:

(1) Promptly notify the applicant or member that additional corroborative evidence is needed, and

(2) Specify the type of document which is needed.

c. When the applicant or member requests assistance in securing evidence, the income maintenance unit shall:

(1) Advise the applicant or member how to obtain the necessary documents, and

(2) Make a reasonable effort to obtain any specific documents which the applicant or member is not reasonably able to obtain without assistance.

d. When a claim is based on the applicant's or member's anticipation of physical harm and corroborative evidence is not submitted in support of the claim:

(1) The income maintenance unit shall investigate the good cause claim when the office believes that the claim is credible without corroborative evidence and corroborative evidence is not available.

(2) Good cause shall be found when the claimant's statement and investigation which is conducted satisfies the county office that the applicant or member has good cause for refusing to cooperate.

(3) A determination that good cause exists shall be reviewed and approved or disapproved by the worker's immediate supervisor and the findings shall be recorded in the case record.

e. The income maintenance unit may further verify the good cause claim when the applicant's or member's statement of the claim together with the corroborative evidence do not provide sufficient basis for making a determination. When the income maintenance unit determines that it is necessary, the unit may conduct an investigation of good cause claims to determine that good cause does or does not exist.

f. When it conducts an investigation of a good cause claim, the income maintenance unit shall:

(1) Contact the absent parent or putative father from whom support would be sought when the contact is determined to be necessary to establish the good cause claim.

(2) Before making the necessary contact, notify the applicant or member so the applicant or member may present additional corroborative evidence or information so that contact with the parent or putative father becomes unnecessary, withdraw the application for assistance or have the case closed, or have the good cause claim denied.

75.14(12) Enforcement without specified relative's cooperation. When the income maintenance unit makes a determination that good cause exists, the unit shall also make a determination of whether or not

child support enforcement can proceed without risk of harm to the child or specified relative when the enforcement or collection activities do not involve their participation.

a. The child support recovery unit shall have an opportunity to review and comment on the findings and basis for the proposed determination and the income maintenance unit shall consider any recommendations from the child support recovery unit.

b. The determination shall be in writing, contain the income maintenance unit's findings and basis for the determination, and be entered into the case record.

c. When the income maintenance unit excuses cooperation but determines that the child support recovery unit may proceed to establish paternity or enforce support, the income maintenance unit shall notify the applicant or member to enable the individual to withdraw the application for assistance or have the case closed.

This rule is intended to implement Iowa Code sections 249A.3 and 249A.4.

441—75.15(249A) Disqualification for long-term care assistance due to substantial home equity. Notwithstanding any other provision of this chapter, if an individual's equity interest in the individual's home exceeds $500,000, the individual shall not be eligible for medical assistance with respect to nursing facility services or other long-term care services except as provided in 75.15(2). This provision is effective for all applications or requests for payment of long-term care services filed on or after January 1, 2006.

75.15(1) The limit on the equity interest in the individual's home for purposes of this rule shall be increased from year to year, beginning with 2011, based on the percentage increase in the consumer price index for all urban consumers (all items; United States city average), rounded to the nearest $1,000.

75.15(2) Disqualification based on equity interest in the individual's home shall not apply when one of the following persons is lawfully residing in the home:

a. The individual's spouse; or

b. The individual's child who is under age 21 or is blind or disabled as defined in Section 1614 of the federal Social Security Act.

This rule is intended to implement Iowa Code section 249A.4.

441—75.16(249A) Client participation in payment for medical institution care. Medicaid clients are required to participate in the cost of medical institution care. However, no client participation is charged when the combination of Medicare payments and the Medicaid benefits available to qualified Medicare beneficiaries covers the cost of institutional care.

75.16(1) *Income considered in determining client participation.* The department determines the amount of client participation based on the client's total monthly income, with the following exceptions:

a. *FMAP-related clients.* The income of a client and family whose eligibility is FMAP-related is not available for client participation when both of the following conditions exist:

(1) The client has a parent or child at home.

(2) The family's income is considered together in determining eligibility.

b. *SSI-related clients who are employed.* If a client receives SSI and is substantially gainfully employed, as determined by the Social Security Administration, the client shall have the SSI and any mandatory state supplementary assistance payment exempt from client participation for the two full months after entry to a medical institution.

c. *SSI-related clients returning home within three months.* If the Social Security Administration continues a client's SSI or federally administered state supplementary assistance payments for three months because it is expected that the client will return home within three months, these payments shall be exempt from client participation.

d. *Married couples.*

(1) Institutionalized spouse and community spouse. If there is a community spouse, only the institutionalized person's income shall be considered in determining client participation.

(2) Both spouses institutionalized. Client participation for each partner in a marriage shall be based on one-half of the couple's combined income when the partners are considered together for eligibility.

Client participation for each partner who is considered individually for eligibility shall be determined individually from each person's income.

(3) Rescinded, IAB 7/11/90, effective 7/1/90.

e. State supplementary assistance recipients. The amount of client participation that a client paid under the state supplementary assistance program is not available for Medicaid client participation in the month of the client's entry to a medical institution.

f. Foster care recipients. The amount of income paid for foster care for the days that a child is in foster care in the same month as entry to a medical institution is not available for client participation.

g. Clients receiving a VA pension. The amount of $90 of veteran's pension income shall be exempt from client participation if the client is a veteran or a surviving spouse of a veteran who:

(1) Receives a reduced pension pursuant to 38 U.S.C. Section 5503(d)(2), or

(2) Resides at the Iowa Veterans Home and does not have a spouse or minor child.

75.16(2) *Allowable deductions from income.* In determining the amount of client participation, the department allows the following deductions from the client's income, taken in the order they appear:

a. Ongoing personal needs allowance. All clients shall retain $50 of their monthly income for a personal needs allowance. (See rules 441—81.23(249A), 441—82.19(249A), and 441—85.47(249A) regarding potential state-funded personal needs supplements.)

(1) If the client has a trust described in Section 1917(d)(4) of the Social Security Act (including medical assistance income trusts and special needs trusts), a reasonable amount paid or set aside for necessary expenses of the trust is added to the personal needs allowance. This amount shall not exceed $10 per month except with court approval.

(2) If the client has earned income, an additional $65 is added to the ongoing personal needs allowance from the earned income only.

(3) Rescinded IAB 7/4/07, effective 7/1/07.

b. Personal needs in the month of entry.

(1) Single person. A single person shall be given an allowance for stated home living expenses during the month of entry, up to the amount of the SSI benefit for a single person.

(2) Spouses entering institutions together and living together. Partners in a marriage who enter a medical institution in the same month and live in the same room shall be given an allowance for stated home living expenses during the month of entry, up to the amount of the SSI benefit for a couple.

(3) Spouses entering an institution together but living apart. Partners in a marriage who enter a medical institution during the same month and who are considered separately for eligibility shall each be given an allowance for stated home living expenses during the month of entry, up to one-half of the amount of the SSI benefit for a married couple. However, if the income of one spouse is less than one-half of the SSI benefit for a couple, the remainder of the allowance shall be given to the other spouse. If the couple's eligibility is determined together, an allowance for stated home living expenses shall be given to them during the month of entry up to the SSI benefit for a married couple.

(4) Community spouse enters a medical institution. When the second member of a married couple enters a medical institution in a later month, that spouse shall be given an allowance for stated expenses during the month of entry, up to the amount of the SSI benefit for one person.

c. Personal needs in the month of discharge. The client shall be allowed a deduction for home living expenses in the month of discharge. The amount of the deduction shall be the SSI benefit for one person (or for a couple, if both members are discharged in the same month). This deduction does not apply when a spouse is at home.

d. Maintenance needs of spouse and other dependents.

(1) Persons covered. An ongoing allowance shall be given for the maintenance needs of a community spouse. The allowance is limited to the extent that income of the institutionalized spouse is made available to or for the benefit of the community spouse. If there are minor or dependent children, dependent parents, or dependent siblings of either spouse who live with the community spouse, an ongoing allowance shall also be given to meet their needs.

(2) Income considered. The verified gross income of the spouse and dependents shall be considered in determining maintenance needs. The gross income of the spouse and dependent shall

include all monthly earned and unearned income and assistance from the family investment program (FIP), supplemental security income (SSI), and state supplementary assistance (SSA). It shall also include the proceeds of any annuity or contract for sale of real property. Otherwise, the income shall be considered as the SSI program considers income. In addition, the spouse and dependents shall be required to apply for every income benefit for which they are eligible except that they shall not be required to accept SSI, FIP or SSA in lieu of the maintenance needs allowance. Failure to apply for all benefits shall mean reduction of the maintenance needs allowance by the amount of the anticipated income from the source not applied for.

(3) Needs of spouse. The maintenance needs of the spouse shall be determined by subtracting the spouse's gross income from the maximum amount allowed as a minimum monthly maintenance needs allowance for the community spouse by Section 1924(d)(3)(C) of the Social Security Act (42 U.S.C. § 1396r-5(d)(3)(C)). (This amount is indexed for inflation annually according to the consumer price index.)

However, if either spouse has established through the appeal process that the community spouse needs income above the minimum monthly maintenance needs allowance, due to exceptional circumstances resulting in significant financial duress, an amount adequate to provide additional income as is necessary shall be substituted.

Also, if a court has entered an order against an institutionalized spouse for monthly income to support the community spouse, then the community spouse income allowance shall not be less than this amount.

(4) Needs of other dependents. The maintenance needs of the other dependents shall be established by subtracting each person's gross income from 133 percent of the monthly federal poverty level for a family of two and dividing the result by three. (Effective July 1, 1992, the percent shall be 150 percent.)

e. Maintenance needs of children (without spouse). When the client has children under 21 at home, an ongoing allowance shall be given to meet the children's maintenance needs.

The income of the children is considered in determining maintenance needs. The children's countable income shall be their gross income less the disregards allowed in the FIP program.

The children's maintenance needs shall be determined by subtracting the children's countable income from the FIP payment standard for that number of children. (However, if the children receive FIP, no deduction is allowed for their maintenance needs.)

f. Client's medical expenses. A deduction shall be allowed for the client's incurred expenses for medical or remedial care that are not subject to payment by a third party and were not incurred for long-term care services during the imposition of a transfer of assets penalty period pursuant to rule 441—75.23(249A). This includes Medicare premiums and other health insurance premiums, deductibles or coinsurance, and necessary medical or remedial care recognized under state law but not covered under the state Medicaid plan.

This rule is intended to implement Iowa Code sections 249A.3 and 249A.4.

[**ARC 8444B**, IAB 1/13/10, effective 3/1/10]

441—75.17(249A) Verification of pregnancy. For the purpose of establishing Medicaid eligibility for pregnant women under this chapter, the applicant's self-declaration of the pregnancy and the date of conception shall serve as verification of pregnancy, unless questionable.

75.17(1) *Multiple pregnancy.* If the pregnant woman claims to be carrying more than one fetus, a medical professional who has examined the woman must verify the number of fetuses in order for more than one to be considered in the household size.

75.17(2) *Cost of examination.* When an examination is required and other medical resources are not available to meet the expense of the examination, the provider shall be authorized to make the examination and submit the claim for payment.

This rule is intended to implement Iowa Code section 249A.3.

441—75.18(249A) Continuous eligibility for pregnant women. A pregnant woman who applies for Medicaid prior to the end of her pregnancy and subsequently establishes initial Medicaid eligibility under

the provisions of this chapter shall remain continuously eligible throughout the pregnancy and the 60-day postpartum period, as provided in subrule 75.1(24), regardless of any changes in family income.

This rule is intended to implement Iowa Code section 249A.3.

441—75.19(249A) Continuous eligibility for children. A child under the age of 19 who is determined eligible for ongoing Medicaid shall retain that eligibility for up to 12 months regardless of changes in family circumstances except as described in this rule.

75.19(1) *Exceptions to coverage.* This rule does not apply to the following children:

a. Children whose eligibility was determined under the newborn coverage group described at subrule 75.1(20).

b. Children whose eligibility was determined under the medically needy coverage group described at subrule 75.1(35).

c. Children whose medical assistance is state-funded only.

75.19(2) *Duration of coverage.* Coverage under this rule shall extend through the earliest of the following months:

a. The month of the household's annual eligibility review;

b. The month when the child reaches the age of 19; or

c. The month when the child moves out of Iowa.

75.19(3) *Assignment of review date.* Children entering an existing Medicaid household shall be assigned the same annual eligibility review date as that established for the household.

This rule is intended to implement Iowa Code Supplement section 249A.3 as amended by 2008 Iowa Acts, House File 2539.

441—75.20(249A) Disability requirements for SSI-related Medicaid.

75.20(1) *Applicants receiving federal benefits.* An applicant receiving supplemental security income on the basis of disability, social security disability benefits under Title II of the Social Security Act, or railroad retirement benefits based on the Social Security law definition of disability by the Railroad Retirement Board, shall be deemed disabled without further determination of disability.

75.20(2) *Applicants not receiving federal benefits.* When disability has not been established based on the receipt of social security disability or railroad retirement benefits based on the same disability criteria as used by the Social Security Administration, the department shall determine eligibility for SSI-related Medicaid based on disability as follows:

a. A Social Security Administration (SSA) disability determination under either a social security disability (Title II) application or a supplemental security income application is binding on the department until changed by SSA unless the applicant meets one of the following criteria:

(1) The applicant alleges a disabling condition different from, or in addition to, that considered by SSA in making its determination.

(2) The applicant alleges more than 12 months after the most recent SSA determination denying disability that the applicant's condition has changed or deteriorated since that SSA determination and alleges a new period of disability which meets the durational requirements, and has not applied to SSA for a determination with respect to these allegations.

(3) The applicant alleges less than 12 months after the most recent SSA determination denying disability that the applicant's condition has changed or deteriorated since that SSA determination, alleges a new period of disability which meets the durational requirements, and:

1. The applicant has applied to SSA for reconsideration or reopening of its disability decision and SSA refused to consider the new allegations, or

2. The applicant no longer meets the nondisability requirements for SSI but may meet the department's nondisability requirements for Medicaid eligibility.

b. When there is no binding SSA decision and the department is required to establish eligibility for SSI-related Medicaid based on disability, initial determinations shall be made by disability determination services, a bureau of the Iowa department of education under the division of vocational rehabilitation services. The applicant or the applicant's authorized representative shall complete and submit Form

470-4459 or 470-4459(S), Authorization to Disclose Information to the Department of Human Services, and either:

(1) Form 470-2465, Disability Report for Adults, if the applicant is aged 18 or over; or

(2) Form 470-3912, Disability Report for Children, if the applicant is under the age of 18.

c. When an SSA decision on disability is pending when the person applies for Medicaid or when the person applies for either Title II benefits or SSI within ten working days of the Medicaid application, the department shall stay a decision on disability pending the SSA decision on disability.

75.20(3) *Time frames for decisions.* Determination of eligibility based on disability shall be completed within 90 days unless the applicant or an examining physician delays or fails to take a required action, or there is an administrative or other emergency beyond the department's or applicant's control.

75.20(4) *Redeterminations of disability.* In connection with any independent determination of disability, the department will determine whether reexamination of the member's medical condition will be necessary for periodic redeterminations of eligibility. When reexamination is required, the member or the member's authorized representative shall complete and submit the same forms as required in paragraph 75.20(2)*"b."*

75.20(5) *Members whose disability was determined by the department.* When a Medicaid member has been approved for Medicaid based on disability determined by the department and later is determined by SSA not to be disabled for SSI, the member shall continue to be considered disabled for Medicaid eligibility purposes for 65 days from the date of the SSA denial. If at the end of the 65 days there is no appeal to the SSA, Medicaid shall be canceled with timely notice. If there is an appeal within 65 days, the member shall continue to be considered disabled for Medicaid eligibility purposes until a final SSA decision.

This rule is intended to implement Iowa Code section 249A.4.

441—75.21(249A) Health insurance premium payment (HIPP) program. Under the health insurance premium payment program, the department shall pay for the cost of premiums, coinsurance and deductibles for Medicaid-eligible individuals when the department determines that those costs will be less than the cost of paying for the individual's care through Medicaid. Payment shall include only the cost to the Medicaid member or household.

75.21(1) *Condition of eligibility for group plans.* The Medicaid member or a person acting on the member's behalf shall cooperate in providing information necessary for the department to establish availability and the cost-effectiveness of a group health plan. When the department has determined that a group health plan is cost-effective, enrollment in the plan is a condition of Medicaid eligibility unless it can be established that insurance is being maintained on the Medicaid members through another source (e.g., an absent parent is maintaining insurance on the Medicaid-eligible children).

a. When a parent fails to provide information necessary to determine availability and cost-effectiveness of a group health plan, fails to enroll in a group health plan that has been determined cost-effective, or disenrolls from a group health plan that has been determined cost-effective, Medicaid benefits of the parent shall be terminated unless good cause for failure to cooperate is established.

b. Good cause for failure to cooperate shall be established when the parent or family demonstrates one or more of the following conditions exist:

(1) There was a serious illness or death of the parent or a member of the parent's family.

(2) There was a family emergency or household disaster, such as a fire, flood, or tornado.

(3) The parent offers a good cause beyond the parent's control.

(4) There was a failure to receive the department's request for information or notification for a reason not attributable to the parent. Lack of a forwarding address is attributable to the parent.

c. Medicaid benefits of a child shall not be terminated due to the failure of the parent to cooperate. Additionally, the Medicaid benefits of a spouse who cannot enroll in the plan independently of the other spouse shall not be terminated due to the other spouse's failure to cooperate.

d. The presence of good cause does not relieve the parent of the requirement to cooperate. When necessary, the parent may be given additional time to cooperate when good cause is determined to exist.

75.21(2) *Individual health plans.* Participation in an individual health plan is not a condition of Medicaid eligibility. The department shall pay for the cost of premiums, coinsurance, and deductibles of individual health insurance plans for a Medicaid member if:

a. A household member is currently enrolled in the plan; and

b. The health plan is cost-effective as defined in subrule 75.21(3).

75.21(3) *Cost-effectiveness.* Cost-effectiveness for both group and individual health plans shall mean the expenditures in Medicaid payments for a set of services are likely to be greater than the cost of paying the premiums and cost-sharing obligations under the health plan for those services. When determining the cost-effectiveness of the health plan, the following data shall be considered:

a. The cost to the Medicaid member or household of the insurance premium, coinsurance, and deductibles. No cost paid by an employer or other plan sponsor shall be considered in the cost-effectiveness determination.

b. The scope of services covered under the health plan, including but not limited to exclusions for preexisting conditions.

c. The average anticipated Medicaid utilization, by age, sex, institutional status, Medicare eligibility, and coverage group, for members covered under the health plan.

d. The specific health-related circumstances of the members covered under the health plan. The HIPP Medical History Questionnaire, Form 470-2868, shall be used to obtain this information. When the information indicates any health conditions that could be expected to result in higher than average bills for any Medicaid member:

(1) If the member is currently covered by the health plan, the department shall obtain from the insurance company a summary of the member's paid claims for the previous 12 months. If there is sufficient evidence to indicate that such claims can be expected to continue in the next 12 months, the claims will be considered in determining the cost-effectiveness of the plan. The cost of providing the health insurance is compared to the actual claims to determine the cost-effectiveness of providing the coverage.

(2) If the member was not covered by the health plan in the previous 12 months, paid Medicaid claims may be used to project the cost-effectiveness of the plan.

e. Annual administrative expenditures of $50 per Medicaid member covered under the health plan.

f. Whether the estimated savings to Medicaid for members covered under the health insurance plan are at least $5 per month per household.

75.21(4) *Coverage of non-Medicaid-eligible family members.*

a. When a group health plan is determined to be cost-effective, the department shall pay for health insurance premiums for non-Medicaid-eligible family members if a non-Medicaid-eligible family member must be enrolled in the health plan in order to obtain coverage for the Medicaid-eligible family members. However:

(1) The needs of the non-Medicaid-eligible family members shall not be taken into consideration when determining cost-effectiveness, and

(2) Payments for deductibles, coinsurances or other cost-sharing obligations shall not be made on behalf of family members who are not Medicaid-eligible.

b. When an individual health plan is determined cost-effective, the department shall pay for the portion of the premium necessary to cover the Medicaid-eligible family members. If the portion of the premium to cover the Medicaid-eligible family members cannot be established, the department shall pay the entire premium. The family members who are not Medicaid-eligible shall not be considered when determining cost-effectiveness.

75.21(5) *Exceptions to payment.* Premiums shall not be paid for health insurance plans under any of the following circumstances:

a. The insurance plan is that of an absent parent.

b. The insurance plan is an indemnity policy which supplements the policyholder's income or pays only a predetermined amount for services covered under the policy (e.g., $50 per day for hospital services instead of 80 percent of the charge).

c. The insurance plan is a school plan offered on basis of attendance or enrollment at the school.

d. The premium is used to meet a spenddown obligation under the medically needy program, as provided in subrule 75.1(35), when all persons in the household are eligible or potentially eligible only under the medically needy program. When some of the household members are eligible for full Medicaid benefits under coverage groups other than medically needy, the premium shall be paid if it is determined to be cost-effective when considering only the persons receiving full Medicaid coverage. In those cases, the premium shall not be allowed as a deduction to meet the spenddown obligation for those persons in the household participating in the medically needy program.

e. The insurance plan is designed to provide coverage only for a temporary period of time (e.g., 30 to 180 days).

f. The persons covered under the plan are not Medicaid-eligible on the date the decision regarding eligibility for the HIPP program is made. No retroactive payments shall be made if the case is not Medicaid-eligible on the date of decision.

g. The person is eligible only for a coverage group that does not provide full Medicaid services, such as the specified low-income Medicare beneficiary (SLMB) coverage group in accordance with subrule 75.1(34) or the IowaCare program in accordance with the provisions of 441—Chapter 92. Members under the medically needy coverage group who must meet a spenddown are not eligible for HIPP payment.

h. Insurance coverage is being provided through the Health Insurance Plan of Iowa (HIPIOWA), in accordance with Iowa Code chapter 514E.

i. Insurance is being maintained on the Medicaid-eligible persons in the household through another source (e.g., an absent parent is maintaining insurance on the Medicaid-eligible children).

j. The insurance is a Medicare supplemental policy and the Health Insurance Premium Payment Application, Form 470-2875, was received on or after March 1, 1996.

k. The person has health coverage through Medicare. If other Medicaid members in the household are covered by the health plan, cost-effectiveness is determined without including the Medicare-covered member.

l. The health plan does not provide major medical coverage but pays only for specific situations (i.e., accident plans) or illnesses (i.e., cancer policy).

m. The health plan pays secondary to another plan.

n. The only Medicaid members covered by the health plan are currently in foster care.

o. All Medicaid members covered by the health plan are eligible for Medicaid only under subrule 75.1(43). This coverage group requires the parent to apply for, enroll in, and pay for coverage available from the employer as a condition of Medicaid eligibility for the children.

75.21(6) *Duplicate policies.* When more than one cost-effective health plan is available, the department shall pay the premium for only one plan. The member may choose the cost-effective plan in which to enroll.

75.21(7) *Discontinuation of premium payments.*

a. When the household loses Medicaid eligibility, premium payments shall be discontinued as of the month of Medicaid ineligibility.

b. When only part of the household loses Medicaid eligibility, the department shall complete a review in order to ascertain whether payment of the health insurance premium continues to be cost-effective. If the department determines that the health plan is no longer cost-effective, premium payment shall be discontinued pending timely and adequate notice.

c. If the household fails to cooperate in providing information necessary to establish ongoing eligibility, the department shall discontinue premium payment after timely and adequate notice. The department shall request all information in writing and allow the household ten calendar days in which to provide it.

d. If the policyholder leaves the Medicaid household, premium payments shall be discontinued pending timely and adequate notice.

e. If the health plan is no longer available or the policy has lapsed, premium payments shall be discontinued as of the effective date of the termination of the coverage.

75.21(8) *Effective date of premium payment.* The effective date of premium payments for a cost-effective health plan shall be determined as follows:

a. Premium payments shall begin no earlier than the later of:

(1) The first day of the month in which the Employer's Statement of Earnings, Form 470-2844, the Health Insurance Premium Payment Application, Form 470-2875, or the automated HIPP referral, Form H301-1, is received by the HIPP unit; or

(2) The first day of the first month in which the health plan is determined to be cost-effective.

b. If the person is not enrolled in the health plan when eligibility for participation in the HIPP program is established, premium payments shall begin in the month in which the first premium payment is due after enrollment occurs.

c. If there was a lapse in coverage during the application process (e.g., the health plan is dropped and reenrollment occurs at a later date), premium payments shall not be made for any period of time before the current effective date of coverage.

d. In no case shall payments be made for premiums that were used as a deduction to income when determining client participation or the amount of the spenddown obligation.

e. The Employer Verification of Insurance Coverage, Form 470-3036, shall be used to verify the effective date of coverage and costs for persons enrolled in group health plans through an employer.

f. The effective date of coverage for individual health plans or for group health plans not obtained through an employer shall be verified by a copy of the certificate of coverage for the plan or by some other verification from the insurer.

75.21(9) *Method of premium payment.* Payments of premiums will be made directly to the insurance carrier except as follows:

a. The department may arrange for payment to an employer in order to circumvent a payroll deduction.

b. When an employer will not agree to accept premium payments from the department in lieu of a payroll deduction to the employee's wages, the department shall reimburse the employee directly for payroll deductions or for payments made directly to the employer for the payment of premiums. The department shall issue reimbursement to the employee five working days before the employee's pay date.

c. When premium payments are occurring through an automatic withdrawal from a bank account by the insurance carrier, the department may reimburse the policyholder for those withdrawals.

d. Payments for COBRA coverage shall be made directly to the insurance carrier or the former employer. Payments may be made directly to the former employee only in those cases where:

(1) Information cannot be obtained for direct payment, or

(2) The department pays for only part of the total premium.

e. Reimbursements may also be paid by direct deposit to the member's own account in a financial institution or by means of electronic benefits transfer.

75.21(10) *Payment of claims.* Claims from medical providers for persons participating in this program shall be paid in the same manner as claims are paid for other persons with a third-party resource in accordance with the provisions of 441—Chapters 79 and 80.

75.21(11) *Reviews of cost-effectiveness and eligibility.* Reviews of cost-effectiveness and eligibility shall be completed annually and may be conducted more frequently at the discretion of the department.

a. For a group health plan, the review of cost-effectiveness and eligibility may be completed at the time of the health plan contract renewal date. The employer shall complete Health Insurance Premium Payment (HIPP) Program Review, Form 470-3016, for the review.

b. For individual health plans, the client shall complete HIPP Individual Policy Review, Form 470-3017, for the review.

c. Failure of the household to cooperate in the review process shall result in cancellation of premium payment and may result in Medicaid ineligibility as provided in subrule 75.21(1).

d. Redeterminations shall be completed whenever:

(1) A premium rate, deductible, or coinsurance changes,

(2) A person covered under the policy loses full Medicaid eligibility,

(3) Changes in employment or hours of employment affect the availability of health insurance,

(4) The insurance carrier changes,

(5) The policyholder leaves the Medicaid home, or

(6) There is a decrease in the services covered under the policy.

e. The policyholder shall report changes that may affect the availability or cost-effectiveness of the policy within ten calendar days from the date of the change. Changes may be reported by telephone, in writing, or in person.

f. If a change in the number of members in the Medicaid household causes the health plan not to be cost-effective, lesser health plan options, as defined in paragraph 75.21(16)*"a,"* shall be considered if available and cost-effective.

g. When employment ends, hours of employment are reduced, or some other qualifying event affecting the availability of the group health plan occurs, the department shall verify whether coverage may be continued under the provisions of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985, the Family Leave Act, or other coverage continuation provisions.

(1) The Employer Verification of COBRA Eligibility, Form 470-3037, shall be used for this purpose.

(2) If cost-effective to do so, the department shall pay premiums to maintain insurance coverage for Medicaid members after the occurrence of the event which would otherwise result in termination of coverage.

75.21(12) *Time frames for determining cost-effectiveness.* The department shall determine cost-effectiveness of the health plan and notify the applicant of the decision regarding payment of the premiums within 65 calendar days from the date an application or referral (as defined in subrule 75.21(8)) is received. Additional time may be taken when, for reasons beyond the control of the department or the applicant, information needed to establish cost-effectiveness cannot be obtained within the 65-day period.

75.21(13) *Notices.*

a. An adequate notice shall be provided to the household under the following circumstances:

(1) To inform the household of the initial decision on cost-effectiveness and premium payment.

(2) To inform the household that premium payments are being discontinued because Medicaid eligibility has been lost by all persons covered under the health plan.

(3) The health plan is no longer available to the family (e.g., the employer drops insurance coverage or the policy is terminated by the insurance company).

b. The department shall provide a timely and adequate notice as defined in 441—subrule 7.7(1) to inform the household of a decision to discontinue payment of the health insurance premium because:

(1) The department has determined the health plan is no longer cost-effective, or

(2) The member has failed to cooperate in providing information necessary to establish continued eligibility for the program.

75.21(14) *Rate refund.* The department shall be entitled to any rate refund made when the health insurance carrier determines a return of premiums to the policyholder is due for any time period for which the department paid the premium.

75.21(15) *Reinstatement of eligibility.*

a. When eligibility for the HIPP program is canceled because the persons covered under the health plan lose Medicaid eligibility, HIPP eligibility shall be reinstated when Medicaid eligibility is reestablished if all other eligibility factors are met.

b. When HIPP eligibility is canceled because of the member's failure to cooperate in providing information necessary to establish continued eligibility for the HIPP program, benefits shall be reinstated the first day of the first month in which cooperation occurs, if all other eligibility factors are met.

75.21(16) *Amount of premium paid.*

a. For group health plans, the individual eligible to enroll in the plan shall provide verification of the cost of all possible health plan options (i.e., single, employee/children, family).

(1) The HIPP program shall pay only for the option that provides coverage to the Medicaid-eligible family members in the household and is determined to be cost-effective.

(2) The HIPP program shall not pay the portion of the premium cost which is the responsibility of the employer or other plan sponsor.

b. For individual health plans, the HIPP program shall pay the cost of covering the Medicaid members covered by the plan.

c. For both group and individual health plans, if another household member must be covered to obtain coverage for the Medicaid members, the HIPP program shall pay the cost of covering that household member if the coverage is cost-effective as determined pursuant to subrules 75.21(3) and 75.21(4).

75.21(17) *Reporting changes.* Failure to report and verify changes may result in cancellation of Medicaid benefits.

a. The client shall verify changes in an employer-sponsored health plan by providing a pay stub reflecting the change or a statement from the employer.

b. Changes in employment or the employment-related insurance carrier shall be verified by the employer.

c. The client shall verify changes in individual policies, such as premiums or deductibles, with a statement from the insurance carrier.

d. Any benefits paid during a period in which there was ineligibility for HIPP due to unreported changes shall be subject to recovery in accordance with the provisions of 441—Chapter 11.

e. Any underpayment that results from an unreported change shall be paid effective the first day of the month in which the change is reported.

This rule is intended to implement Iowa Code section 249A.3.

[**ARC 7935B**, IAB 7/1/09, effective 9/1/09; **ARC 8503B**, IAB 2/10/10, effective 1/13/10]

441—75.22(249A) AIDS/HIV health insurance premium payment program. For the purposes of this rule, "AIDS" and "HIV" are defined in accordance with Iowa Code section 141A.1.

75.22(1) *Conditions of eligibility.* The department shall pay for the cost of continuing health insurance coverage to persons with AIDS or HIV-related illnesses when the following criteria are met:

a. The person with AIDS or HIV-related illness shall be the policyholder, or the spouse of the policyholder, of an individual or group health plan.

b. The person shall be a resident of Iowa in accordance with the provisions of rule 441—75.10(249A).

c. The person shall not be eligible for Medicaid. The person shall be required to apply for Medicaid benefits when it appears Medicaid eligibility may exist. Persons who are required to meet a spenddown obligation under the medically needy program, as provided in subrule 75.1(35), are not considered Medicaid-eligible for the purpose of establishing eligibility under these provisions.

When Medicaid eligibility is attained, premium payments shall be made under the provisions of rule 441—75.21(249A) if all criteria of that rule are met.

d. A physician's statement shall be provided verifying the policyholder or the spouse of the policyholder suffers from AIDS or an HIV-related illness. The physician's statement shall also verify that the policyholder or the spouse of the policyholder is or will be unable to continue employment in the person's current position or that hours of employment will be significantly reduced due to AIDS or HIV-related illness. The Physician's Verification of Diagnosis, Form 470-2958, shall be used to obtain this information from the physician.

e. Gross income shall not exceed 300 percent of the federal poverty level for a family of the same size. The gross income of all family members shall be counted using the definition of gross income under the supplemental security income (SSI) program.

f. Liquid resources shall not exceed $10,000 per household. The following are examples of countable resources:

(1) Unobligated cash.

(2) Bank accounts.

(3) Stocks, bonds, certificates of deposit, excluding Internal Revenue Service defined retirement plans.

g. The health insurance plan must be cost-effective based on the amount of the premium and the services covered.

75.22(2) *Application process.*

a. *Application.* Persons applying for participation in this program shall complete the AIDS/HIV Health Insurance Premium Payment Application, Form 470-2953. The applicant shall be required to provide documentation of income and assets. The application shall be available from and may be filed at any county departmental office or at the Division of Medical Services, Department of Human Services, Hoover State Office Building, 1305 East Walnut, Des Moines, Iowa 50319-0114.

An application shall be considered as filed on the date an AIDS/HIV Health Insurance Premium Payment Application, Form 470-2953, containing the applicant's name, address and signature is received and date-stamped in any county departmental office or the division of medical services.

b. *Time limit for decision.* Every reasonable effort will be made to render a decision within 30 days. Additional time for rendering a decision may be taken when, due to circumstances beyond the control of the applicant or the department, a decision regarding the applicant's eligibility cannot be reached within 30 days (e.g., verification from a third party has not been received).

c. *Eligible on the day of decision.* No payments will be made for current or retroactive premiums if the person with AIDS or an HIV-related illness is deceased prior to a final eligibility determination being made on the application, if the insurance plan has lapsed, or if the person has otherwise lost coverage under the insurance plan.

d. *Waiting list.* After funds appropriated for this purpose are obligated, pending applications shall be denied by the division of medical services. A denial shall require a notice of decision to be mailed within ten calendar days following the determination that funds have been obligated. The notice shall state that the applicant meets eligibility requirements but no funds are available and that the applicant will be placed on the waiting list, or that the applicant does not meet eligibility requirements. Applicants not awarded funding who meet the eligibility requirements will be placed on a statewide waiting list according to the order in which the completed applications were filed. In the event that more than one application is received at one time, applicants shall be entered on the waiting list on the basis of the day of the month of the applicant's birthday, lowest number being first on the waiting list. Any subsequent tie shall be decided by the month of birth, January being month one and the lowest number.

75.22(3) *Presumed eligibility* The applicant may be presumed eligible to participate in the program for a period of two calendar months or until a decision regarding eligibility can be made, whichever is earlier. Presumed eligibility shall be granted when:

a. The application is accompanied by a completed Physician's Verification of Diagnosis, Form 470-2958.

b. The application is accompanied by a premium statement from the insurance carrier indicating the policy will lapse before an eligibility determination can be made.

c. It can be reasonably anticipated that the applicant will be determined eligible from income and resource statements on the application.

75.22(4) *Family coverage.* When the person is enrolled in a policy that provides health insurance coverage to other members of the family, only that portion of the premium required to maintain coverage for the policyholder or the policyholder's spouse with AIDS or an HIV-related illness shall be paid under this rule unless modification of the policy would result in a loss of coverage for the person with AIDS or an HIV-related illness.

75.22(5) *Method of premium payment.* Premiums shall be paid in accordance with the provisions of subrule 75.21(9).

75.22(6) *Effective date of premium payment.* Premium payments shall be effective with the month of application or the effective date of eligibility, whichever is later.

75.22(7) *Reviews.* The circumstances of persons participating in the program shall be reviewed quarterly to ensure eligibility criteria continues to be met. The AIDS/HIV Health Insurance Premium Payment Program Review, Form 470-2877, shall be completed by the recipient or someone acting on the recipient's behalf for this purpose.

75.22(8) *Termination of assistance.* Premium payments for otherwise eligible persons shall be paid under this rule until one of the following conditions is met:

a. The person becomes eligible for Medicaid. In which case, premium payments shall be paid in accordance with the provisions of rule 441—75.21(249A).

b. The insurance coverage is no longer available.

c. Maintaining the insurance plan is no longer considered the most cost-effective way to pay for medical services.

d. Funding appropriated for the program is exhausted.

e. The person with AIDS or an HIV-related illness dies.

f. The person fails to provide requested information necessary to establish continued eligibility for the program.

75.22(9) *Notices.*

a. An adequate notice as defined in 441—subrule 7.7(1) shall be provided under the following circumstances:

(1) To inform the applicant of the initial decision regarding eligibility to participate in the program.

(2) To inform the recipient that premium payments are being discontinued under these provisions because Medicaid eligibility has been attained and premium payments will be made under the provisions of rule 441—75.21(249A).

(3) To inform the recipient that premium payments are being discontinued because the policy is no longer available.

(4) To inform the recipient that premium payments are being discontinued because funding for the program is exhausted.

(5) The person with AIDS or an HIV-related illness dies.

b. A timely and adequate notice as defined in 441—subrule 7.7(1) shall be provided to the recipient informing the recipient of a decision to discontinue payment of the health insurance premium when the recipient no longer meets the eligibility requirements of the program or fails to cooperate in providing information to establish eligibility.

75.22(10) *Confidentiality.* The department shall protect the confidentiality of persons participating in the program in accordance with Iowa Code section 141A.9. When it is necessary for the department to contact a third party to obtain information in order to determine initial or ongoing eligibility, a Consent to Obtain and Release Information, Form 470-0429, shall be signed by the recipient authorizing the department to make the contact.

This rule is intended to implement Iowa Code section 249A.4.

441—75.23(249A) Disposal of assets for less than fair market value after August 10, 1993. In determining Medicaid eligibility for persons described in 441—Chapters 75 and 83, a transfer of assets occurring after August 10, 1993, will affect Medicaid payment for medical services as provided in this rule.

75.23(1) *Ineligibility for services.* When an individual or spouse has transferred or disposed of assets for less than fair market value as defined in 75.23(11) on or after the look-back date specified in 75.23(2), the individual shall be ineligible for medical assistance as provided in this subrule.

a. Institutionalized individual. When an institutionalized individual or the spouse of the individual disposed of assets for less than fair market value on or after the look-back date, the institutionalized individual is ineligible for medical assistance payment for nursing facility services, a level of care in any institution equivalent to that of nursing facility services, and home- and community-based waiver services. The period of ineligibility is equal to the number of months specified in 75.23(3). The department shall determine the beginning of the period of ineligibility as follows:

(1) Transfer before February 8, 2006. When the transfer of assets was made before February 8, 2006, the period of ineligibility shall begin on the first day of the first month during which the assets were transferred, except as provided in subparagraph (3).

(2) Transfer on or after February 8, 2006. Within the limits of subparagraph (3), when the transfer of assets was made on or after February 8, 2006, the period of ineligibility shall begin on the later of:

1. The first day of the first month during which the assets were transferred; or

2. The date on which the individual is eligible for medical assistance under this chapter and would be receiving nursing facility services, a level of care in any institution equivalent to that of nursing facility services, or home- and community-based waiver services, based on an approved application for such care, but for the application of this rule.

(3) Exclusive period. The period of ineligibility due to the transfer shall not begin during any other period of ineligibility under this rule.

b. Noninstitutionalized individual. When a noninstitutionalized individual or the spouse of the individual disposed of assets for less than fair market value on or after the look-back date, the individual is ineligible for medical assistance payment for home health care services, home and community care for functionally disabled elderly individuals, personal care services, and other long-term care services. The period of ineligibility is equal to the number of months specified in 75.23(3). The department shall determine the beginning of the period of ineligibility as follows:

(1) Transfer before February 8, 2006. When the transfer of assets was made before February 8, 2006, the period of ineligibility shall begin on the first day of the first month during which the assets were transferred, except as provided in subparagraph (3).

(2) Transfer on or after February 8, 2006. Within the limits of subparagraph (3), when the transfer of assets was made on or after February 8, 2006, the period of ineligibility shall begin on the later of:

1. The first day of the first month during which the assets were transferred; or

2. The date on which the individual is eligible for medical assistance under this chapter and would be receiving home health care services, home and community care for functionally disabled elderly individuals, personal care services, or other long-term care services, based on an approved application for such care, but for the application of this rule.

(3) Exclusive period. The period of ineligibility due to the transfer shall not begin during any other period of ineligibility under this rule.

c. Client participation after period of ineligibility. Expenses incurred for long-term care services during a transfer of assets penalty period may not be deducted as medical expenses in determining client participation pursuant to subrule 75.16(2).

75.23(2) *Look-back date.*

a. Transfer before February 8, 2006. For transfers made before February 8, 2006, the look-back date is the date that is 36 months (or, in the case of payments from a trust or portion of a trust that are treated as assets disposed of by the individual, 60 months) before:

(1) The date an institutionalized individual is both an institutionalized individual and has applied for medical assistance; or

(2) The date a noninstitutionalized individual applies for medical assistance.

b. Transfer on or after February 8, 2006. For transfers made on or after February 8, 2006, the look-back date is the date that is 60 months before:

(1) The date an institutionalized individual is both an institutionalized individual and has applied for medical assistance; or

(2) The date a noninstitutionalized individual applies for medical assistance.

75.23(3) *Period of ineligibility.* The number of months of ineligibility shall be equal to the total cumulative uncompensated value of all assets transferred by the individual (or the individual's spouse) on or after the look-back date specified in 75.23(2), divided by the statewide average private-pay rate for nursing facility services at the time of application. The department shall determine the average statewide cost to a private-pay resident for nursing facilities and update the cost annually. For the period from July 1, 2009, through June 30, 2010, this average statewide cost shall be $4,598.61 per month or $151.27 per day.

75.23(4) *Reduction of period of ineligibility.* The number of months of ineligibility otherwise determined with respect to the disposal of an asset shall be reduced by the months of ineligibility applicable to the individual prior to a change in institutional status.

75.23(5) *Exceptions.* An individual shall not be ineligible for medical assistance, under this rule, to the extent that:

a. The assets transferred were a home and title to the home was transferred to either:

(1) A spouse of the individual.

(2) A child of the individual who is under the age of 21 or is blind or permanently and totally disabled as defined in 42 U.S.C. Section 1382c.

(3) A sibling of the individual who has an equity interest in the home and who was residing in the individual's home for a period of at least one year immediately before the individual became institutionalized.

(4) A son or daughter of the individual who was residing in the individual's home for a period of at least two years immediately before the date of institutionalization and who provided care to the individual which permitted the individual to reside at home rather than in an institution or facility.

b. The assets were transferred:

(1) To the individual's spouse or to another for the sole benefit of the individual's spouse.

(2) From the individual's spouse to another for the sole benefit of the individual's spouse.

(3) To a child of the individual who is blind or permanently and totally disabled as defined in 42 U.S.C. Section 1382c or to a trust established solely for the benefit of such a child.

(4) To a trust established solely for the benefit of an individual under 65 years of age who is disabled as defined in 42 U.S.C. Section 1382c.

c. A satisfactory showing is made that:

(1) The individual intended to dispose of the assets either at fair market value, or for other valuable consideration.

(2) The assets were transferred exclusively for a purpose other than to qualify for medical assistance.

(3) All assets transferred for less than fair market value have been returned to the individual.

d. The denial of eligibility would work an undue hardship. Undue hardship shall exist only when all of the following conditions are met:

(1) Application of the transfer of asset penalty would deprive the individual of medical care such that the individual's health or life would be endangered or of food, clothing, shelter, or other necessities of life.

(2) The person who transferred the resource or the person's spouse has exhausted all means including legal remedies and consultation with an attorney to recover the resource.

(3) The person's remaining available resources (after the attribution for the community spouse) are less than the monthly statewide average cost of nursing facility services to a private pay resident, counting the value of all resources except for:

1. The home if occupied by a dependent relative or if a licensed physician verifies that the person is expected to return home.

2. Household goods.

3. A vehicle required by the client for transportation.

4. Funds for burial of $4,000 or less.

Hardship will not be found if the resource was transferred to a person who was handling the financial affairs of the client or to the spouse or children of a person handling the financial affairs of the client unless the client demonstrates that payments cannot be obtained from the funds of the person who handled the financial affairs to pay for long-term care services.

75.23(6) *Assets held in common.* In the case of an asset held by an individual in common with another person or persons in a joint tenancy, tenancy in common, or similar arrangement, the asset, or the affected portion of the asset, shall be considered to be transferred by the individual when any action is taken, either by the individual or by any other person, that reduces or eliminates the individual's ownership or control of the asset.

75.23(7) *Transfer by spouse.* In the case of a transfer by a spouse of an individual which results in a period of ineligibility for medical assistance under the state plan for the individual, the period of ineligibility shall be apportioned between the individual and the individual's spouse if the spouse otherwise becomes eligible for medical assistance under the state plan. The remaining penalty period

shall be evenly divided on a monthly basis, with any remaining month of penalty (prorated as a half month to each spouse) applied to the spouse who initiated the transfer action.

If a spouse subsequently dies prior to the end of the penalty period, the remaining penalty period shall be applied to the surviving spouse's period of ineligibility.

75.23(8) *Definitions.* In this rule the following definitions apply:

"Assets" shall include all income and resources of the individual and the individual's spouse, including any income or resources which the individual or the individual's spouse is entitled to but does not receive because of action by:

1. The individual or the individual's spouse.
2. A person, including a court or administrative body, with legal authority to act in place of or on behalf of the individual or the individual's spouse.
3. Any person, including any court or administrative body, acting at the direction or upon the request of the individual or the individual's spouse.

"Income" shall be defined by 42 U.S.C. Section 1382a.

"Institutionalized individual" shall mean an individual who is an inpatient in a nursing facility, who is an inpatient in a medical institution and with respect to whom payment is made based on a level of care provided in a nursing facility or who is eligible for home- and community-based waiver services.

"Resources" shall be defined by 42 U.S.C. Section 1382b without regard (in the case of an institutionalized individual) to the exclusion of the home and land appertaining thereto.

"Transfer or disposal of assets" means any transfer or assignment of any legal or equitable interest in any asset as defined above, including:

1. Giving away or selling an interest in an asset;
2. Placing an interest in an asset in a trust that is not available to the grantor (see 75.24(2)*"b"*(2));
3. Removing or eliminating an interest in a jointly owned asset in favor of other owners;
4. Disclaiming an inheritance of any property, interest, or right pursuant to Iowa Code section 633.704 on or after July 1, 2000 (see Iowa Code section 249A.3(11)*"c"*);
5. Failure to take a share of an estate as a surviving spouse (also known as "taking against a will") on or after July 1, 2000, to the extent that the value received by taking against the will would have exceeded the value of the inheritance received under the will (see Iowa Code section 249A.3(11)*"d"*); or
6. Transferring or disclaiming the right to income not yet received.

75.23(9) *Purchase of annuities.*

a. The entire amount used to purchase an annuity on or after February 8, 2006, shall be treated as assets transferred for less than fair market value unless the annuity meets one of the conditions described in subparagraphs (1) through (3) of this paragraph and also meets the condition described in subparagraph (4).

(1) The annuity is an annuity described in Subsection (b) or (q) of Section 408 of the United States Internal Revenue Code of 1986.

(2) The annuity is purchased with proceeds from:

1. An account or trust described in Subsection (a), (c), or (p) of Section 408 of the United States Internal Revenue Code of 1986;
2. A simplified employee pension (within the meaning of Section 408(k) of the United States Internal Revenue Code of 1986); or
3. A Roth IRA described in Section 408A of the United States Internal Revenue Code of 1986.

(3) The annuity:

1. Is irrevocable and nonassignable;
2. Is actuarially sound (as determined in accordance with actuarial publications of the Office of the Chief Actuary of the United States Social Security Administration); and
3. Provides for payments in equal amounts during the term of the annuity, with no deferral and no balloon payments made.

(4) Iowa is named as the remainder beneficiary either:

1. In the first position for at least the total amount of medical assistance paid on behalf of the annuitant; or

2. In the second position after the community spouse or minor or disabled child and in the first position if the spouse or a representative of the child disposes of any of the remainder for less than fair market value.

b. Funds used to purchase an annuity for more than its fair market value shall be treated as assets transferred for less than fair market value regardless of when the annuity was purchased or whether the conditions described in 75.23(9)*"a"* were met.

75.23(10) *Purchase of promissory notes, loans, or mortgages.*

a. Funds used to purchase a promissory note, loan, or mortgage after February 8, 2006, shall be treated as assets transferred for less than fair market value in the amount of the outstanding balance due on the note, loan, or mortgage as of the date of the individual's application for medical assistance for services described in 75.23(1), unless the note, loan, or mortgage meets all of the following conditions:

(1) The note, loan, or mortgage has a repayment term that is actuarially sound (as determined in accordance with actuarial publications of the Office of the Chief Actuary of the United States Social Security Administration).

(2) The note, loan, or mortgage provides for payments to be made in equal amounts during the term of the loan, with no deferral and no balloon payments made.

(3) The note, loan, or mortgage prohibits the cancellation of the balance upon the death of the lender.

b. Funds used to purchase a promissory note, loan, or mortgage for less than its fair market value shall be treated as assets transferred for less than fair market value regardless of whether:

(1) The note, loan, or mortgage was purchased before February 8, 2006; or

(2) The note, loan, or mortgage was purchased on or after February 8, 2006, and the conditions described in 75.23(9)*"a"* were met.

75.23(11) *Purchase of life estates.*

a. The entire amount used to purchase a life estate in another individual's home after February 8, 2006, shall be treated as assets transferred for less than fair market value, unless the purchaser resides in the home for at least one year after the date of the purchase.

b. Funds used to purchase a life estate in another individual's home for more than its fair market value shall be treated as assets transferred for less than fair market value regardless of whether:

(1) The life estate was purchased before February 8, 2006; or

(2) The life estate was purchased on or after February 8, 2006, and the purchaser resided in the home for one year after the date of purchase.

This rule is intended to implement Iowa Code sections 249A.3 and 249A.4.

[**ARC 7834B**, IAB 6/3/09, effective 7/8/09; **ARC 8444B**, IAB 1/13/10, effective 3/1/10]

441—75.24(249A) Treatment of trusts established after August 10, 1993. For purposes of determining an individual's eligibility for, or the amount of, medical assistance benefits, trusts established after August 10, 1993, (except for trusts specified in 75.24(3)) shall be treated in accordance with 75.24(2).

75.24(1) *Establishment of trust.*

a. For the purposes of this rule, an individual shall be considered to have established a trust if assets of the individual were used to form all or part of the principal of the trust and if any of the following individuals established the trust other than by will: the individual, the individual's spouse, a person (including a court or administrative body, with legal authority to act in place of or on behalf of the individual or the individual's spouse), or a person (including a court or administrative body) acting at the direction or upon the request of the individual or the individual's spouse.

b. The term "assets," with respect to an individual, includes all income and resources of the individual and of the individual's spouse, including any income or resources which the individual or the individual's spouse is entitled to but does not receive because of action by the individual or the individual's spouse, by a person (including a court or administrative body, with legal authority to act in

place of or on behalf of the individual's spouse), or by any person (including a court or administrative body) acting at the direction or upon the request of the individual or the individual's spouse.

c. In the case of a trust, the principal of which includes assets of an individual and assets of any other person or persons, the provisions of this rule shall apply to the portion of the trust attributable to the individual.

d. This rule shall apply without regard to:

(1) The purposes for which a trust is established.

(2) Whether the trustees have or exercise any discretion under the trust.

(3) Any restrictions on when or whether distribution may be made for the trust.

(4) Any restriction on the use of distributions from the trust.

e. The term "trust" includes any legal instrument or device that is similar to a trust, including a conservatorship.

75.24(2) *Treatment of revocable and irrevocable trusts.*

a. In the case of a revocable trust:

(1) The principal of the trust shall be considered an available resource.

(2) Payments from the trust to or for the benefit of the individual shall be considered income of the individual.

(3) Any other payments from the trust shall be considered assets disposed of by the individual, subject to the penalties described at rule 441—75.23(249A) and 441—Chapter 89.

b. In the case of an irrevocable trust:

(1) If there are any circumstances under which payment from the trust could be made to or for the benefit of the individual, the portion of the principal from which, or the income on the principal from which, payment to the individual could be made shall be considered an available resource to the individual and payments from that principal or income to or for the benefit of the individual shall be considered income to the individual. Payments for any other purpose shall be considered a transfer of assets by the individual subject to the penalties described at rule 441—75.23(249A) and 441—Chapter 89.

(2) Any portion of the trust from which, or any income on the principal from which, no payment could under any circumstances be made to the individual shall be considered, as of the date of establishment of the trust (or, if later, the date on which payment to the individual was foreclosed) to be assets disposed of by the individual subject to the penalties specified at 75.23(3) and 441—Chapter 89. The value of the trust shall be determined for this purpose by including the amount of any payments made from this portion of the trust after this date.

75.24(3) *Exceptions.* This rule shall not apply to any of the following trusts:

a. A trust containing the assets of an individual under the age of 65 who is disabled (as defined in Section 1614(a)(3) of the Social Security Act) and which is established for the benefit of the individual by a parent, grandparent, legal guardian of the individual, or a court if the state will receive all amounts remaining in the trust upon the death of the individual up to an amount equal to the total medical assistance paid on behalf of the individual.

b. A trust established for the benefit of an individual if the trust is composed only of pension, social security, and other income to the individual (and accumulated income of the trust), and the state will receive all amounts remaining in the trust upon the death of the individual up to the amount equal to the total medical assistance paid on behalf of the individual.

For disposition of trust amounts pursuant to Iowa Code sections 633C.1 to 633C.5, the average statewide charges and Medicaid rates for the period from July 1, 2009, to June 30, 2010, shall be as follows:

(1) The average statewide charge to a private-pay resident of a nursing facility is $4,189 per month.

(2) and (3) Rescinded IAB 7/7/04, effective 7/1/04.

(4) The maximum statewide Medicaid rate for a resident of an intermediate care facility for the mentally retarded is $20,960 per month.

(5) The average statewide charge to a resident of a mental health institute is $17,758 per month.

(6) The average statewide charge to a private-pay resident of a psychiatric medical institution for children is $5,044 per month.

(7) The average statewide charge to a home- and community-based waiver applicant or recipient shall be consistent with the level of care determination and correspond with the average charges and rates set forth in this paragraph.

c. A trust containing the assets of an individual who is disabled (as defined in 1614(a)(3) of the Social Security Act) that meets the following conditions:

(1) The trust is established and managed by a nonprofit association.

(2) A separate account is maintained for each beneficiary of the trust, but, for purposes of investment and management of funds, the trust pools these accounts.

(3) Accounts in the trust are established solely for the benefit of individuals who are disabled (as defined in 1614(a)(3) of the Social Security Act) by the parent, grandparent, or legal guardian of the individuals, by the individuals or by a court.

(4) To the extent that amounts remaining in the beneficiary's account upon death of the beneficiary are not retained by the trust, the trust pays to the state from the remaining amounts in the account an amount equal to the total amount of medical assistance paid on behalf of the beneficiary.

This rule is intended to implement Iowa Code section 249A.4.

[**ARC 7834B**, IAB 6/3/09, effective 7/8/09]

441—75.25(249A) Definitions. Unless otherwise specified, the definitions in this rule shall apply to 441—Chapters 75 through 85 and 88.

"Aged" shall mean a person 65 years of age or older.

"Applicant" shall mean a person who is requesting assistance, including recertification under the medically needy program, on the person's own behalf or on behalf of another person. This also includes parents living in the home with the children and the nonparental relative who is requesting assistance for the children.

"Blind" shall mean a person with central visual acuity of 20/200 or less in the better eye with use of corrective lens or visual field restriction to 20 degrees or less.

"Break in assistance" for medically needy shall mean the lapse of more than three months from the end of the medically needy certification period to the beginning of the next current certification period.

"Central office" shall mean the state administrative office of the department of human services.

"Certification period" for medically needy shall mean the period of time not to exceed two consecutive months in which a person is conditionally eligible.

"Client" shall mean all of the following:

1. A Medicaid applicant;
2. A Medicaid member;
3. A person who is conditionally eligible for Medicaid; and
4. A person whose income or assets are considered in determining eligibility for an applicant or member.

"CMAP-related medically needy" shall mean those individuals under the age of 21 who would be eligible for the child medical assistance program except for excess income or resources.

"Community spouse" shall mean a spouse of an institutionalized spouse for the purposes of rules 441—75.5(249A), 441—75.16(249A), and 441—76.10(249A).

"Conditionally eligible" shall mean that a person has completed the application process and has been assigned a medically needy certification period and spenddown amount but has not met the spenddown amount for the certification period or has been assigned a monthly premium but has not yet paid the premium for that month.

"Coverage group" shall mean a group of persons who meet certain common eligibility requirements.

"Department" shall mean the Iowa department of human services.

"Disabled" shall mean a person who is unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment which has lasted or is expected to last for a continuous period of not less than 12 months from the date of application.

"FMAP-related medically needy" shall mean those persons who would be eligible for the family medical assistance program except for excess income or resources.

"Health insurance" shall mean protection which provides payment of benefits for covered sickness or injury.

"Incurred medical expenses" for medically needy shall mean (1) medical bills paid by a client, responsible relative, or state or political subdivision program other than Medicaid during the retroactive certification period or certification period, or (2) unpaid medical expenses for which the client or responsible relative remains obligated.

"Institutionalized person" shall mean a person who is an inpatient in a nursing facility or a Medicare-certified skilled nursing facility, who is an inpatient in a medical institution and for whom payment is made based on a level of care provided in a nursing facility, or who is a person described in 75.1(18) for the purposes of rule 441—75.5(249A).

"Institutionalized spouse" shall mean a married person living in a medical institution, or nursing facility, or home- and community-based waiver setting who is likely to remain living in these circumstances for at least 30 consecutive days, and whose spouse is not in a medical institution or nursing facility for the purposes of rules 441—75.5(249A), 441—75.16(249A), and 441—76.10(249A).

"Local office" shall mean the county office of the department of human services or the mental health institute or hospital school.

"Medically needy income level (MNIL)" shall mean 133 1/3 percent of the schedule of basic needs based on family size. (See subrule 75.58(2).)

"Member" shall mean a person who has been determined eligible for medical assistance under rule 441—75.1(249A). For the medically needy program, "member" shall mean a medically needy person who has income at or less than the medically needy income level (MNIL) or who has reduced countable income to the MNIL during the certification period through spenddown. "Member" may be used interchangeably with "recipient." This definition does not apply to the phrase "household member."

"Necessary medical and remedial services" for medically needy shall mean medical services recognized by law which are currently covered under the Iowa Medicaid program.

"Noncovered Medicaid services" for medically needy shall mean medical services that are not covered under Medicaid because the provider was not enrolled in Medicaid, the bill is for a responsible relative who is not in the Medicaid-eligible group or the bill is for services delivered before the start of a certification period.

"Nursing facility services" shall mean the level of care provided in a medical institution licensed for nursing services or skilled nursing services for the purposes of rule 441—75.23(249A).

"Obligated medical expense" for medically needy shall mean a medical expense for which the client or responsible relative continues to be legally liable.

"Ongoing eligibility" for medically needy shall mean that eligibility continues for an SSI-related, CMAP-related, or FMAP-related medically needy person with a zero spenddown.

"Pay and chase" shall mean that the state pays the total amount allowed under the agency's payment schedule and then seeks reimbursement from the liable third party. The pay and chase provision applies to Medicaid claims for prenatal care, for preventive pediatric services, and for all services provided to a person for whom there is court-ordered medical support.

"Payee" refers to an SSI payee as defined in Iowa Code subsections 633.33(7) and 633.3(20).

"Recertification" in the medically needy coverage group shall mean establishing a new certification period when the previous period has expired and there has not been a break in assistance.

"Recipient" shall mean a person who is receiving assistance including receiving assistance for another person.

"Responsible relative" for medically needy shall mean a spouse, parent, or stepparent living in the household of the client.

"Retroactive certification period" for medically needy shall mean one, two, or three calendar months prior to the date of application. The retroactive certification period begins with the first month Medicaid-covered services were received and continues to the end of the month immediately prior to the month of application.

"Retroactive period" shall mean the three calendar months immediately preceding the month in which an application is filed.

"Spenddown" shall mean the process by which a medically needy person obligates excess income for allowable medical expenses to reduce income to the appropriate MNIL.

"SSI-related" shall mean those persons whose eligibility is derived from regulations governing the supplemental security income (SSI) program except that income shall be considered prospectively.

"SSI-related medically needy" shall mean those persons whose eligibility is derived from regulations governing the supplemental security income (SSI) program except for income or resources.

"Supply" shall mean the requested information is received by the department by the specified due date.

"Transfer of assets" shall mean transfer of resources or income for less than fair market value for the purposes of rule 441—75.23(249A). For example, a transfer of resources or income could include establishing a trust, contributing to a charity, removing a name from a resource or income, or reducing ownership interest in a resource or income.

"Unborn child" shall include an unborn child during the entire term of pregnancy.

This rule is intended to implement Iowa Code sections 249A.3 and 249A.4.

[**ARC 7935B**, IAB 7/1/09, effective 9/1/09]

441—75.26(249A) References to the family investment program. Rescinded IAB 10/8/97, effective 12/1/97.

441—75.27(249A) AIDS/HIV settlement payments. The following payments are exempt as income and resources when determining eligibility for or the amount of Medicaid benefits under any coverage group if the payments are kept in a separate, identifiable account:

75.27(1) *Class settlement payments.* Payments made from any fund established pursuant to a class settlement in the case of Susan Walker v. Bayer Corporation, et al., 96-C-5024 (N.D. Ill.) are exempt.

75.27(2) *Other settlement payments.* Payments made pursuant to a release of all claims in a case that is entered into in lieu of the class settlement referred to in subrule 75.27(1) and that is signed by all affected parties in the cases on or before the later of December 31, 1997, or the date that is 270 days after the date on which the release is first sent to the person (or the legal representative of the person) to whom payment is to be made are exempt.

This rule is intended to implement Iowa Code sections 249A.3 and 249A.4.

441—75.28 to **75.49** Reserved.

DIVISION II
ELIGIBILITY FACTORS SPECIFIC TO COVERAGE GROUPS RELATED TO
THE FAMILY MEDICAL ASSISTANCE PROGRAM (FMAP)

441—75.50(249A) Definitions. The following definitions apply to this division in addition to the definitions in rule 441—75.25(249A).

"Applicant" shall mean a person who is requesting assistance on the person's own behalf or on behalf of another person, including recertification under the medically needy program. This also includes parents living in the home with the children and the nonparental relative who is requesting assistance for the children.

"Application period" means the months beginning with the month in which the application is considered to be filed, through and including the month in which an eligibility determination is made.

"Assistance unit" includes any person whose income is considered when determining eligibility.

"Bona fide offer" means an actual or genuine offer which includes a specific wage or a training opportunity at a specified place when used to determine whether the parent has refused an offer of training or employment.

"Central office" shall mean the state administrative office of the department of human services.

"Change in income" means a permanent change in hours worked or rate of pay, any change in the amount of unearned income, or the beginning or ending of any income.

"Change in work expenses" means a permanent change in the cost of dependent care or the beginning or ending of dependent care.

"Department" shall mean the Iowa department of human services.

"Dependent" means an individual who can be claimed by another individual as a dependent for federal income tax purposes.

"Dependent child" or *"dependent children"* means a child or children who meet the nonfinancial eligibility requirements of the applicable FMAP-related coverage group.

"Income in-kind" is any gain or benefit which is not in the form of money payable directly to the eligible group including nonmonetary benefits, such as meals, clothing, and vendor payments. Vendor payments are money payments which are paid to a third party and not to the eligible group.

"Initial two months" means the first two consecutive months for which eligibility is granted.

"Medical institution," when used in this division, shall mean a facility which is organized to provide medical care, including nursing and convalescent care, in accordance with accepted standards as authorized by state law and as evidenced by the facility's license. A medical institution may be public or private. Medical institutions include the following:

1. Hospitals.
2. Extended care facilities (skilled nursing).
3. Intermediate care facilities.
4. Mental health institutions.
5. Hospital schools.

"Needy specified relative" means a nonparental specified relative, listed in 75.55(1), who meets all the eligibility requirements of the FMAP coverage group, listed in 75.1(14).

"Nonrecurring lump sum unearned income" means a payment in the nature of a windfall, for example, an inheritance, an insurance settlement for pain and suffering, an insurance death benefit, a gift, lottery winnings, or a retroactive payment of benefits such as social security, job insurance or workers' compensation.

"Parent" means a legally recognized parent, including an adoptive parent, or a biological father if there is no legally recognized father.

"Prospective budgeting" means the determination of eligibility and the amount of assistance for a calendar month based on the best estimate of income and circumstances which will exist in that calendar month.

"Recipient" means a person for whom Medicaid is received as well as parents living in the home with the eligible children and other specified relatives as defined in subrule 75.55(1) who are receiving Medicaid for the children. Unless otherwise specified, a person is not a recipient for any month in which the assistance issued for that person is subject to recoupment because the person was ineligible.

"Schedule of needs" means the total needs of a group as determined by the schedule of living costs, described at subrule 75.58(2).

"Stepparent" means a person who is not the parent of the dependent child, but is the legal spouse of the dependent child's parent by ceremonial or common-law marriage.

"Unborn child" shall include an unborn child during the entire term of the pregnancy.

"Uniformed service" means the Army, Navy, Air Force, Marine Corps, Coast Guard, National Oceanographic and Atmospheric Administration, or Public Health Service of the United States.

441—75.51(249A) Reinstatement of eligibility. Rescinded IAB 2/10/10, effective 3/1/10.

441—75.52(249A) Continuing eligibility.

75.52(1) *Reviews.* Eligibility factors shall be reviewed at least annually for the FMAP-related programs. Reviews shall be conducted using information contained in and verification supplied with the review form specified in subrule 75.52(3).

75.52(2) *Additional reviews.* A redetermination of specific eligibility factors shall be made when:

a. The member reports a change in circumstances (for example, a change in income, as defined at rule 441—75.50(249A)), or

b. A change in the member's circumstances comes to the attention of a staff member.

75.52(3) *Forms.*

a. Information for the annual review shall be submitted on Form 470-2881, 470-2881(M), 470-2881(S), or 470-2881(MS), Review/Recertification Eligibility Document (RRED), with the following exceptions:

(1) When the client has completed Form 470-0462 or 470-0466 (Spanish), Health and Financial Support Application, for another purpose, this form may be used as the review document for the annual review.

(2) Information for recertification of family medical assistance-related medically needy shall be submitted on Form 470-3118 or 470-3118(S), Medicaid Review.

b. The department shall supply the review form to the client as needed, or upon request, and shall pay the cost of postage to return the form.

(1) When the review form is issued in the department's regular end-of-month mailing, the client shall return the completed form to the department by the fifth calendar day of the following month.

(2) When the review form is not issued in the department's regular end-of-month mailing, the client shall return the completed form to the department by the seventh day after the date the form is mailed by the department.

(3) A copy of a review form received by fax or electronically shall have the same effect as an original form.

c. The review information for foster children or children in subsidized adoption or subsidized guardianship shall be submitted on Form 470-2914, Foster Care, Adoption, and Guardianship Medicaid Review.

75.52(4) *Client responsibilities.* For the purposes of this subrule, "clients" shall include persons who received assistance subject to recoupment because the persons were ineligible.

a. The client shall cooperate by giving complete and accurate information needed to establish eligibility.

b. The client shall complete the required review form when requested by the department in accordance with subrule 75.52(3). If the department does not receive a completed form, assistance shall be canceled. A completed form is one that has all items answered, is signed, is dated, and is accompanied by verification as required in paragraphs 75.57(1)*"f"* and 75.57(2)*"l."*

c. The client shall report any change in the following circumstances at the annual review or upon the addition of an individual to the eligible group:

(1) Income from all sources, including any change in care expenses.

(2) Resources.

(3) Members of the household.

(4) School attendance.

(5) A stepparent recovering from an incapacity.

(6) Change of mailing or living address.

(7) Payment of child support.

(8) Receipt of a social security number.

(9) Payment for child support, alimony, or dependents as defined in paragraph 75.57(8)*"b."*

(10) Health insurance premiums or coverage.

d. All clients shall timely report any change in the following circumstances at any time:

(1) Members of the household.

(2) Change of mailing or living address.

(3) Sources of income.

(4) Health insurance premiums or coverage.

e. Clients described at subrule 75.1(35) shall also timely report any change in income from any source and any change in care expenses at any time.

f. A report shall be considered timely when made within ten days from the date:

(1) A person enters or leaves the household.

(2) The mailing or living address changes.

(3) A source of income changes.

(4) A health insurance premium or coverage change is effective.

(5) Of any change in income.

(6) Of any change in care expenses.

g. When a change is not reported as required in paragraphs 75.52(4)*"c"* through *"e,"* any excess Medicaid paid shall be subject to recovery.

h. When a change in any circumstance is reported, its effect on eligibility shall be evaluated and eligibility shall be redetermined, if appropriate, regardless of whether the report of the change was required in paragraphs 75.52(4)*"c"* through *"e."*

75.52(5) *Effective date.* After assistance has been approved, eligibility for continuing assistance shall be effective as of the first of each month. Any change affecting eligibility reported during a month shall be effective the first day of the next calendar month, subject to timely notice requirements at rule 441—7.6(217) for any adverse actions.

a. When the change creates ineligibility, eligibility under the current coverage group shall be canceled and an automatic redetermination of eligibility shall be completed in accordance with rule 441—76.11(249A).

b. Rescinded IAB 10/4/00, effective 10/1/00.

c. When an individual included in the eligible group becomes ineligible, that individual's Medicaid shall be canceled effective the first of the next month unless the action must be delayed due to timely notice requirements at rule 441—7.6(217).

[**ARC 8260B**, IAB 11/4/09, effective 1/1/10; **ARC 8500B**, IAB 2/10/10, effective 3/1/10]

441—75.53(249A) Iowa residency policies specific to FMAP and FMAP-related coverage groups. Notwithstanding the provisions of rule 441—75.10(249A), the following rules shall apply when determining eligibility for persons under FMAP or FMAP-related coverage groups.

75.53(1) *Definition of resident.* A resident of Iowa is one:

a. Who is living in Iowa voluntarily with the intention of making that person's home there and not for a temporary purpose. A child is a resident of Iowa when living there on other than a temporary basis. Residence may not depend upon the reason for which the individual entered the state, except insofar as it may bear upon whether the individual is there voluntarily or for a temporary purpose; or

b. Who, at the time of application, is living in Iowa, is not receiving assistance from another state, and entered Iowa with a job commitment or seeking employment in Iowa, whether or not currently employed. Under this definition the child is a resident of the state in which the specified relative is a resident.

75.53(2) *Retention of residence.* Residence is retained until abandoned. Temporary absence from Iowa, with subsequent returns to Iowa, or intent to return when the purposes of the absence have been accomplished does not interrupt continuity of residence.

75.53(3) *Suitability of home.* The home shall be deemed suitable until the court has ruled it unsuitable and, as a result of such action, the child has been removed from the home.

75.53(4) *Absence from the home.*

a. An individual who is absent from the home shall not be included in the eligible group, except as described in paragraph *"b."*

(1) A parent who is a convicted offender but is permitted to live at home while serving a court-imposed sentence by performing unpaid public work or unpaid community service during the workday is considered absent from the home.

(2) A parent whose absence from the home is due solely to a pattern of employment is not considered to be absent.

(3) A parent whose absence is occasioned solely by reason of the performance of active duty in the uniformed services of the United States is considered absent from the home. "Uniformed service" means

the Army, Navy, Air Force, Marine Corps, Coast Guard, National Oceanographic and Atmospheric Administration, or Public Health Service of the United States.

b. The needs of an individual who is temporarily out of the home are included in the eligible group if otherwise eligible. A temporary absence exists in the following circumstances:

(1) An individual is anticipated to be in the medical institution for less than a year, as verified by a physician's statement. Failure to return within one year from the date of entry into the medical institution will result in the individual's needs being removed from the eligible group.

(2) An individual is out of the home to secure education or training as defined for children in paragraph 75.54(1)*"b"* as long as the child remains a dependent and as defined for adults in 441—subrule 93.114(1), first sentence.

(3) An individual is out of the home for reasons other than reasons in subparagraphs (1) and (2) and intends to return to the home within three months. Failure to return within three months from the date the individual left the home will result in the individual's needs being removed from the eligible group.

441—75.54(249A) Eligibility factors specific to child.

75.54(1) *Age.* Unless otherwise specified at rule 441—75.1(249A), Medicaid shall be available to a needy child under the age of 18 years without regard to school attendance.

a. A child is eligible for the entire month in which the child's eighteenth birthday occurs, unless the birthday falls on the first day of the month.

b. Medicaid shall also be available to a needy child aged 18 years who is a full-time student in a secondary school, or in the equivalent level of vocational or technical training, and who is reasonably expected to complete the program before reaching the age of 19 if the following criteria are met.

(1) A child shall be considered attending school full-time when enrolled or accepted in a full-time (as certified by the school or institute attended) elementary, secondary or the equivalent level of vocational or technical school or training leading to a certificate or diploma. Correspondence school is not an allowable program of study.

(2) A child shall also be considered to be in regular attendance in months when the child is not attending because of an official school or training program vacation, illness, convalescence, or family emergency. A child meets the definition of regular school attendance until the child has been officially dropped from the school rolls.

(3) When a child's education is temporarily interrupted pending adjustment of an education or training program, exemption shall be continued for a reasonable period of time to complete the adjustment.

75.54(2) *Residing with a relative.* The child shall be living in the home of one of the relatives specified in subrule 75.55(1). When the mother intends to place her child for adoption shortly after birth, the child shall be considered as living with the mother until the time custody is actually relinquished.

a. Living with relatives implies primarily the existence of a relationship involving an accepted responsibility on the part of the relative for the child's welfare, including the sharing of a common household.

b. Home is the family setting maintained or in the process of being established as evidenced by the assumption and continuation of responsibility for the child by the relative.

75.54(3) *Deprivation of parental care and support.* Rescinded IAB 11/1/00, effective 1/1/01.

75.54(4) *Continuous eligibility for children.* Rescinded IAB 11/5/08, effective 11/1/08.

441—75.55(249A) Eligibility factors specific to specified relatives.

75.55(1) *Specified relationship.*

a. A child may be considered as meeting the requirement of living with a specified relative if the child's home is with one of the following or with a spouse of the relative even though the marriage is terminated by death or divorce:

Father or adoptive father.

Mother or adoptive mother.

Grandfather or grandfather-in-law, meaning the subsequent husband of the child's natural grandmother, i.e., stepgrandfather or adoptive grandfather.

Grandmother or grandmother-in-law, meaning the subsequent wife of the child's natural grandfather, i.e., stepgrandmother or adoptive grandmother.

Great-grandfather or great-great-grandfather.

Great-grandmother or great-great-grandmother.

Stepfather, but not his parents.

Stepmother, but not her parents.

Brother, brother-of-half-blood, stepbrother, brother-in-law or adoptive brother.

Sister, sister-of-half-blood, stepsister, sister-in-law or adoptive sister.

Uncle or aunt, of whole or half blood.

Uncle-in-law or aunt-in-law.

Great uncle or great-great-uncle.

Great aunt or great-great-aunt.

First cousins, nephews, or nieces.

b. A relative of the putative father can qualify as a specified relative if the putative father has acknowledged paternity by the type of written evidence on which a prudent person would rely.

75.55(2) *Liability of relatives.* All appropriate steps shall be taken to secure support from legally liable persons on behalf of all persons in the eligible group, including the establishment of paternity as provided in rule 441—75.14(249A).

a. When necessary to establish eligibility, the department shall make the initial contact with the absent parent at the time of application. Subsequent contacts shall be made by the child support recovery unit.

b. When contact with the family or other sources of information indicates that relatives other than parents and spouses of the eligible children are contributing toward the support of members of the eligible group, have contributed in the past, or are of such financial standing they might reasonably be expected to contribute, the department shall contact these persons to verify current contributions or arrange for contributions on a voluntary basis.

441—75.56(249A) Resources.

75.56(1) *Limitation.* Unless otherwise specified, a client may have the following resources and be eligible for the family medical assistance program (FMAP) or FMAP-related programs. Any resource not specifically exempted shall be counted toward the applicable resource limit when determining eligibility for adults. All resources shall be disregarded when determining eligibility for children.

a. A homestead without regard to its value. A mobile home or similar shelter shall be considered as a homestead when it is occupied by the client. Temporary absence from the homestead with a defined purpose for the absence and with intent to return when the purpose of the absence has been accomplished shall not be considered to have altered the exempt status of the homestead. Except as described at paragraph 75.56(1)*"n"* or *"o,"* the net market value of any other real property shall be considered with personal property.

b. Household goods and personal effects without regard to their value. Personal effects are personal or intimate tangible belongings of an individual, especially those that are worn or carried on the person, which are maintained in one's home, and include clothing, books, grooming aids, jewelry, hobby equipment, and similar items.

c. Life insurance which has no cash surrender value. The owner of the life insurance policy is the individual paying the premium on the policy with the right to change the policy as the individual sees fit.

d. One motor vehicle per household. If the household includes more than one adult or working teenaged child whose resources must be considered as described in subrule 75.56(2), an equity not to exceed a value of $3,000 in one additional motor vehicle shall be disregarded for each additional adult or working teenaged child.

(1) The disregard for an additional motor vehicle shall be allowed when a working teenager is temporarily absent from work.

(2) The equity value of any additional motor vehicle in excess of $3,000 shall be counted toward the resource limit in paragraph 75.56(1)*"e."* When a motor vehicle is modified with special equipment for the handicapped, the special equipment shall not increase the value of the motor vehicle.

(3) Beginning July 1, 1994, and continuing in succeeding state fiscal years, the motor vehicle equity value to be disregarded shall be increased by the latest increase in the consumer price index for used vehicles during the previous state fiscal year.

e. A reserve of other property, real or personal, not to exceed $2,000 for applicant assistance units and $5,000 for member assistance units. EXCEPTION: Applicant assistance units that contain at least one person who was a Medicaid member in Iowa in the month before the month of application are subject to the $5,000 limit. Resources of the assistance unit shall be determined in accordance with persons considered, as described at subrule 75.56(2).

f. Money which is counted as income for the month and that part of lump-sum income defined at paragraph 75.57(9)*"c"*reserved for the current or future month's income.

g. Payments which are exempted for consideration as income and resources under subrule 75.57(6).

h. An equity not to exceed $1,500 in one funeral contract or burial trust for each member of the eligible group. Any amount in excess of $1,500 shall be counted toward resource limits unless it is established that the funeral contract or burial trust is irrevocable.

i. One burial plot for each member of the eligible group. A burial plot is defined as a conventional gravesite, crypt, mausoleum, urn, or other repository which is customarily and traditionally used for the remains of a deceased person.

j. Settlements for payment of medical expenses.

k. Life estates.

l. Federal or state earned income tax credit payments in the month of receipt and the following month, regardless of whether these payments are received with the regular paychecks or as a lump sum with the federal or state income tax refund.

m. The balance in an individual development account (IDA), including interest earned on the IDA.

n. An equity not to exceed $10,000 for tools of the trade or capital assets of self-employed households.

When the value of any resource is exempted in part, that portion of the value which exceeds the exemption shall be considered in calculating whether the eligible group's property is within the reserve defined in paragraph *"e."*

o. Nonhomestead property that produces income consistent with the property's fair market value.

75.56(2) *Persons considered.*

a. Resources of persons in the eligible group shall be considered in establishing property limits.

b. Resources of the parent who is living in the home with the eligible children but who is not eligible for Medicaid shall be considered in the same manner as if the parent were eligible for Medicaid.

c. Resources of the stepparent living in the home shall not be considered when determining eligibility of the eligible group, with one exception: The resources of a stepparent included in the eligible group shall be considered in the same manner as a parent.

d. The resources of supplemental security income (SSI) members shall not be counted in establishing property limitations. When property is owned by both the SSI beneficiary and a Medicaid member in another eligible group, each shall be considered as having a half interest in order to determine the value of the resource, unless the terms of the deed or purchase contract clearly establish ownership on a different proportional basis.

e. The resources of a nonparental specified relative who elects to be included in the eligible group shall be considered in the same manner as a parent.

75.56(3) *Homestead defined.* The homestead consists of the house, used as a home, and may contain one or more contiguous lots or tracts of land, including buildings and appurtenances. When within a city plat, it shall not exceed ½ acre in area. When outside a city plat it shall not contain, in the aggregate, more than 40 acres. When property used as a home exceeds these limitations, the equity value of the excess property shall be determined in accordance with subrule 75.56(5).

75.56(4) *Liquidation.* When proceeds from the sale of resources or conversion of a resource to cash, together with other nonexempted resources, exceed the property limitations, the member is ineligible to receive assistance until the amount in excess of the resource limitation has been expended unless immediately used to purchase a homestead, or reduce the mortgage on a homestead.

a. Property settlements. Property settlements which are part of a legal action in a dissolution of marriage or palimony suit are considered as resources upon receipt.

b. Property sold under installment contract. Property sold under an installment contract or held as security in exchange for a price consistent with its fair market value is exempt as a resource. If the price is not consistent with the contract's fair market value, the resource value of the installment contract is the gross price for which it can be sold or discounted on the open market, less any legal debts, claims, or liens against the installment contract.

Payments from property sold under an installment contract are exempt as income as specified in paragraphs 75.57(1)*"d"* and 75.57(7)*"ag."* The portion of any payment received representing principal is considered a resource upon receipt. The interest portion of the payment is considered a resource the month following the month of receipt.

75.56(5) *Net market value defined.* Net market value is the gross price for which property or an item can currently be sold on the open market, less any legal debts, claims, or liens against the property or item.

75.56(6) *Availability.*

a. A resource must be available in order for it to be counted toward resource limitations. A resource is considered available under the following circumstances:

(1) The applicant or member owns the property in part or in full and has control over it. That is, it can be occupied, rented, leased, sold, or otherwise used or disposed of at the individual's discretion.

(2) The applicant or member has a legal interest in a liquidated sum and has the legal ability to make the sum available for support and maintenance.

b. Rescinded IAB 6/30/99, effective 9/1/99.

c. When property is owned by more than one person, unless otherwise established, it is assumed that all persons hold equal shares in the property.

d. When the applicant or member owns nonhomestead property, the property shall be considered exempt for so long as the property is publicly advertised for sale at an asking price that is consistent with its fair market value.

75.56(7) *Damage judgments and insurance settlements.*

a. Payment resulting from damage to or destruction of an exempt resource shall be considered a resource to the applicant or member the month following the month the payment was received. When the applicant or member signs a legal binding commitment no later than the month after the month the payment was received, the funds shall be considered exempt for the duration of the commitment providing the terms of the commitment are met within eight months from the date of commitment.

b. Payment resulting from damage to or destruction of a nonexempt resource shall be considered a resource in the month following the month in which payment was received.

75.56(8) *Conservatorships.*

a. Conservatorships established prior to February 9, 1994. The department shall determine whether assets from a conservatorship, except one established solely for the payment of medical expenses, are available by examining the language of the order establishing the conservatorship.

(1) Funds clearly conserved and available for care, support, or maintenance shall be considered toward resource or income limitations.

(2) When the department worker questions whether the funds in a conservatorship are available, the worker shall refer the conservatorship to the central office. When assets in the conservatorship are not clearly available, central office staff may contact the conservator and request that the funds in the conservatorship be made available for current support and maintenance. When the conservator chooses not to make the funds available, the department may petition the court to have the funds released either partially or in their entirety or as periodic income payments.

(3) Funds in a conservatorship that are not clearly available shall be considered unavailable until the conservator or court actually makes the funds available.

(4) Payments received from the conservatorship for basic or special needs are considered income.

b. Conservatorships established on or after February 9, 1994. Conservatorships established on or after February 9, 1994, shall be treated according to the provisions of paragraphs 75.24(1)*"e"* and 75.24(2)*"b."*

75.56(9) *Not considered a resource.* Inventories and supplies, exclusive of capital assets, that are required for self-employment shall not be considered a resource. Inventory is defined as all unsold items, whether raised or purchased, that are held for sale or use and shall include, but not be limited to, merchandise, grain held in storage and livestock raised for sale. Supplies are items necessary for the operation of the enterprise, such as lumber, paint, and seed. Capital assets are those assets which, if sold at a later date, could be used to claim capital gains or losses for federal income tax purposes. When self-employment is temporarily interrupted due to circumstances beyond the control of the household, such as illness, inventory or supplies retained by the household shall not be considered a resource.

441—75.57(249A) Income. When determining initial and ongoing eligibility for the family medical assistance program (FMAP) and FMAP-related Medicaid coverage groups, all unearned and earned income, unless specifically exempted, disregarded, deducted for work expenses, or diverted as defined in these rules, shall be considered. Unless otherwise specified at rule 441—75.1(249A), the determination of initial eligibility is a three-step process. Initial eligibility shall be granted only when (1) the countable gross nonexempt unearned and earned income received by the eligible group and available to meet the current month's needs is no more than 185 percent of living costs as identified in the schedule of needs at subrule 75.58(2) for the eligible group (Test 1); (2) the countable net earned and unearned income is less than the schedule of living costs as identified in the schedule of needs at subrule 75.58(2) for the eligible group (Test 2); and (3) the countable net unearned and earned income, after applying allowable disregards, is less than the schedule of basic needs as identified at subrule 75.58(2) for the eligible group (Test 3). The determination of continuing eligibility is a two-step process. Continuing eligibility shall be granted only when (1) countable gross nonexempt income, as described for initial eligibility, does not exceed 185 percent of the living costs as identified in the schedule of needs at subrule 75.58(2) for the eligible group (Test 1); and (2) countable net unearned and earned income is less than the schedule of basic needs as identified in the schedule of needs at subrule 75.58(2) for the eligible group (Test 3). Child support assigned to the department in accordance with 441—subrule 41.22(7) shall be considered unearned income for the purpose of determining continuing eligibility, except as specified at paragraphs 75.57(1)*"e,"*75.57(6)*"u,"* and 75.57(7)*"o."* Expenses for care of children or disabled adults, deductions, and diversions shall be allowed when verification is provided. The department shall return all verification to the applicant or member.

75.57(1) *Unearned income.* Unearned income is any income in cash that is not gained by labor or service. When taxes are withheld from unearned income, the amount considered will be the net income after the withholding of taxes (Federal Insurance Contribution Act, state and federal income taxes). Net unearned income shall be determined by deducting reasonable income-producing costs from the gross unearned income. Money left after this deduction shall be considered gross income available to meet the needs of the eligible group.

a. Social security income is the amount of the entitlement before withholding of a Medicare premium.

b. Financial assistance received for education or training. Rescinded IAB 2/11/98, effective 2/1/98.

c. Rescinded IAB 2/11/98, effective 2/1/98.

d. When the client sells property on contract, proceeds from the sale shall be considered exempt as income. The portion of any payment that represents principal is considered a resource upon receipt as defined in subrule 75.56(4). The interest portion of the payment is considered a resource the month following the month of receipt.

e. Support payments in cash shall be considered as unearned income in determining initial and continuing eligibility.

(1) Any nonexempt cash support payment, for a member of the eligible group, made while the application is pending shall be treated as unearned income.

(2) Support payments shall be considered as unearned income in the month in which the IV-A agency (income maintenance) is notified of the payment by the IV-D agency (child support recovery unit).

The amount of income to consider shall be the actual amount paid or the monthly entitlement, whichever is less.

(3) Support payments reported by child support recovery during a past month for which eligibility is being determined shall be used to determine eligibility for the month. Support payments anticipated to be received in future months shall be used to determine eligibility for future months. When support payments terminate in the month of decision of an FMAP-related Medicaid application, both support payments already received and support payments anticipated to be received in the month of decision shall be used to determine eligibility for that month.

(4) When the reported support payment, combined with other income, creates ineligibility under the current coverage group, an automatic redetermination of eligibility shall be conducted in accordance with the provisions of rule 441—76.11(249A). Persons receiving Medicaid under the family medical assistance program in accordance with subrule 75.1(14) may be entitled to continued coverage under the provisions of subrule 75.1(21). Eligibility may be reestablished for any month in which the countable support payment combined with other income meets the eligibility test.

f. The client shall cooperate in supplying verification of all unearned income and of any change in income, as defined at rule 441—75.50(249A).

(1) When the information is available, the department shall verify job insurance benefits by using information supplied to the department by Iowa workforce development. When the department uses this information as verification, job insurance benefits shall be considered received the second day after the date that the check was mailed by Iowa workforce development. When the second day falls on a Sunday or federal legal holiday, the time shall be extended to the next mail delivery day.

(2) When the client notifies the department that the amount of job insurance benefits used is incorrect, the client shall be allowed to verify the discrepancy. The client must report the discrepancy before the eligibility month or within ten days of the date on the Notice of Decision, Form 470-0485, 470-0485(S), 470-0486, or 470-0486(S), applicable to the eligibility month, whichever is later.

75.57(2) *Earned income.* Earned income is defined as income in the form of a salary, wages, tips, bonuses, commission earned as an employee, income from Job Corps, or profit from self-employment. Earned income from commissions, wages, tips, bonuses, Job Corps, or salary means the total gross amount irrespective of the expenses of employment. With respect to self-employment, earned income means the net profit from self-employment, defined as gross income less the allowable costs of producing the income. Income shall be considered earned income when it is produced as a result of the performance of services by an individual.

a. Each person in the assistance unit whose gross nonexempt earned income, earned as an employee or net profit from self-employment, considered in determining eligibility is entitled to one 20 percent earned income deduction of nonexempt monthly gross earnings. The deduction is intended to include work-related expenses other than child care. These expenses shall include, but are not limited to, all of the following: taxes, transportation, meals, uniforms, and other work-related expenses.

b. Each person in the assistance unit is entitled to a deduction for care expenses subject to the following limitations.

(1) Persons in the eligible group and excluded parents shall be allowed care expenses for a child or incapacitated adult in the eligible group.

(2) Stepparents as described at paragraph 75.57(8)*"b"* and self-supporting parents on underage parent cases as described at paragraph 75.57(8)*"c"* shall be allowed incapacitated adult care or child care expenses for the ineligible dependents of the stepparent or self-supporting parent.

(3) Unless both parents are in the home and one parent is physically and mentally able to provide the care, child care or care for an incapacitated adult shall be considered a work expense in the amount paid for care of each child or incapacitated adult, not to exceed $175 per month, or $200 per month for a child under the age of two, or the going rate in the community, whichever is less.

(4) If both parents are in the home, adult or child care expenses shall not be allowed when one parent is unemployed and is physically and mentally able to provide the care.

(5) The deduction is allowable only when the care covers the actual hours of the individual's employment plus a reasonable period of time for commuting; or the period of time when the individual who would normally care for the child or incapacitated adult is employed at such hours that the individual is required to sleep during the waking hours of the child or incapacitated adult, excluding any hours a child is in school.

(6) Any special needs of a physically or mentally handicapped child or adult shall be taken into consideration in determining the deduction allowed.

(7) If the amount claimed is questionable, the expense shall be verified by a receipt or a statement from the provider of care. The expense shall be allowed when paid to any person except a parent or legal guardian of the child, another member of the eligible group, or any person whose needs are met by diversion of income from any person in the eligible group.

c. Work incentive disregard. After deducting the allowable work-related expenses as defined at paragraphs 75.57(2)*"a"* and *"b"* and income diversions as defined at subrule 75.57(4), 58 percent of the total of the remaining monthly nonexempt earned income, earned as an employee or the net profit from self-employment, of each person whose income must be considered is disregarded in determining eligibility for the family medical assistance program (FMAP) and those FMAP-related coverage groups subject to the three-step process for determining initial eligibility as described at rule 441—75.57(249A).

(1) The work incentive disregard is not time-limited.

(2) Initial eligibility under the first two steps of the three-step process is determined without the application of the work incentive disregard as described at subparagraphs 75.57(9)*"a"*(2) and (3).

(3) A person who is not eligible for Medicaid because the person has refused to cooperate in applying for or accepting benefits from other sources, in accordance with the provisions of rule 441—75.2(249A), 441—75.3(249A), or 441—75.21(249A), is eligible for the work incentive disregard.

d. Rescinded IAB 6/30/99, effective 9/1/99.

e. A person is considered self-employed when the person:

(1) Is not required to report to the office regularly except for specific purposes such as sales training meetings, administrative meetings, or evaluation sessions.

(2) Establishes the person's own working hours, territory, and methods of work.

(3) Files quarterly reports of earnings, withholding payments, and FICA payments to the Internal Revenue Service.

f. The net profit from self-employment income in a non-home-based operation shall be determined by deducting only the following expenses that are directly related to the production of the income:

(1) The cost of inventories and supplies purchased that are required for the business, such as items for sale or consumption and raw materials.

(2) Wages, commissions, and mandated costs relating to the wages for employees of the self-employed.

(3) The cost of shelter in the form of rent, the interest on mortgage or contract payments; taxes; and utilities.

(4) The cost of machinery and equipment in the form of rent or the interest on mortgage or contract payments.

(5) Insurance on the real or personal property involved.

(6) The cost of any repairs needed.

(7) The cost of any travel required.

(8) Any other expense directly related to the production of income, except the purchase of capital equipment and payment on the principal of loans for capital assets and durable goods or any cost of depreciation.

g. When the client is renting out apartments in the client's home, the following shall be deducted from the gross rentals received to determine the profit:

(1) Shelter expense in excess of that set forth on the chart of basic needs components at subrule 75.58(2) for the eligible group.

(2) That portion of expense for utilities furnished to tenants which exceeds the amount set forth on the chart of basic needs components at subrule 75.58(2).

(3) Ten percent of gross rentals to cover the cost of upkeep.

h. In determining profit from furnishing board, room, operating a family life home, or providing nursing care, the following amounts shall be deducted from the payments received:

(1) $41 plus an amount equivalent to the monthly maximum food assistance program benefit for a one-member household for a boarder and roomer or an individual in the home to receive nursing care, or $41 for a roomer, or an amount equivalent to the monthly maximum food assistance program benefit for a one-member household for a boarder.

(2) Ten percent of the total payment to cover the cost of upkeep for individuals receiving a room or nursing care.

i. Gross income from providing child care in the applicant's or member's own home shall include the total payments received for the service and any payment received due to the Child Nutrition Amendments of 1978 for the cost of providing meals to children.

(1) In determining profit from providing child care services in the applicant's or member's own home, 40 percent of the total gross income received shall be deducted to cover the costs of producing the income, unless the applicant or member requests to have actual expenses in excess of the 40 percent considered.

(2) When the applicant or member requests to have expenses in excess of the 40 percent considered, profit shall be determined in the same manner as specified at paragraph 75.57(2)*"j."*

j. In determining profit for a self-employed enterprise in the home other than providing room and board, renting apartments or providing child care services, the following expenses shall be deducted from the income received:

(1) The cost of inventories and supplies purchased that are required for the business, such as items for sale or consumption and raw materials.

(2) Wages, commissions, and mandated costs relating to the wages for employees.

(3) The cost of machinery and equipment in the form of rent; or the interest on mortgage or contract payment; and any insurance on such machinery equipment.

(4) Ten percent of the total gross income to cover the costs of upkeep when the work is performed in the home.

(5) Any other direct cost involved in the production of the income, except the purchase of capital equipment and payment on the principal of loans for capital equipment and payment on the principal of loans for capital assets and durable goods or any cost of depreciation.

k. Rescinded IAB 6/30/99, effective 9/1/99.

l. The applicant or member shall cooperate in supplying verification of all earned income and of any change in income, as defined at rule 441—75.50(249A). A self-employed applicant or member shall keep any records necessary to establish eligibility.

75.57(3) *Shared living arrangements.* When an applicant or member shares living arrangements with another family or person, funds combined to meet mutual obligations for shelter and other basic needs are not income. Funds made available to the applicant or member, exclusively for the applicant's or member's needs, are considered income.

75.57(4) *Diversion of income.*

a. Nonexempt earned and unearned income of the parent shall be diverted to meet the unmet needs of the ineligible children of the parent living in the family group who meet the age and school attendance requirements specified in subrule 75.54(1). Income of the parent shall be diverted to meet the unmet needs of the ineligible children of the parent and a companion in the home only when the income and resources of the companion and the children are within family medical assistance program standards. The maximum income that shall be diverted to meet the needs of the ineligible children shall be the

difference between the needs of the eligible group if the ineligible children were included and the needs of the eligible group with the ineligible children excluded, except as specified at paragraph 75.57(8)*"b."*

b. Nonexempt earned and unearned income of the parent shall be diverted to permit payment of court-ordered support to children not living with the parent when the payment is actually being made.

75.57(5) *Income of unmarried specified relatives under the age of 19.*

a. Income of the unmarried specified relative under the age of 19 when that specified relative lives with a parent who receives coverage under family medical assistance-related programs or lives with a nonparental relative or in an independent living arrangement.

(1) The income of the unmarried, underage specified relative who is also an eligible child in the eligible group of the specified relative's parent shall be treated in the same manner as that of any other child. The income for the unmarried, underage specified relative who is not an eligible child in the eligible group of the specified relative's parent shall be treated in the same manner as though the specified relative had attained majority.

(2) The income of the unmarried, underage specified relative living with a nonparental relative or in an independent living arrangement shall be treated in the same manner as though the specified relative had attained majority.

b. Income of the unmarried specified relative under the age of 19 who lives in the same home as a self-supporting parent. The income of the unmarried specified relative under the age of 19 living in the same home as a self-supporting parent shall be treated in accordance with subparagraphs (1), (2), and (3) below.

(1) When the unmarried specified relative is under the age of 18 and not a parent of the dependent child, the income of the specified relative shall be exempt.

(2) When the unmarried specified relative is under the age of 18 and a parent of the dependent child, the income of the specified relative shall be treated in the same manner as though the specified relative had attained majority. The income of the specified relative's self-supporting parents shall be treated in accordance with paragraph 75.57(8)*"c."*

(3) When the unmarried specified relative is 18 years of age, the specified relative's income shall be treated in the same manner as though the specified relative had attained majority.

75.57(6) *Exempt as income and resources.* The following shall be exempt as income and resources:

a. Food reserves from home-produced garden products, orchards, domestic animals, and the like, when used by the household for its own consumption.

b. The value of the food assistance program benefit.

c. The value of the United States Department of Agriculture donated foods (surplus commodities).

d. The value of supplemental food assistance received under the Child Nutrition Act and the special food service program for children under the National School Lunch Act.

e. Any benefits received under Title III-C, Nutrition Program for the Elderly, of the Older Americans Act.

f. Benefits paid to eligible households under the Low Income Home Energy Assistance Act of 1981.

g. Any payment received under Title II of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 and the Federal-Aid Highway Act of 1968.

h. Any judgment funds that have been or will be distributed per capita or held in trust for members of any Indian tribe. When the payment, in all or part, is converted to another type of resource, that resource is also exempt.

i. Payments to volunteers participating in the Volunteers in Service to America (VISTA) program, except that this exemption will not be applied when the director of ACTION determines that the value of all VISTA payments, adjusted to reflect the number of hours the volunteers are serving, is equivalent to or greater than the minimum wage then in effect under the Fair Labor Standards Act of 1938, or the minimum wage under the laws of the state where the volunteers are serving, whichever is greater.

j. Payments for supporting services or reimbursement of out-of-pocket expenses received by volunteers in any of the programs established under Titles II and III of the Domestic Volunteer Services Act.

k. Tax-exempt portions of payments made pursuant to the Alaskan Native Claims Settlement Act.

l. Experimental housing allowance program payments made under annual contribution contracts entered into prior to January 1, 1975, under Section 23 of the U.S. Housing Act of 1936 as amended.

m. The income of a supplemental security income recipient.

n. Income of an ineligible child.

o. Income in-kind.

p. Family support subsidy program payments.

q. Grants obtained and used under conditions that preclude their use for current living costs.

r. All earned and unearned educational funds of an undergraduate or graduate student or a person in training. Any extended social security or veterans benefits received by a parent or nonparental relative as defined at subrule 75.55(1), conditional to school attendance, shall be exempt. However, any additional amount received for the person's dependents who are in the eligible group shall be counted as nonexempt income.

s. Subsidized guardianship program payments.

t. Any income restricted by law or regulation which is paid to a representative payee living outside the home, unless the income is actually made available to the applicant or member by the representative payee.

u. The first $50 received by the eligible group which represents a current monthly support obligation or a voluntary support payment, paid by a legally responsible individual, but in no case shall the total amount exempted exceed $50 per month per eligible group.

v. Bona fide loans. Evidence of a bona fide loan may include any of the following:

(1) The loan is obtained from an institution or person engaged in the business of making loans.

(2) There is a written agreement to repay the money within a specified time.

(3) If the loan is obtained from a person not normally engaged in the business of making a loan, there is borrower's acknowledgment of obligation to repay (with or without interest), or the borrower expresses intent to repay the loan when funds become available in the future, or there is a timetable and plan for repayment.

w. Payments made from the Agent Orange Settlement Fund or any other fund established pursuant to the settlement in the In re Agent Orange product liability litigation, M.D.L. No. 381 (E.D.N.Y.).

x. The income of a person ineligible due to receipt of state-funded foster care, IV-E foster care, or subsidized adoption assistance.

y. Payments for major disaster and emergency assistance provided under the Disaster Relief Act of 1974 as amended by Public Law 100-707, the Disaster Relief and Emergency Assistance Amendments of 1988.

z. Payments made to certain United States citizens of Japanese ancestry and resident Japanese aliens under Section 105 of Public Law 100-383, and payments made to certain eligible Aleuts under Section 206 of Public Law 100-383, entitled "Wartime Relocation of Civilians."

aa. Payments received from the Radiation Exposure Compensation Act.

ab. Deposits into an individual development account (IDA) when determining eligibility. The amount of the deposit is exempt as income and shall not be used in the 185 percent eligibility test. Deposits shall be deducted from nonexempt earned and unearned income beginning with the month following the month in which verification that deposits have begun is received. The client shall be allowed a deduction only when the deposit is made from the client's money. The earned income deductions at paragraphs 75.57(2)*"a," "b,"* and *"c"* shall be applied to nonexempt earnings from employment or net profit from self-employment that remains after deducting the amount deposited into the account. Allowable deductions shall be applied to any nonexempt unearned income that remains after deducting the amount of the deposit. If the client has both nonexempt earned and unearned income, the amount deposited into the IDA account shall first be deducted from the client's nonexempt unearned income. Deposits shall not be deducted from earned or unearned income that is exempt.

75.57(7) *Exempt as income.* The following are exempt as income.

a. Reimbursements from a third party.

b. Reimbursement from the employer for a job-related expense.

c. The following nonrecurring lump sum payments:

(1) Income tax refund.

(2) Retroactive supplemental security income benefits.

(3) Settlements for the payment of medical expenses.

(4) Refunds of security deposits on rental property or utilities.

(5) That part of a lump sum received and expended for funeral and burial expenses.

(6) That part of a lump sum both received and expended for the repair or replacement of resources.

d. Payments received by the family for providing foster care when the family is operating a licensed foster home.

e. A small monetary nonrecurring gift, such as a Christmas, birthday or graduation gift, not to exceed $30 per person per calendar quarter.

When a monetary gift from any one source is in excess of $30, the total gift is countable as unearned income. When monetary gifts from several sources are each $30 or less, and the total of all gifts exceeds $30, only the amount in excess of $30 is countable as unearned income.

f. Federal or state earned income tax credit.

g. Supplementation from county funds, providing:

(1) The assistance does not duplicate any of the basic needs as recognized by the chart of basic needs components in accordance with subrule 75.58(2), or

(2) The assistance, if a duplication of any of the basic needs, is made on an emergency basis, not as ongoing supplementation.

h. Any payment received as a result of an urban renewal or low-cost housing project from any governmental agency.

i. A retroactive corrective family investment program (FIP) payment.

j. The training allowance issued by the division of vocational rehabilitation, department of education.

k. Payments from the PROMISE JOBS program.

l. The training allowance issued by the department for the blind.

m. Payments from passengers in a car pool.

n. Support refunded by the child support recovery unit for the first month of termination of eligibility and the family does not receive the family investment program.

o. Rescinded IAB 10/4/00, effective 10/1/00.

p. Rescinded IAB 10/4/00, effective 10/1/00.

q. Income of a nonparental relative as defined at subrule 75.55(1) except when the relative is included in the eligible group.

r. Rescinded IAB 10/4/00, effective 10/1/00.

s. Compensation in lieu of wages received by a child funded through an employment and training program of the U.S. Department of Labor.

t. Any amount for training expenses included in a payment funded through an employment and training program of the U.S. Department of Labor.

u. Earnings of a person aged 19 or younger who is a full-time student as defined at subparagraphs 75.54(1)*"b"*(1) and (2). The exemption applies through the entire month of the person's twentieth birthday.

EXCEPTION: When the twentieth birthday falls on the first day of the month, the exemption stops on the first day of that month.

v. Income attributed to an unmarried, underage parent in accordance with paragraph 75.57(8)*"c"* effective the first day of the month following the month in which the unmarried, underage parent turns age 18 or reaches majority through marriage. When the unmarried, underage parent turns 18 on the first day of a month, the income of the self-supporting parents becomes exempt as of the first day of that month.

w. Incentive payments received from participation in the adolescent pregnancy prevention programs.

x. Payments received from the comprehensive child development program, funded by the Administration for Children, Youth, and Families, provided the payments are considered complimentary assistance by federal regulation.

y. Incentive allowance payments received from the work force investment project, provided the payments are considered complimentary assistance by federal regulation.

z. Interest and dividend income.

aa. Rescinded IAB 10/4/00, effective 10/1/00.

ab. Honorarium income. All moneys paid to an eligible household in connection with the welfare reform demonstration longitudinal study or focus groups shall be exempted.

ac. Income that an individual contributes to a trust as specified at paragraph 75.24(3)*"b"* shall not be considered for purposes of determining eligibility for the family medical assistance program (FMAP) or FMAP-related Medicaid coverage groups.

ad. Benefits paid to the eligible household under the family investment program (FIP).

ae. Moneys received through the pilot self-sufficiency grants program or through the pilot diversion program.

af. Earnings from new employment of any person whose income is considered when determining eligibility during the first four calendar months of the new employment. The date the new employment or self-employment begins shall be verified before approval of the exemption. This four-month period shall be referred to as the work transition period (WTP).

(1) The exempt period starts the first day of the month in which the client receives the first pay from the new employment and continues through the next three benefit months, regardless if the job ends during the four-month period.

(2) To qualify for this disregard, the person shall not have earned more than $1,200 in the 12 calendar months prior to the month in which the new job begins, the income must be reported timely in accordance with rule 441—76.10(249A), and the new job must have started after the date the application is filed. For purposes of this policy, the $1,200 earnings limit applies to the gross amount of income without any allowance for exemptions, disregards, work deductions, diversions, or the costs of doing business used in determining net profit from any income test in rule 441—75.57(249A).

(3) If another new job or self-employment enterprise starts while a WTP is in progress, the exemption shall also be applied to earnings from the new source that are received during the original 4-month period, provided that the earnings were less than $1,200 in the 12-month period before the month the other new job or self-employment enterprise begins.

(4) An individual is allowed the 4-month exemption period only once in a 12-month period. An additional 4-month exemption shall not be granted until the month after the previous 12-month period has expired.

(5) If a person whose income is considered enters the household, the new job must start after the date the person enters the home or after the person is reported in the home, whichever is later, in order for that person to qualify for the exemption.

(6) When a person living in the home whose income is not considered subsequently becomes an assistance unit member whose income is considered, the new job must start after the date of the change that causes the person's income to be considered in order for that person to qualify for the exemption.

(7) A person who begins new employment or self-employment that is intermittent in nature may qualify for the WTP. "Intermittent" includes, but is not limited to, working for a temporary agency that places the person in different job assignments on an as-needed or on-call basis, or self-employment from providing child care for one or more families. However, a person is not considered as starting new employment or self-employment each time intermittent employment restarts or changes such as when the same temporary agency places the person in a new assignment or a child care provider acquires another child care client.

ag. Payments from property sold under an installment contract as specified in paragraphs 75.56(4)*"b"* and 75.57(1)*"d."*

ah. All census earnings received by temporary workers from the Bureau of the Census.

ai. Payments received through participation in the preparation for adult living program pursuant to 441—Chapter 187.

75.57(8) *Treatment of income in excluded parent cases, stepparent cases, and underage parent cases.*

a. Treatment of income in excluded parent cases. A parent who is living in the home with the eligible children but who is not eligible for Medicaid is eligible for the 20 percent earned income deduction, child care expenses for children in the eligible group, the 58 percent work incentive disregard described at paragraphs 75.57(2)*"a," "b,"* and *"c,"* and diversions described at subrule 75.57(4). All remaining nonexempt income of the parent shall be applied against the needs of the eligible group.

b. Treatment of income in stepparent cases. The income of a stepparent who is not included in the eligible group but who is living with the parent in the home of an eligible child shall be given the same consideration and treatment as that of a parent subject to the limitations of subparagraphs (1) through (10) below.

(1) The stepparent's monthly gross nonexempt earned income, earned as an employee or monthly net profit from self-employment, shall receive a 20 percent earned income deduction.

(2) The stepparent's monthly nonexempt earned income remaining after the 20 percent earned income deduction shall be allowed child care expenses for the stepparent's ineligible dependents in the home, subject to the restrictions described at subparagraphs 75.57(2)*"b"*(1) through (5).

(3) Any amounts actually paid by the stepparent to individuals not living in the home, who are claimed or could be claimed by the stepparent as dependents for federal income tax purposes, shall be deducted from nonexempt monthly earned and unearned income of the stepparent.

(4) The stepparent shall also be allowed a deduction from nonexempt monthly earned and unearned income for alimony and child support payments made to individuals not living in the home with the stepparent.

(5) Except as described at subrule 75.57(10), the nonexempt monthly earned and unearned income of the stepparent remaining after application of the deductions at subparagraphs 75.57(8)*"b"*(1) through (4) above shall be used to meet the needs of the stepparent and the stepparent's dependents living in the home, when the dependents' needs are not included in the eligible group and the stepparent claims or could claim the dependents for federal income tax purposes. These needs shall be determined in accordance with the schedule of needs for a family group of the same composition in accordance with subrule 75.58(2).

(6) The stepparent shall be allowed the 58 percent work incentive disregard from monthly earnings. The disregard shall be applied to earnings that remain after all other deductions at subparagraphs 75.57(8)*"b"*(1) through (5) have been subtracted from the earnings. However, the work incentive disregard is not allowed when determining initial eligibility as described at subparagraphs 75.57(9)*"a"*(2) and (3).

(7) The deductions described in subparagraphs (1) through (6) shall first be subtracted from earned income in the same order as they appear above.

When the stepparent has both nonexempt earned and unearned income and earnings are less than the allowable deductions, then any remaining portion of the deductions in subparagraphs (3) through (5) shall be subtracted from unearned income. Any remaining income shall be applied as unearned income to the needs of the eligible group.

If the stepparent has earned income remaining after allowable deductions, then any nonexempt unearned income shall be added to the earnings and the resulting total counted as unearned income to the needs of the eligible group.

(8) A nonexempt, nonrecurring lump sum received by a stepparent shall be considered as income and counted in computing eligibility in the same manner as it would be treated for a parent. Any portion of the nonrecurring lump sum retained by the stepparent in the month following the month of receipt shall be considered a resource to the stepparent if that portion is not exempted according to paragraph 75.56(1)*"f."*

(9) When the income of the stepparent, not in the eligible group, is insufficient to meet the needs of the stepparent and the stepparent's dependents living in the home who are not eligible for FMAP-related

Medicaid, the income of the parent may be diverted to meet the unmet needs of the children of the current marriage except as described at subrule 75.57(10).

(10) When the needs of the stepparent, living in the home, are not included in the eligible group, the eligible group and any children of the parent living in the home who are not eligible for FMAP-related Medicaid shall be considered as one unit, and the stepparent and the stepparent's dependents, other than the spouse, shall be considered a separate unit.

(11) Rescinded IAB 6/30/99, effective 9/1/99.

c. Treatment of income in underage parent cases. In the case of a dependent child whose unmarried parent is under the age of 18 and living in the same home as the unmarried, underage parent's own self-supporting parents, the income of each self-supporting parent shall be considered available to the eligible group after appropriate deductions unless the provisions of rule 441—75.59(249A) apply. The deductions to be applied are the same as are applied to the income of a stepparent pursuant to subparagraphs 75.57(8)*"b"*(1) through (7). Child care expenses at subparagraph 75.57(8)*"b"*(2) shall be allowed for the self-supporting parent's ineligible children. Nonrecurring lump sum income received by the self-supporting parent(s) shall be treated in accordance with subparagraph 75.57(8)*"b"*(8).

When the self-supporting spouse of a self-supporting parent is also living in the home, the income of that spouse shall be attributable to the self-supporting parent in the same manner as the income of a stepparent is determined pursuant to subparagraphs 75.57(8)*"b"*(1) through (7) unless the provisions of rule 441—75.59(249A) apply. Child care expenses at subparagraph 75.57(8)*"b"*(2) shall be allowed for the ineligible dependents of the self-supporting spouse who is a stepparent of the minor parent. Nonrecurring lump sum income received by the spouse of the self-supporting parent shall be treated in accordance with subparagraph 75.57(8)*"b"*(8). The self-supporting parent and any ineligible dependents of that person shall be considered as one unit. The self-supporting spouse and the spouse's ineligible dependents, other than the self-supporting parent, shall be considered a separate unit.

75.57(9) *Budgeting process.*

a. Initial and ongoing eligibility. Both initial and ongoing eligibility shall be based on a projection of income based on the best estimate of future income.

(1) Upon application, the department shall use all earned and unearned income received by the eligible group to project future income. Allowable work expenses shall be deducted from earned income, except in determining eligibility under the 185 percent test defined at rule 441—75.57(249A). The determination of initial eligibility is a three-step process as described at rule 441—75.57(249A).

(2) Test 1. When countable gross nonexempt earned and unearned income exceeds 185 percent of the schedule of living costs (Test 1), as identified at subrule 75.58(2) for the eligible group, eligibility does not exist under any coverage group for which these income tests apply. Countable gross income means nonexempt gross income, as defined at rule 441—75.57(249A), without application of any disregards, deductions, or diversions.

(3) Test 2. When the countable gross nonexempt earned and unearned income equals or is less than 185 percent of the schedule of living costs for the eligible group, initial eligibility under the schedule of living costs (Test 2) shall then be determined. Initial eligibility under the schedule of living costs is determined without application of the 58 percent work incentive disregard as specified at paragraph 75.57(2)*"c."* All other appropriate exemptions, deductions and diversions are applied. Countable income is then compared to the schedule of living costs (Test 2) for the eligible group. When countable net earned and unearned income equals or exceeds the schedule of living costs for the eligible group, eligibility does not exist under any coverage group for which these income tests apply.

(4) Test 3. After application of Tests 1 and 2 for initial eligibility or of Test 1 for ongoing eligibility, the 58 percent work incentive disregard at paragraph 75.57(2)*"c"* shall be applied when there is eligibility for this disregard. When countable net earned and unearned income, after application of the work incentive disregard and all other appropriate exemptions, deductions, and diversions, equals or exceeds the schedule of basic needs (Test 3) for the eligible group, eligibility does not exist under any coverage group for which these tests apply. When the countable net income is less than the schedule of basic needs for the eligible group, the eligible group meets FMAP or CMAP income requirements.

(5) Rescinded IAB 10/4/00, effective 10/1/00.

(6) When income received weekly or biweekly (once every two weeks) is projected for future months, it shall be projected by adding all income received in the time period being used and dividing the result by the number of instances of income received in that time period. The result shall be multiplied by four if the income is received weekly, or by two if the income is received biweekly, regardless of the number of weekly or biweekly payments to be made in future months.

(7) Rescinded IAB 7/4/07, effective 8/1/07.

(8) When a change in circumstances that is required to be timely reported by the client pursuant to paragraphs 75.52(4)*"d"* and *"e"* is not reported as required, eligibility shall be redetermined beginning with the month following the month in which the change occurred. When a change in circumstances that is required to be reported by the client at annual review or upon the addition of an individual to the eligible group pursuant to paragraph 75.52(4)*"c"* is not reported as required, eligibility shall be redetermined beginning with the month following the month in which the change was required to be reported. All other changes shall be acted upon when they are reported or otherwise become known to the department, allowing for a ten-day notice of adverse action, if required.

b. Recurring lump-sum income. Recurring lump-sum earned and unearned income, except for the income of the self-employed, shall be prorated over the number of months for which the income was received and applied to the eligibility determination for the same number of months.

(1) Income received by an individual employed under a contract shall be prorated over the period of the contract.

(2) Income received at periodic intervals or intermittently shall be prorated over the period covered by the income and applied to the eligibility determination for the same number of months. EXCEPTION: Periodic or intermittent income from self-employment shall be treated as described at paragraph 75.57(9)*"i."*

(3) When the lump-sum income is earned income, appropriate disregards, deductions and diversions shall be applied to the monthly prorated income. Income is prorated when a recurring lump sum is received at any time.

c. Nonrecurring lump-sum income. Moneys received as a nonrecurring lump sum, except as specified in subrules 75.56(4) and 75.56(7) and at paragraphs 75.57(8)*"b"* and *"c,"* shall be treated in accordance with this rule. Nonrecurring lump-sum income includes an inheritance, an insurance settlement or tort recovery, an insurance death benefit, a gift, lottery winnings, or a retroactive payment of benefits, such as social security, job insurance, or workers' compensation.

(1) Nonrecurring lump-sum income shall be considered as income in the month of receipt and counted in computing eligibility, unless the income is exempt.

(2) When countable income exclusive of any family investment program grant but including countable lump-sum income exceeds the needs of the eligible group under their current coverage group, the countable lump-sum income shall be prorated. The number of full months for which a monthly amount of the lump sum shall be counted as income in the eligibility determination is derived by dividing the total of the lump-sum income and any other countable income received in or projected to be received in the month the lump sum was received by the schedule of living costs, as identified at subrule 75.58(2), for the eligible group. This period is referred to as the period of proration. Any income remaining after this calculation shall be applied as income to the first month following the period of proration and disregarded as income thereafter.

(3) The period of proration shall begin with the month when the nonrecurring lump sum was received, whether or not the receipt of the lump sum was timely reported. If receipt of the lump sum was reported timely and the calculation was completed timely, no recoupment shall be made. If receipt of the lump sum was not reported timely or the calculation was not completed timely, recoupment shall begin with the month of receipt of the nonrecurring lump sum.

(4) The period of proration shall be shortened when:

1. The schedule of living costs as defined at subrule 75.58(2) increases; or

2. A portion of the lump sum is no longer available to the eligible group due to loss or theft or because the person controlling the lump sum no longer resides with the eligible group and the lump sum is no longer available to the eligible group; or

3. There is an expenditure of the lump sum made for the following circumstances unless there was insurance available to meet the expense: Payments made on medical services for the former eligible group or their dependents for services listed in 441—Chapters 78, 81, 82, and 85 at the time the expense is reported to the department; the cost of necessary repairs to maintain habitability of the homestead requiring the spending of over $25 per incident; cost of replacement of exempt resources as defined in subrule 75.56(1) due to fire, tornado, or other natural disaster; or funeral and burial expenses. The expenditure of these funds shall be verified.

(5) When countable income, including the lump-sum income, is less than the needs of the eligible group in accordance with the provisions of their current coverage group, the lump sum shall be counted as income for the month of receipt.

(6) For purposes of applying the lump-sum provision, the eligible group is defined as all eligible persons and any other individual whose lump-sum income is counted in determining the period of proration.

(7) During the period of proration, individuals not in the eligible group when the lump-sum income was received may be eligible as a separate eligible group. Income of this eligible group plus income of the parent or other legally responsible person in the home, excluding the lump-sum income already considered, shall be considered as available in determining eligibility.

d. The third digit to the right of the decimal point in any calculation of income, hours of employment and work expenses for care, as defined at paragraph 75.57(2)*"b,"* shall be dropped.

e. In any month for which an individual is determined eligible to be added to a currently active family medical assistance (FMAP) or FMAP-related Medicaid case, the individual's needs, income, and resources shall be included. An individual who is a member of the eligible group and who is determined to be ineligible for Medicaid shall be canceled prospectively effective the first of the following month if the timely notice of adverse action requirements as provided at 441—subrule 76.4(1) can be met.

f. Rescinded IAB 10/4/00, effective 10/1/00.

g. Rescinded IAB 2/11/98, effective 2/1/98.

h. Income from self-employment received on a regular weekly, biweekly, semimonthly or monthly basis shall be budgeted in the same manner as the earnings of an employee. The countable income shall be the net income.

i. Income from self-employment not received on a regular weekly, biweekly, semimonthly or monthly basis that represents an individual's annual income shall be averaged over a 12-month period of time, even if the income is received within a short period of time during that 12-month period. Any change in self-employment shall be handled in accordance with subparagraphs (3) through (5) below.

(1) When a self-employment enterprise which does not produce a regular weekly, biweekly, semimonthly or monthly income has been in existence for less than a year, income shall be averaged over the period of time the enterprise has been in existence and the monthly amount projected for the same period of time. If the enterprise has been in existence for such a short time that there is very little income information, the worker shall establish, with the cooperation of the client, a reasonable estimate which shall be considered accurate and projected for three months, after which the income shall be averaged and projected for the same period of time. Any changes in self-employment shall be considered in accordance with subparagraphs (3) through (5) below.

(2) These policies apply when the self-employment income is received before the month of decision and the income is expected to continue, in the month of decision, after assistance is approved.

(3) A change in the cost of producing self-employment income is defined as an established permanent ongoing change in the operating expenses of a self-employment enterprise. Change in self-employment income is defined as a change in the nature of business.

(4) When a change in operating expenses occurs, the department shall recalculate the expenses on the basis of the change.

(5) When a change occurs in the nature of the business, the income and expenses shall be computed on the basis of the change.

75.57(10) *Restriction on diversion of income.* Rescinded IAB 7/11/01, effective 9/1/01.

75.57(11) *Divesting of income.* Assistance shall not be approved when an investigation proves that income was divested and the action was deliberate and for the primary purpose of qualifying for assistance or increasing the amount of assistance paid.
[**ARC 8500B**, IAB 2/10/10, effective 3/1/10; **ARC 8556B**, IAB 3/10/10, effective 2/10/10]

441—75.58(249A) Need standards.

75.58(1) *Definition of eligible group.* The eligible group consists of all eligible persons specified below and living together, except when one or more of these persons have elected to receive supplemental security income under Title XVI of the Social Security Act or are voluntarily excluded in accordance with the provisions of rule 441—75.59(249A). There shall be at least one child, which may be an unborn child, in the eligible group except when the only eligible child is receiving supplemental security income.

a. The following persons shall be included (except as otherwise provided in these rules) without regard to the person's employment status, income or resources:

(1) All dependent children who are siblings of whole or half blood or adoptive.

(2) Any parent of such children, if the parent is living in the same home as the dependent children.

b. The following persons may be included:

(1) The needy specified relative who assumes the role of parent.

(2) The needy specified relative who acts as caretaker when the parent is in the home but is unable to act as caretaker.

(3) An incapacitated stepparent, upon request, when the stepparent is the legal spouse of the parent by ceremonial or common-law marriage and the stepparent does not have a child in the eligible group.

1. A stepparent is considered incapacitated when a clearly identifiable physical or mental defect has a demonstrable effect upon earning capacity or the performance of the homemaking duties required to maintain a home for the stepchild. The incapacity shall be expected to last for a period of at least 30 days from the date of application.

2. The determination of incapacity shall be supported by medical or psychological evidence. The evidence may be submitted either by letter from the physician or on Form 470-0447, Report on Incapacity.

3. When an examination is required and other resources are not available to meet the expense of the examination, the physician shall be authorized to make the examination and submit the claim for payment on Form 470-0502, Authorization for Examination and Claim for Payment.

4. A finding of eligibility for social security benefits or supplemental security income benefits based on disability or blindness is acceptable proof of incapacity for the family medical assistance program (FMAP) and FMAP-related program purposes.

5. A stepparent who is considered incapacitated and is receiving Medicaid shall be referred to the department of education, division of vocational rehabilitation services, for evaluation and services. Acceptance of these services is optional.

(4) The stepparent who is not incapacitated when the stepparent is the legal spouse of the parent by ceremonial or common-law marriage and the stepparent is required in the home to care for the dependent children. These services must be required to the extent that if the stepparent were not available, it would be necessary to allow for care as a deduction from earned income of the parent.

75.58(2) *Schedule of needs.* The schedule of living costs represents 100 percent of the basic needs. The schedule of living costs is used to determine the needs of individuals when these needs must be determined in accordance with the schedule of needs defined at rule 441—75.50(249A). The 185 percent schedule is included for the determination of eligibility in accordance with rule 441—75.57(249A). The schedule of basic needs is used to determine the basic needs of those persons whose needs are included in the eligible group. The eligible group is considered a separate and distinct group without regard to the presence in the home of other persons, regardless of relationship to or whether they have a liability to support members of the eligible group. The schedule of basic needs is also used to determine the needs of persons not included in the eligible group. The percentage of basic needs paid to one or more persons as compared to the schedule of living costs is shown on the chart below:

SCHEDULE OF NEEDS

Number of Persons	1	2	3	4	5	6	7	8	9	10	Each Additional Person
Test 1 185% of Living Costs	675.25	1330.15	1570.65	1824.10	2020.20	2249.60	2469.75	2695.45	2915.60	3189.40	320.05
Test 2 Schedule of Living Costs	365	719	849	986	1092	1216	1335	1457	1576	1724	173
Test 3 Schedule of Basic Needs	183	361	426	495	548	610	670	731	791	865	87
Ratio of Basic Needs to Living Costs	50.18	50.18	50.18	50.18	50.18	50.18	50.18	50.18	50.18	50.18	50.18

CHART OF BASIC NEEDS COMPONENTS

(all figures are on a per person basis)

Number of Persons	1	2	3	4	5	6	7	8	9	10 or More
Shelter	77.14	65.81	47.10	35.20	31.74	26.28	25.69	22.52	20.91	20.58
Utilities	19.29	16.45	11.77	8.80	7.93	6.57	6.42	5.63	5.23	5.14
Household Supplies	4.27	5.33	4.01	3.75	3.36	3.26	3.10	3.08	2.97	2.92
Food	34.49	44.98	40.31	39.11	36.65	37.04	34.00	33.53	32.87	32.36
Clothing	11.17	11.49	8.70	8.75	6.82	6.84	6.54	6.39	6.20	6.10
Pers. Care & Supplies	3.29	3.64	2.68	2.38	2.02	1.91	1.82	1.72	1.67	1.64
Med. Chest Supplies	.99	1.40	1.34	1.13	1.15	1.11	1.08	1.06	1.09	1.08
Communications	7.23	6.17	3.85	3.25	2.50	2.07	1.82	1.66	1.51	1.49
Transportation	25.13	25.23	22.24	21.38	17.43	16.59	15.24	15.79	15.44	15.19

a. The definitions of the basic need components are as follows:

(1) Shelter: Rental, taxes, upkeep, insurance, amortization.

(2) Utilities: Fuel, water, lights, water heating, refrigeration, garbage.

(3) Household supplies and replacements: Essentials associated with housekeeping and meal preparation.

(4) Food: Including school lunches.

(5) Clothing: Including layette, laundry, dry cleaning.

(6) Personal care and supplies: Including regular school supplies.

(7) Medicine chest items.

(8) Communications: Telephone, newspapers, magazines.

(9) Transportation: Including bus fares.

b. Special situations in determining eligible group:

(1) The needs of a child or children in a nonparental home shall be considered a separate eligible group when the relative is receiving Medicaid for the relative's own children.

(2) When the unmarried specified relative under the age of 19 is living in the same home with a parent or parents who receive Medicaid, the needs of the specified relative, when eligible, shall be included in the same eligible group with the parents. When the specified relative is a parent, the needs of the eligible children for whom the unmarried parent is caretaker shall be included in the same eligible group. When the specified relative is a nonparental relative, the needs of the eligible children for whom the specified relative is caretaker shall be considered a separate eligible group.

When the unmarried specified relative under the age of 19 is living in the same home as a parent who receives Medicaid but the specified relative is not an eligible child, need of the specified relative shall be determined in the same manner as though the specified relative had attained majority.

When the unmarried specified relative under the age of 19 is living with a nonparental relative or in an independent living arrangement, need shall be determined in the same manner as though the specified relative had attained majority.

When the unmarried specified relative is under the age of 18 and living in the same home with a parent who does not receive Medicaid, the needs of the specified relative, when eligible, shall be included in the eligible group with the children when the specified relative is a parent. When the specified relative is a nonparental relative as defined at subrule 75.55(1), only the needs of the eligible children shall be included in the eligible group. When the unmarried specified relative is aged 18, need shall be determined in the same manner as though the specified relative had attained majority.

(3) When a person who would ordinarily be in the eligible group has elected to receive supplemental security income benefits, the person, income and resources shall not be considered in determining eligibility for the rest of the family.

(4) When two individuals, married to each other, are living in a common household and the children of each of them are recipients of Medicaid, the eligibility shall be computed on the basis of their comprising one eligible group.

(5) When a child is ineligible for Medicaid, the income and resources of that child are not used in determining eligibility of the eligible group and the ineligible child is not a part of the household size. However, the income and resources of a parent who is ineligible for Medicaid are used in determining eligibility of the eligible group and the ineligible parent is counted when determining household size.

441—75.59(249A) Persons who may be voluntarily excluded from the eligible group when determining eligibility for the family medical assistance program (FMAP) and FMAP-related coverage groups.

75.59(1) *Exclusions from the eligible group.* In determining eligibility under the family medical assistance program (FMAP) or any FMAP-related Medicaid coverage group in this chapter, the following persons may be excluded from the eligible group when determining Medicaid eligibility of other household members.

a. Siblings (of whole or half blood, or adoptive) of eligible children.

b. Self-supporting parents of minor unmarried parents.

c. Stepparents of eligible children.

d. Children living with a specified relative, as listed at subrule 75.55(1).

75.59(2) *Needs, income, and resource exclusions.* The needs, income, and resources of persons who are voluntarily excluded shall also be excluded. If a self-supporting parent of a minor unmarried parent is voluntarily excluded, then the minor unmarried parent shall not be counted in the household size when determining eligibility for the minor unmarried parent's child. However, the income and resources of the minor unmarried parent shall be used in determining eligibility for the unmarried minor parent's child. If a stepparent is voluntarily excluded, the natural or adoptive parent shall not be counted in the household size when determining eligibility for the natural or adoptive parent's children. However, the income and resources of the natural or adoptive parent shall be used in determining eligibility for the natural or adoptive parent's children.

75.59(3) *Medicaid entitlement.* Persons whose needs are voluntarily excluded from the eligibility determination shall not be entitled to Medicaid under this or any other coverage group.

75.59(4) *Situations where parent's needs are excluded.* In situations where the parent's needs are excluded but the parent's income and resources are considered in the eligibility determination (e.g., minor unmarried parent living with self-supporting parents), the excluded parent shall be allowed the earned income deduction, child care expenses and the work incentive disregard as provided at paragraphs 75.57(2)*"a," "b,"* and *"c."*

75.59(5) *Situations where child's needs, income, and resources are excluded.* In situations where the child's needs, income, and resources are excluded from the eligibility determination pursuant to subrule 75.59(1), and the child's income is not sufficient to meet the child's needs, the parent shall be allowed to divert income to meet the unmet needs of the excluded child. The maximum amount to be diverted shall be the difference between the schedule of basic needs of the eligible group with the child included and the schedule of basic needs with the child excluded, in accordance with the provisions of subrule 75.58(2), minus any countable income of the child.

441—75.60(249A) Pending SSI approval. When a person who would ordinarily be in the eligible group has applied for supplemental security income benefits, the person's needs may be included in the eligible group pending approval of supplemental security income.

These rules are intended to implement Iowa Code section 249A.4.

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CHAPTER 76
APPLICATION AND INVESTIGATION

[Ch 76, 1973 IDR, renumbered as Ch 911]
[Prior to 7/1/83, Social Services[770] Ch 76]
[Prior to 2/11/87, Human Services[498]]

441—76.1(249A) Application. Each person wishing to do so shall have the opportunity to apply for assistance without delay.

76.1(1) *Application forms.* The applicant shall immediately be given an application form to complete. When the applicant requests that the form be mailed, the department shall send the necessary form in the next outgoing mail.

a. An application for family medical assistance-related Medicaid programs shall be submitted on the Health and Financial Support Application, Form 470-0462 or Form 470-0466 (Spanish); the Health Services Application, Form 470-2927 or Form 470-2927(S); the HAWK-I Application, Comm. 156; or the HAWK-I Electronic Application Summary and Signature Page, Form 470-4016. However, no application form is required for express lane eligibility under subrule 76.1(8), based on a determination of eligibility for food assistance.

b. An application for SSI-related Medicaid shall be submitted on the Health Services Application, Form 470-2927 or Form 470-2927(S), or the Health and Financial Support Application, Form 470-0462 or Form 470-0466 (Spanish).

c. A person who is a recipient of Supplemental Security Income (SSI) benefits shall not be required to complete a separate Medicaid application. If the department does not have all information necessary to establish that an SSI recipient meets all Medicaid eligibility requirements, the SSI recipient may be required to complete Form 470-0364, 470-0364(S), 470-0364(M), or 470-0364(MS), SSI Medicaid Information, and may be required to attend an interview to clarify information on this form.

d. An application for Medicaid for persons in foster care shall be submitted on Form 470-2927 or Form 470-2927(S), Health Services Application.

e. The department shall initiate a medical assistance application for a person whose application data is received from the federal Social Security Administration pursuant to 42 U.S.C. 1320b-14(c)(3).

(1) The Social Security Administration transmits data from Form SSA 1020B-OCR-SM, Application for Extra Help with Medicare Prescription Drug Plan Costs, to the department. The date that the Social Security Administration transmits its application data to the department shall be treated as the date of application for medical assistance.

(2) The department shall mail Form 470-4846, Medicare Savings Programs Additional Information Request, to the person whose data was transmitted to gather the rest of the information needed to determine eligibility.

f. An application for presumptive eligibility for children shall be submitted on Form 470-4855 or 470-4855(S), Application: Presumptive Health Care Coverage for Children.

76.1(2) *Place of filing.* An application may be filed over the Internet or in any local office of the department or in any disproportionate share hospital, federally qualified health center or other facility in which outstationing activities are provided. The hospital, health center, or facility shall forward the application to the department office responsible for completing the eligibility determination.

a. The Health Services Application, Form 470-2927 or Form 470-2927(S), may also be filed at the office of a qualified provider of presumptive Medicaid eligibility, a WIC office, a maternal health clinic, or a well child clinic. The office or clinic shall forward the application within two working days to the department office responsible for completing the eligibility determination.

b. The HAWK-I Application, Comm. 156, and the HAWK-I Electronic Application Summary and Signature Page, Form 470-4016, shall be filed with the third-party administrator as provided at 441—subrule 86.3(3). If it appears that the family is Medicaid-eligible, the third-party administrator shall forward the application to the department office responsible for determining Medicaid eligibility.

c. Those persons eligible for supplemental security income and those who would be eligible if living outside a medical institution may make application at the social security district office.

d. Women applying for medical assistance for family planning services under 441—subrule 75.1(41) or 441—Chapter 87 may also apply at any family planning agency as defined in rule 441—87.1(82GA,ch1187).

e. Persons applying for presumptive eligibility for children shall submit the application to a qualified entity as described under 441—subrule 75.1(44).

76.1(3) *Date and method of filing application.* An application is considered filed on the date an identifiable application, Form 470-0462, 470-0466 (Spanish), 470-2927, or 470-2927(S), is received and date-stamped in any place of filing specified in subrule 76.1(2).

a. When an application is delivered to a closed office, it will be considered received on the first day that is not a weekend or state holiday following the day that the office was last open.

b. An identifiable application, Form 470-2927 or 470-2927(S), which is filed to apply for FMAP or FMAP-related Medicaid at a WIC office, well child health clinic, maternal health clinic, or the office of a qualified provider for presumptive eligibility, shall be considered filed on the date received and date-stamped in one of these offices.

c. When a HAWK-I Application, Comm. 156, or HAWK-I Electronic Application Summary and Signature Page, Form 470-4016, is filed with the third-party administrator and subsequently referred to the department for a Medicaid eligibility determination, the date the application is received and date-stamped by the third-party administrator shall be the filing date.

d. A copy of an application received by fax or electronically at one of the places described above shall have the same effect as an original application.

e. An identifiable application is an application containing a legible name, address, and signature.

f. If an authorized representative signed the application on behalf of an applicant, the signature of the applicant or the responsible person must be on the application before the application can be approved. For FMAP and FMAP-related Medicaid, the signature of a parent or stepparent in the home must be on the application before the application can be approved.

76.1(4) *Applicant cooperation.* An applicant must cooperate with the department in the application process, which may include providing information or verification, attending a scheduled face-to-face interview, or signing documents. Failure to cooperate in the application process shall serve as a basis for rejection of an application.

76.1(5) *Application not required.* For family medical assistance-related programs, a new application is not required when an eligible person is added to an existing Medicaid eligible group or when a responsible relative becomes a member of a Medicaid eligible household. This person is considered to be included in the application that established the existing eligible group. However, in these instances the date of application to add a person is the date the change is reported. When it is reported that a person is anticipated to enter the home, the date of application to add the person shall be no earlier than the date of entry or the date of report, whichever is later.

a. In those instances where a person previously ineligible for Medicaid for failure to cooperate in obtaining medical support or establishing paternity as described at 441—subrule 75.14(2) is to be granted Medicaid benefits, the person shall be granted Medicaid benefits effective the first of the month in which the person becomes eligible by cooperating in obtaining medical support or establishing paternity.

b. In those instances where a person previously ineligible for Medicaid for failure to provide a social security number or proof of application for a social security number as described at rule 441—75.7(249A) is to be granted Medicaid benefits, the person shall be granted Medicaid benefits effective the first of the month in which the person becomes eligible by providing a social security number or proof of application for a social security number.

c. In those instances where a person who has been voluntarily excluded from the eligible group in accordance with the provisions of rule 441—75.59(249A) is being added to the eligible group, the person shall be added effective the first of the month after the month in which the household requests that the person no longer be voluntarily excluded.

76.1(6) *Right to withdraw the application.* After an application has been filed, the applicant may withdraw the application at any time before the eligibility determination. The applicant may request that the application be withdrawn entirely or may, before the date the application is processed, request

withdrawal for any month covered by the application process except as provided in the medically needy program in accordance with the provisions of 441—subrule 75.1(35). Requests for voluntary withdrawal of the application shall be documented in the case record and a Notice of Decision, Form 470-0485, 470-0486, 470-0486(S), or 470-0490, shall be sent to the applicant confirming the request.

76.1(7) *Responsible persons and authorized representatives.*

a. Responsible person. If the applicant or member is unable to act on the applicant's or member's behalf because the applicant or member is incompetent, physically incapacitated, or deceased, a responsible person may act responsibly for the applicant or member. The responsible person shall be a family member, friend or other person who has knowledge of the applicant's or member's financial affairs and circumstances and a personal interest in the applicant's or member's welfare or a legal representative such as a conservator, guardian, executor or someone with power of attorney. The responsible person shall assume the applicant's or member's position and responsibilities during the application process or for ongoing eligibility. The responsible person may designate an authorized representative as provided for in paragraph 76.1(7)*"b"* to represent the incompetent, physically incapacitated, or deceased applicant's or member's position and responsibilities during the application process or for ongoing eligibility. This authorization does not relieve the responsible person from assuming the incompetent, physically incapacitated, or deceased applicant's or member's position and responsibilities during the application process or for ongoing eligibility.

(1) When there is no person as described above to act on the incompetent, physically incapacitated, or deceased applicant's or member's behalf, any individual or organization shall be allowed to act as the responsible person if the individual or organization conducts a diligent search and completes Form 470-3356, Inability to Find a Responsible Person, attesting to the inability to find a responsible person to act on behalf of the incompetent, physically incapacitated, or deceased applicant or member.

(2) The department may require verification of incompetence or death and the person's relationship to the applicant or member or the legal representative status.

(3) Copies of all department correspondence that would normally be provided to the applicant or member shall be provided to the responsible person and the representative if one has been authorized by the responsible person.

b. Authorized representative. A competent applicant or member or a responsible person as described in paragraph 76.1(7)*"a"* may authorize any individual or organization to represent the applicant or member in the application process or for ongoing eligibility.

(1) The authorization must be in writing, and signed and dated by the applicant or member or a responsible person before the department shall recognize the authorized representative.

(2) If the authorization indicates the time period or dates of medical services it is to cover, this stated period or dates of medical services shall be honored and may include subsequent applications, if necessary, that relate to the time period or dates of medical services indicated on the authorization. If the authorization does not indicate the time period or dates of medical services it is to cover, the authorization shall be valid for any applications filed within 120 days from the date the authorization was signed and all subsequent actions pertaining to the applications filed within the 120-day period.

(3) Anytime an applicant or member or a responsible person notifies the department in writing that the applicant or member or a responsible person no longer wants an authorized representative to act on the applicant's or member's behalf, the department shall no longer recognize that person or organization as the applicant's or member's representative.

(4) Designation of an authorized representative does not relieve a competent applicant or member or a responsible person as defined in 76.1(7)*"a"* of the primary responsibility to cooperate with the department in the determination of initial and ongoing eligibility, which may include providing information or verification, attending a scheduled face-to-face interview, or signing documents on which the authorized representative's signature would be inadequate.

(5) Copies of all departmental correspondence shall be provided to the client and the representative if one has been authorized by the applicant or member.

76.1(8) *Express lane eligibility.* For purposes of an initial determination of medical assistance eligibility, the department will use express lane procedures as allowed by 42 U.S.C. § 1396a(e)(13) and as described in this subrule.

a. The department shall rely on a determination of eligibility for food assistance pursuant to 441—Chapter 65 as establishing that a child under the age of 19 meets all eligibility requirements established in 441—subrule 75.1(28) except for citizenship or alienage requirements, unless:

(1) The child's household already includes other persons receiving FMAP-related Medicaid, or

(2) The child was previously granted express lane eligibility and the household has not had at least a two-month break in food assistance eligibility since that time, or

(3) The household's income as calculated by the food assistance program exceeds the income limit for the mothers and children coverage group found at 441—subparagraph 75.1(28)*"a"*(1).

b. To obtain express lane eligibility, the child's household must request medical assistance for the child on Form 470-4851, Express Lane Medicaid for Children. The department will mail Form 470-4851 to the household when a child eligible for the express lane option is approved for food assistance pursuant to 441—Chapter 65. An adult member of the child's household or a child receiving food assistance as head of household must sign Form 470-4851 and return it to the department within 30 calendar days of issuance.

c. As a condition of express lane eligibility, the child must meet citizenship or alienage requirements of rule 441—75.11(249A).

d. The month of application for express lane eligibility is the month of the child's food assistance effective date. Express lane eligibility begins on the first day of the month of the child's food assistance effective date.

e. Retroactive eligibility is available for any of the three months before the effective date of the child's express lane eligibility when the child:

(1) Has medical bills for covered services that were received in that period, and

(2) Would have been eligible for medical assistance benefits in the month services were received if application for medical assistance had been made in that month, determined without regard to food assistance eligibility.

f. After the initial express lane determination of medical assistance eligibility, all redeterminations of medical assistance eligibility shall be made without reliance on any food assistance eligibility determination.

[**ARC 7544B**, IAB 2/11/09, effective 1/14/09; **ARC 8260B**, IAB 11/4/09, effective 1/1/10; **ARC 8439B**, IAB 1/13/10, effective 3/1/10; **ARC 8642B**, IAB 4/7/10, effective 6/1/10]

441—76.2(249A) Information and verification procedure. The decision with respect to eligibility shall be based primarily on information and verification furnished by the applicant or member. Signing a general authorization for release of information to the department does not meet this responsibility.

76.2(1) *Interviews.*

a. In processing applications for Medicaid for adults, the department may require a face-to-face or telephone interview upon written notice to the applicant. An interview is not required as a condition of eligibility for children.

b. For SSI-related Medicaid for adults, the department may require a face-to-face or telephone interview at the time of review.

c. The department shall notify the applicant in writing of the date, time and method of an interview. This notice shall be provided to the applicant personally or by mail or facsimile. Interviews that are rescheduled at the request of the applicant or authorized representative may be agreed upon verbally; a written confirmation is not required.

d. Failure of the applicant or member to attend a scheduled interview shall serve as a basis for rejection of an application or cancellation of assistance for adults. Failure of the applicant or member to attend an interview shall not serve as a basis for rejection of an application or cancellation of assistance for children.

76.2(2) *Choice of coverage groups.* An applicant who meets the eligibility requirements of more than one coverage group shall be given the choice of coverage group under which eligibility shall be determined.

76.2(3) *Conditional benefits granted previous to October 1, 1993.* When the client is receiving Medicaid under the conditional benefit policy of the SSI program pursuant to subrule 75.13(2), the client shall be required to describe the efforts that are made to sell the property on Form 470-2908, Description of Efforts to Sell Property, as requested by the department. The department shall request that the form be completed no more often than specified. For personal property being sold Form 470-2908 shall be completed no more often than every 30 days during the conditional benefit period. For real property being sold Form 470-2908 shall be completed beginning 35 days after conditional benefits are granted and no more often than every 60 days thereafter for nine months. If eligibility continues and the real property is not sold, the form shall be completed no more often than every 90 days.

76.2(4) *Providing additional information.* The department shall notify the applicant in writing of additional information or verification that is required to establish eligibility. This notice shall be provided to the applicant or member personally or by mail or facsimile.

a. The department shall allow the applicant five working days to supply the information or verification requested. Applicants for whom eligibility is determined in whole or in part by the Social Security Administration shall make application to the Social Security Administration within five working days of referral by the department.

b. The department may extend the deadline for a reasonable period of time when the applicant is making every effort but is unable to secure the required information or verification from a third party.

c. The application shall be denied or assistance shall be canceled if the department does not receive one of the following by the due date:

(1) The information or verification,

(2) An authorization to obtain the information or verification, or

(3) A request for an extension of the due date.

d. If benefits are denied for failure to provide information and the information is provided within 14 calendar days of the effective date of the denial, the department shall complete the eligibility determination as though the information were received timely. If the fourteenth calendar day falls on a weekend or state holiday, the applicant shall have until the next business day to provide the information.

76.2(5) *Reporting of changes.* The applicant shall report any change as defined at 441—paragraph 75.52(4)*"c"* which occurs during the application process within five working days of the change. Changes that occur after approval for benefits shall be reported in accordance with paragraph 75.52(4)*"c."*

[**ARC 7740B**, IAB 5/6/09, effective 6/10/09; **ARC 8500B**, IAB 2/10/10, effective 3/1/10]

441—76.3(249A) Time limit for decision. Applications shall be investigated by the county department of human services. A determination of approval, conditional eligibility, or denial shall be made as soon as possible, but no later than 30 days following the date of filing the application unless one or more of the following conditions exist.

76.3(1) The application is being processed for eligibility under the medically needy coverage group as defined in 441—subrule 75.1(35). Applicants for medically needy shall receive a written notice of approval, conditional eligibility, or denial as soon as possible, but no later than 45 days from the date the application was filed.

76.3(2) An application on the client's behalf for supplemental security income benefits is pending.

76.3(3) The application is pending due to completion of the requirement in 441—subrule 75.1(7).

76.3(4) The application is pending due to nonreceipt of information which is beyond the control of the applicant or department. It is the responsibility of the applicant to provide information to the department timely or to ask for an extension of time before the due date when additional time is needed to secure the information or verification.

76.3(5) The application is pending due to the disability determination process performed through the department.

76.3(6) Unusual circumstances exist which prevent a decision from being made within the specified time limit. Unusual circumstances include those situations where the department and the applicant have made every reasonable effort to secure necessary information which has not been supplied by the date the time limit has expired or because of emergency situations such as fire, flood, or other conditions beyond the administrative control of the department.

441—76.4(249A) Notification of decision. The applicant or member will be notified in writing of the decision of the department regarding the applicant's or member's eligibility for Medicaid. If the applicant or member has been determined to be ineligible an explanation of the reason will be provided.

76.4(1) The member shall be given a timely and adequate written notice as provided in 441—subrule 7.7(1) when any decision or action is being taken by the department which adversely affects Medicaid eligibility or the amount of benefits.

76.4(2) Timely notice may be dispensed with but adequate notice shall be sent, no later than the effective date of action, when one or more of the conditions in 441—subrule 7.7(2) are met.

76.4(3) A written notice of decision shall be issued to the applicant the next working day following a determination of eligibility, conditional eligibility or ineligibility.

441—76.5(249A) Effective date.

76.5(1) *Three-month retroactive eligibility.*

a. Medical assistance benefits shall be available for all or any of the three months preceding the month in which the application is filed to persons who meet both of the following conditions:

(1) Have medical bills for covered services which were received during the three-month retroactive period.

(2) Would have been eligible for medical assistance benefits in the month services were received, if application for medical assistance had been made in that month.

b. The applicant need not be eligible in the month of application to be eligible in any of the three months prior to the month of application.

c. Retroactive medical assistance benefits shall be made available when an application has been made on behalf of a deceased person if the conditions in paragraph *"a"* are met.

d. Persons receiving only Supplemental Security Income benefits who wish to make application for Medicaid benefits for three months preceding the month of application shall complete Form 470-0364, 470-0364(S), 470-0364(M), or 470-0364(MS), SSI Medicaid Information.

e. Rescinded IAB 10/8/97, effective 12/1/97.

76.5(2) *First day of month.*

a. For persons approved for the family medical assistance-related programs, medical assistance benefits shall be effective on the first day of a month when eligibility was established anytime during the month.

b. For persons approved for supplemental security income, programs related to supplemental security income, or state supplementary assistance, medical assistance benefits shall be effective on the first day of a month when the individual was resource eligible as of the first moment of the first day of the month and met all other eligibility criteria at any time during the month.

c. When a request is made to add a new person to the eligible group, and that person meets the eligibility requirements, assistance shall be effective the first of the month in which the request was made.

d. When a request is made to add a person to the eligible group who previously was excluded, in accordance with the provisions of rule 441—75.59(249A), assistance shall be effective no earlier than the first of the month following the month in which the request was made.

76.5(3) *Care prior to approval.* No payment shall be made for medical care received prior to the effective date of approval.

76.5(4) *Reinstatement.*

a. Eligibility for medical assistance may be reinstated without a new application when all information necessary to establish eligibility, including verification of any changes, is provided within

14 calendar days of the effective date of the cancellation. If the fourteenth calendar day falls on a weekend or state holiday, the client shall have until the next business day to provide the information.

b. When medical assistance has been canceled for failure to return a completed review form as required by subrule 75.52(3), assistance may be reinstated without a new application if the department receives the completed form within 14 calendar days of the effective date of cancellation. If the fourteenth calendar day falls on a weekend or state holiday, the client shall have until the next business day to provide the information.

[**ARC 8500B**, IAB 2/10/10, effective 3/1/10; **ARC 8642B**, IAB 4/7/10, effective 6/1/10]

441—76.6(249A) Certification for services. The department of human services shall issue a Medical Assistance Eligibility Card, Form 470-1911, to persons who have been determined to be eligible for the benefits provided under the Medicaid program unless one of the following situations exists:

76.6(1) *Pregnant woman.* The eligible person is a pregnant woman determined presumptively eligible in accordance with 441—subrule 75.1(30). These persons shall be issued a Presumptive Medicaid Eligibility Notice of Decision, Form 470-2580 or 470-2580(S), by the provider.

76.6(2) *IowaCare.* A person who is enrolled in the IowaCare program shall be issued an IowaCare Medical Card, Form 470-4164.

76.6(3) *Breast and cervical cancer.* The eligible person is one who has been determined presumptively eligible for treatment of breast or cervical cancer or a precancerous condition in accordance with 441—paragraph 75.1(40)*"c."* These persons shall be issued a Presumptive Medicaid Eligibility Notice of Decision, Form 470-2580 or 470-2580(S), by the provider.

441—76.7(249A) Reinvestigation. Reinvestigation shall be made as often as circumstances indicate but in no instance shall the period of time between reinvestigations exceed 12 months.

76.7(1) The member shall supply, insofar as the member is able, additional information needed to establish eligibility within ten working days from the date a written request is issued.

a. The member shall give written permission for the release of information when the member is unable to furnish information needed to establish eligibility.

b. Failure to supply the information or verification requested or refusal to request assistance and authorize the department to secure the requested information from other sources shall serve as a basis for cancellation of Medicaid. Signing a general authorization for release of information to the department does not meet this responsibility.

76.7(2) Eligibility criteria for persons whose eligibility for Medicaid is related to the family medical assistance program shall be reviewed according to policies found in rule 441—75.52(249A).

76.7(3) Persons whose eligibility for Medicaid is related to supplemental security income shall complete Form 470-3118 or 470-3118(S), Medicaid Review, as part of the reinvestigation process when requested to do so by the department.

76.7(4) The review for foster children or children in subsidized adoption or subsidized guardianship shall be completed on Form 470-2914, Foster Care, Adoption, and Guardianship Medicaid Review, according to the schedule of the family medical assistance program or supplemental security income program for disabled children, as applicable.

76.7(5) Women eligible for family planning services only shall complete Form 470-4071, Family Planning Medicaid Review, as part of the reinvestigation process. Form 470-4071 shall be issued at least 30 days before the end of the eligibility period. The woman must submit the completed review form before the end of the eligibility period to any location specified in paragraph 76.1(2)*"d."* Women who fail to submit Form 470-4071 before the end of the eligibility period must reapply as directed in rule 441—76.1(249A).

[**ARC 7740B**, IAB 5/6/09, effective 6/10/09; **ARC 8260B**, IAB 11/4/09, effective 1/1/10; **ARC 8500B**, IAB 2/10/10, effective 3/1/10]

441—76.8(249A) Investigation by quality control or the department of inspections and appeals. The client shall cooperate with the department when the client's case is selected by quality control or the department of inspections and appeals for verification of eligibility unless the investigation revolves solely around the circumstances of a person whose income and resources do not affect medical

assistance eligibility. (See department of inspections and appeals rules in 481—Chapter 72.) Failure to do so shall serve as a basis for cancellation of assistance unless the Medicaid eligibility is determined by the Social Security Administration. Once a person's eligibility is denied or canceled for failure to cooperate, the person may reapply but shall not be determined eligible until cooperation occurs.

441—76.9(249A) Member lock-in. In order to promote high quality health care and to prevent harmful practices such as duplication of medical services, drug abuse or overuse, and possible drug interactions, recipients that utilize medical assistance services or items at a frequency or in an amount which is considered to be overuse of services as defined in subrule 76.9(7) may be restricted (locked-in) to receive services from a designated provider(s).

76.9(1) A lock-in or restriction shall be imposed for a minimum of 24 months with longer restrictions determined on an individual basis.

76.9(2) Provider selection. The member may select the provider(s) from which services will be received. The designated providers will be identified on the department's eligibility verification system (ELVS). Only prescriptions written or approved by the designated primary physician(s) will be reimbursed. Other providers of the restricted service will be reimbursed only under circumstances specified in subrule 76.9(3).

76.9(3) Payment will be made to provider(s) other than the designated (lock-in) provider(s) in the following instances:

a. Emergency care is required and the designated provider is not available. Emergency care is defined as care necessary to sustain life or prevent a condition which could cause physical disability.

b. The designated provider requires consultation with another provider. Reimbursement shall be made for office visits only. Prescriptions will be reimbursed only if written or approved by the primary physician(s). Referred physicians may be added to the designation as explained in subrule 76.9(5).

c. The designated provider refers the recipient to another provider. Reimbursement shall be made for office visits only. Prescriptions will be reimbursed only if written or approved by the primary physician(s). Referred physicians may be added to the designation as explained in subrule 76.9(5).

76.9(4) When the recipient fails to choose a provider(s) within 30 days of the request, the division of medical services will select the provider(s) based on previously utilized provider(s) and reasonable access for the recipient.

76.9(5) Recipients may change designated provider(s) when a change is warranted, such as when the recipient has moved, the provider no longer participates, or the provider refuses to see the patient. The worker for the recipient shall make the determination when the recipient has demonstrated that a change is warranted. Recipients may add additional providers to the original designation with approval of a health professional employed by the department for this purpose.

76.9(6) When lock-in is imposed on a recipient, timely and adequate notice shall be sent and an opportunity for a hearing given in accordance with 441—Chapter 7.

76.9(7) Overuse of services is defined as receipt of treatments, drugs, medical supplies or other Medicaid benefits from one or multiple providers of service in an amount, duration, or scope in excess of that which would reasonably be expected to result in a medical or health benefit to the patient.

a. Determination of overuse of service shall be based on utilization data generated by the Surveillance and Utilization Review Subsystem of the Medicaid Management Information System. The system employs an exception reporting technique to identify the recipients most likely to be program overutilizers by reporting cases in which the utilization exceeds the statistical average.

b. In addition to referrals from the Surveillance and Utilization Review Subsystem described in paragraph *"a,"* referrals for utilization review shall be made when utilization data generated by the Medicaid Management Information System reflects that utilization of Medicaid recipient outpatient visits to physicians, advanced registered nurse practitioners, federally qualified health centers, rural health centers, other clinics, and emergency rooms exceeds 24 visits in any 12-month period. This utilization review shall not apply to Medicaid recipients who are enrolled in the MediPASS program or a health maintenance organization, or who are children under 21 years of age or residents of a nursing facility. For the purposes of this paragraph, the term "physician" does not include a psychiatrist.

c. An investigation process of Medicaid recipients determined in paragraphs *"a"* or *"b"* to be subject to a review of overutilization shall be conducted to determine if actual overutilization exists by verifying that the information reported by the computer system is valid and is also unusual based on professional medical judgment. Medical judgments shall be made by physicians, pharmacists, nurses and other health professionals either employed by, under contract to, or consultants for the department. These medical judgments shall be made by the health professionals on the basis of the body of knowledge each has acquired which meets the standards necessary for licensure or certification under the Iowa licensing statutes for the particular health discipline.

441—76.10(249A) Client responsibilities.

76.10(1) In coverage groups for which Medicaid eligibility is determined using income and resource policies related to the supplemental security income (SSI) program, clients shall timely report any changes in the following circumstances to the department. EXCEPTION: Persons actually receiving SSI benefits are exempted from these reporting requirements unless they have a trust or are applying for or receiving home- and community-based waiver services.

a. Income from all sources.

b. Resources.

c. Membership of the household.

d. Recovery from disability.

e. Mailing or living address.

f. Health insurance premiums or coverage.

g. Medicare premiums or coverage.

h. Receipt of social security number.

i. Gross income of the community spouse or dependent children, parents or siblings of the institutionalized or community spouse living with a community spouse when a diversion is made to the community spouse or family. (See definitions in rule 441—75.25(249A).)

j. Income and resources of parents and spouses when income and resources are used in determining Medicaid eligibility, client participation or spenddown.

k. Residence in a medical institution for other than respite care for more than 15 days for home and community-based recipients.

76.10(2) In coverage groups for which Medicaid eligibility is determined using the family medical assistance program (FMAP) income and resource policies, clients shall report changes in accordance with 441—paragraphs 75.52(4)*"c"* through *"e."* After assistance has been approved, changes occurring during the month are effective the first day of the next calendar month, provided the notification requirements at rule 441—76.4(249A) can be met.

76.10(3) A report shall be considered timely when received by the department:

a. Within ten days from the date the change is known to the member or authorized representative; or

b. Within five days from the date the change is known to the applicant or authorized representative.

76.10(4) When a change is not timely reported, any incorrect program expenditures shall be subject to recovery from the client.

76.10(5) Effective date of change. When a request is made to add a new person to the eligible group, and that person meets the eligibility requirements, assistance shall be effective the first day of the month in which the request was made unless otherwise specified at rule 441—76.5(249A). After assistance has been approved, changes reported during the month shall be effective the first day of the next calendar month, unless:

a. Timely notice of adverse action is required as specified in 441—subrule 7.7(1).

b. The certification has expired for persons receiving assistance under the medically needy program in accordance with the provisions of 441—subrule 75.1(35).

c. Rescinded IAB 10/31/01, effective 1/1/02.

441—76.11(249A) Automatic redetermination. Whenever a Medicaid member no longer meets the eligibility requirements of the current coverage group, an automatic redetermination of eligibility for other Medicaid coverage groups shall be made. If the reason for ineligibility under the initial coverage group pertained to a condition of eligibility which applies to all coverage groups, such as failure to cooperate, no further redetermination shall be required. When the redetermination is completed, the member shall be notified of the decision in writing. The redetermination process shall be completed as follows:

76.11(1) *Information received by the tenth of the month.* If information that creates ineligibility under the current coverage group is received in the department by the tenth of the month, the redetermination process shall be completed by the end of that month unless the provisions of subrule 76.11(3) apply. The effective date of cancellation for the current coverage group shall be the first day of the month following the month the information is received.

76.11(2) *Information received after the tenth of the month.* If information that creates ineligibility under the current coverage group is received in the department after the tenth of the month, the redetermination process shall be completed by the end of the following month unless the provisions of subrule 76.11(3) apply. The effective date of cancellation for the current coverage group shall be the first day of the second month following the month the information is received.

76.11(3) *Change in federal law.* If a change in federal law affects the eligibility of large numbers of Medicaid members and the Secretary of Health and Human Services has extended the redetermination time limits, in accordance with 42 CFR Sec. 435.1003 as amended to January 13, 1997, the redetermination process shall be completed within the extended time limit and the effective date of cancellation for the current coverage group shall be no later than the first day of the month following the month in which the extended time limit expires.

76.11(4) *Referral for HAWK-I program.* When the only coverage group under which a child will qualify for Medicaid is the medically needy program with a spenddown as provided in 441—subrule 75.1(35), a referral to the Hawk-I program shall be made in accordance with 441—subrule 86.4(4) as part of the automatic redetermination process when it appears the child is otherwise eligible.

441—76.12(249A) Recovery.

76.12(1) *Definitions.*

"Administrative overpayment" means medical assistance incorrectly paid to or for the client because of continuing assistance during the appeal process or allowing a deduction for the Medicare part B premium in determining client participation while the department arranges to pay the Medicare premium directly.

"Agency error" means medical assistance incorrectly paid to or for the client because of action attributed to the department as the result of one or more of the following circumstances:

1. Misfiling or loss of forms or documents.
2. Errors in typing or copying.
3. Computer input errors.
4. Mathematical errors.
5. Failure to determine eligibility correctly or to certify assistance in the correct amount when all essential information was available to the department.
6. Failure to make prompt revisions in medical payment following changes in policies requiring the changes as of a specific date.

"Client" means a current or former Medicaid member.

"Client error" means medical assistance incorrectly paid to or for the client because the client or client's representative failed to disclose information, or gave false or misleading statements, oral or written, regarding the client's income, resources, or other eligibility and benefit factors. It also means assistance incorrectly paid to or for the client because of failure by the client or client's representative to timely report as defined in rule 441—76.10(249A).

"Department" means the department of human services.

76.12(2) *Amount subject to recovery.* The department shall recover from a client all Medicaid funds incorrectly expended to or on behalf of the client. The incorrect expenditures may result from client or agency error, or administrative overpayment.

76.12(3) *Notification.* All clients shall be promptly notified when it is determined that assistance was incorrectly expended. Notification shall include for whom assistance was paid; the time period during which assistance was incorrectly paid; the amount of assistance subject to recovery; and the reason for the incorrect expenditure.

76.12(4) *Source of recovery.* Recovery shall be made from the client or from parents of children under age 21 when the parents completed the application and had responsibility for reporting changes. Recovery may come from income, resources, the estate, income tax refunds, and lottery winnings of the client.

76.12(5) *Repayment.* The repayment of incorrectly expended Medicaid funds shall be made to the department.

However, repayment of funds incorrectly paid to a nursing facility, a Medicare-certified skilled nursing facility, a psychiatric medical institution for children, an intermediate care facility for the mentally retarded, or mental health institute enrolled as an inpatient psychiatric facility may be made by the client to the facility. The department shall then recover the funds from the facility through a vendor adjustment.

76.12(6) *Appeals.* The client shall have the right to appeal the amount of funds subject to recovery under the provisions of 441—Chapter 7.

76.12(7) *Estate recovery.* Medical assistance is subject to recovery from the estate of a Medicaid member, the estate of the member's surviving spouse, or the estate of the member's surviving child as provided in this subrule. Effective January 1, 2010, medical assistance that has been paid for Medicare cost sharing or for benefits described in Section 1902(a)(10)(E) of the Social Security Act is not subject to recovery. All assets included in the estate of the member, the surviving spouse, or the surviving child are subject to probate for the purposes of medical assistance estate recovery pursuant to Iowa Code section 249A.5(2)*"d."* The classification of the debt is defined at Iowa Code section 633.425(7).

a. Definition of estate. For the purpose of this subrule, the "estate" of a Medicaid member, a surviving spouse, or a surviving child shall include all real property, personal property, or any other asset in which the member, spouse, or surviving child had any legal title or interest at the time of death, or at the time a child reaches the age of 21, to the extent of that interest. An estate includes, but is not limited to, interest in jointly held property, retained life estates, and interests in trusts.

b. Debt due for member 55 years of age or older. Receipt of medical assistance when a member is 55 years of age or older creates a debt due to the department from the member's estate upon the member's death for all medical assistance provided on the member's behalf on or after July 1, 1994.

c. Debt due for member under the age of 55 in a medical institution.

(1) Receipt of medical assistance creates a debt due to the department from the member's estate upon the member's death for all medical assistance provided on the member's behalf on or after July 1,1994, when the member:

1. Is under the age of 55; and

2. Is a resident of a nursing facility, an intermediate care facility for the mentally retarded, or a mental health institute; and

3. Cannot reasonably be expected to be discharged and return home.

(2) If the member is discharged from the facility and returns home before staying six consecutive months, no debt will be assessed for medical assistance payments made on the member's behalf for the time in the institution.

(3) If the member remains in the facility for six consecutive months or longer or dies before staying six consecutive months, the department shall presume that the member cannot or could not reasonably be expected to be discharged and return home and a debt due shall be established. The department shall notify the member of the presumption and the establishment of a debt due.

d. Request for a determination of ability to return home. Upon receipt of a notice of the establishment of a debt due based on the presumption that the member cannot return home, the member

or someone acting on the member's behalf may request that the department determine whether the member can or could reasonably have been expected to return home.

(1) When a written request is made within 30 days of the notice that a debt due will be established, no debt due shall be established until the department has made a decision on the member's ability to return home. If the determination is that there is or was no ability to return home, a debt due shall be established for all medical assistance as of the date of entry into the institution.

(2) When a written request is made more than 30 days after the notice that a debt due will be established, a debt due will be established for medical assistance provided before the request even if the determination is that the member can or could have returned home.

e. Determination of ability to return home. When the member or someone acting on the member's behalf requests that the department determine if the member can or could have returned home, the determination shall be made by the Iowa Medicaid enterprise (IME) medical services unit.

(1) The IME medical services unit cannot make a determination until the member has been in an institution at least six months or after the death of the member, whichever is earlier. The IME medical services unit will notify the member or the member's representative and the department of the determination.

(2) If the determination is that the member can or could return home, the IME medical services unit shall establish the date the return is expected or could have been expected to occur.

(3) If the determination is that the member cannot or could not return home, a debt due will be established unless the member or the member's representative asks for a reconsideration of the decision. The IME medical services unit will notify the member or the member's representative and the department of the reconsideration decision.

(4) If the reconsideration decision is that the member cannot or could not return home, a debt due will be established against the member unless the decision is appealed pursuant to 441—Chapter 7. The appeal decision will determine the final outcome for the establishment of a debt due and the period when the debt is established.

f. Debt collection.

(1) A nursing facility participating in the medical assistance program shall notify the IME revenue collection unit upon the death of a member residing in the facility by submitting Form 470-4331, Estate Recovery Program Nursing Home Referral.

(2) Upon receipt of Form 470-4331 or a report of a member's death through other means, the IME revenue collection unit will use Form 470-4339, Medical Assistance Debt Response, to request a statement of the member's assets from the member's personal representative. The representative shall sign and return Form 470-4339 indicating whether assets remain and, if so, what the assets are and what higher priority expenses exist. EXCEPTION: The procedures in this subparagraph are not necessary when a probate estate has been opened, because probate procedures provide for an inventory, an accounting, and a final report of the estate.

g. Waiving the collection of the debt.

(1) The department shall waive the collection of the debt created under this subrule from the estate of the member to the extent that collection of the debt would result in either of the following:

1. Reduction in the amount received from the member's estate by a surviving spouse or by a surviving child who is under the age of 21, blind, or permanently and totally disabled at the time of the member's death.

2. Creation of an undue hardship for the person seeking a waiver of estate recovery. Undue hardship exists when total household income is less than 200 percent of the poverty level for a household of the same size, total household resources do not exceed $10,000, and application of estate recovery would result in deprivation of food, clothing, shelter, or medical care such that life or health would be endangered. For this purpose, "income" and "resources" shall be defined as under the family medical assistance program.

(2) To apply for a waiver of estate recovery due to undue hardship, the person shall provide a written statement and supporting verification to the department within 30 days of the notice of estate recovery pursuant to Iowa Code section 633.425.

(3) The department shall determine whether undue hardship exists on a case-by-case basis. Appeals of adverse decisions regarding an undue hardship determination may be filed in accordance with 441—Chapter 7.

h. Amount waived. If collection of all or part of a debt is waived pursuant to paragraph *"g,"* to the extent that the person received the member's estate, the amount waived shall be a debt due from the following:

(1) The estate of the member's surviving spouse, upon the death of the spouse.

(2) The estate of the member's surviving child who is blind or has a disability, upon the death of the child.

(3) A surviving child who was under 21 years of age at the time of the member's death, when the child reaches the age of 21.

(4) The estate of a surviving child who was under 21 years of age at the time of the member's death, if the child dies before reaching the age of 21.

(5) The hardship waiver recipient, when the hardship no longer exists.

(6) The estate of the recipient of the undue hardship waiver, at the time of death of the hardship waiver recipient.

i. Impact of asset disregard on debt due. The estate of a member who is eligible for medical assistance under 441—subrule 75.5(5) shall not be subject to a claim for medical assistance paid on the member's behalf up to the amount of the assets disregarded by asset disregard. Medical assistance paid on behalf of the member before these conditions shall be recovered from the estate, regardless of the member's having purchased precertified or approved insurance.

j. Interest on debt. Interest shall accrue on a debt due under this subrule at the rate provided pursuant to Iowa Code section 535.3, beginning six months after the death of a Medicaid member, the surviving spouse, or the surviving child, or upon the child's reaching the age of 21.

k. Reimbursement to county. If a county reimburses the department for medical assistance provided under this subrule and the amount of medical assistance is subsequently repaid through a medical assistance income trust or a medical assistance special needs trust as defined in Iowa Code Supplement chapter 633C, the department shall reimburse the county on a proportionate basis.

[**ARC 8343B**, IAB 12/2/09, effective 1/6/10]

441—76.13(249A) Health care data match program. As a condition of doing business in Iowa, health insurers shall provide, upon the request of the state, information with respect to individuals who are eligible for or are provided medical assistance under the state's medical assistance state plan to determine (1) during what period the individual or the individual's spouse or dependents may be or may have been covered by a health insurer and (2) the nature of the coverage that is or was provided by the health insurer. This requirement applies to self-insured plans, group health plans as defined in the federal Employee Retirement Income Security Act of 1974 (Public Law 93-406), service benefit plans, managed care organizations, pharmacy benefits managers, and other parties that are, by statute, contract, or agreement, legally responsible for payment of a claim for a health care item or service.

76.13(1) *Agreement required.* The parties shall sign a data use agreement for the purposes of this rule. The agreement shall prescribe the manner in which information shall be provided to the department of human services and the acceptable uses of the information provided.

a. The initial provision of data shall include the data necessary to enable the department to match covered persons and identify third-party payers for the two-year period before the initial provision of the data. The data shall include the name, address, and identifying number of the plan.

b. Ongoing monthly matches may be limited to changes in the data previously provided, including additional covered persons, with the effective dates of the changes.

76.13(2) *Agreement form.*

a. An agreement with the department shall be in substantially the same form as Form 470-4415, Agreement for Use of Data.

b. An agreement with the department's designee shall be in a form approved by the designee, which shall include privacy protections equivalent to those provided in Form 470-4415, Agreement for Use of Data.

76.13(3) *Confidentiality of data.* The exchange of information carried out under this rule shall be consistent with all laws, regulations, and rules relating to the confidentiality or privacy of personal information or medical records, including but not limited to:

a. The federal Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, and

b. Regulations promulgated in accordance with that Act and published in 45 CFR Parts 160 through 164.

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These rules are intended to implement Iowa Code sections 249.3, 249.4, 249A.4 and 249A.5.

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CHAPTER 78
AMOUNT, DURATION AND SCOPE OF MEDICAL AND REMEDIAL SERVICES

[Prior to 7/1/83, Social Services[770] Ch 78]
[Prior to 2/11/87, Human Services[498]]

441—78.1(249A) Physicians' services. Payment will be approved for all medically necessary services and supplies provided by the physician including services rendered in the physician's office or clinic, the home, in a hospital, nursing home or elsewhere.

Payment shall be made for all services rendered by a doctor of medicine or osteopathy within the scope of this practice and the limitations of state law subject to the following limitations and exclusions:

78.1(1) Payment will not be made for:

a. Drugs dispensed by a physician or other legally qualified practitioner (dentist, podiatrist, therapeutically certified optometrist, physician assistant, or advanced registered nurse practitioner) unless it is established that there is no licensed retail pharmacy in the community in which the legally qualified practitioner's office is maintained. Payment will not be made for biological supplies and drugs provided free of charge to practitioners by the state department of public health. Rate of payment shall be established as in subrule 78.2(2), but no professional fee shall be paid.

b. Routine physical examinations. Rescinded IAB 8/1/07, effective 8/1/07.

c. Treatment of certain foot conditions as specified in 78.5(2)*"a," "b,"* and *"c."*

d. Acupuncture treatments.

e. Rescinded 9/6/78.

f. Unproven or experimental medical and surgical procedures. The criteria in effect in the Medicare program shall be utilized in determining when a given procedure is unproven or experimental in nature.

g. Charges for surgical procedures on the "Outpatient/Same Day Surgery List" produced by the Iowa Foundation for Medical Care or associated inpatient care charges when the procedure is performed in a hospital on an inpatient basis unless the physician has secured approval from the hospital's utilization review department prior to the patient's admittance to the hospital. Approval shall be granted only when inpatient care is deemed to be medically necessary based on the condition of the patient or when the surgical procedure is not performed as a routine, primary, independent procedure. The "Outpatient/Same Day Surgery List" shall be published by the department in the provider manuals for hospitals and physicians. The "Outpatient/Same Day Surgery List" shall be developed by the Iowa Foundation for Medical Care, and shall include procedures which can safely and effectively be performed in a doctor's office or on an outpatient basis in a hospital. The Iowa Foundation for Medical Care may add, delete, or modify entries on the "Outpatient/Same Day Surgery List."

78.1(2) Drugs and supplies may be covered when prescribed by a legally qualified practitioner as provided in this rule.

a. Drugs are covered as provided by rule 441—78.2(249A).

b. Medical supplies are payable when ordered by a legally qualified practitioner for a specific rather than incidental use, subject to the conditions specified in rule 441—78.10(249A). When a member is receiving care in a nursing facility or residential care facility, payment will be approved only for the following supplies when prescribed by a legally qualified practitioner:

(1) Colostomy and ileostomy appliances.

(2) Colostomy and ileostomy care dressings, liquid adhesive and adhesive tape.

(3) Disposable irrigation trays or sets.

(4) Disposable catheterization trays or sets.

(5) Indwelling Foley catheter.

(6) Disposable saline enemas.

(7) Diabetic supplies including needles and syringes, blood glucose test strips, and diabetic urine test supplies.

c. Prescription records are required for all drugs as specified in Iowa Code sections 124.308, 155A.27 and 155A.29. For the purposes of the medical assistance program, prescriptions for medical supplies are required and shall be subject to the same provisions.

d. Rescinded IAB 1/30/08, effective 4/1/08.

e. All physicians who administer vaccines which are available through the Vaccines for Children program to Medicaid members shall enroll in the Vaccines for Children program. Vaccines available through the Vaccines for Children program shall be obtained from the department of public health for Medicaid members. Physicians shall, however, receive reimbursement for the administration of these vaccines to Medicaid members.

f. Nonprescription drugs. Rescinded IAB 1/30/08, effective 4/1/08.

78.1(3) Payment will be approved for injections provided they are reasonable, necessary, and related to the diagnosis and treatment of an illness or injury. When billing for an injection, the legally qualified practitioner must specify the brand name of the drug and the manufacturer, the strength of the drug, the amount administered, and the charge of each injection. When the strength and dosage of the drug is not included, payment will be made based on the customary dosage. The following exclusions are applicable.

a. Payment will not be approved for injections when they are considered by standards of medical practice not to be specific or effective treatment for the particular condition for which they are administered.

b. Payment will not be approved for an injection when administered for a reason other than the treatment of a particular condition, illness, or injury. When injecting an amphetamine or legend vitamin, prior approval must be obtained as specified in 78.1(2)*"a"*(3).

c. Payment will not be approved when injection is not an indicated method of administration according to accepted standards of medical practice.

d. Allergenic extract materials provided the patient for self-administration shall not exceed a 90-day supply.

e. Payment will not be approved when an injection is determined to fall outside of what is medically reasonable or necessary based on basic standards of medical practice for the required level of care for a particular condition.

f. Payment will not be approved for vaccines which are available through the Vaccines for Children program. In lieu of payment, vaccines available through the Vaccines for Children program shall be accessed from the department of public health.

g. Payment will not be approved for injections of "covered Part D drugs" as defined by 42 U.S.C. Section 1395w-102(e)(1)-(2) for any "Part D eligible individual" as defined in 42 U.S.C. Section 1395w-101(a)(3)(A), including an individual who is not enrolled in a Part D plan.

78.1(4) For the purposes of this program, cosmetic, reconstructive, or plastic surgery is surgery which can be expected primarily to improve physical appearance or which is performed primarily for psychological purposes or which restores form but which does not correct or materially improve the bodily functions. When a surgical procedure primarily restores bodily function, whether or not there is also a concomitant improvement in physical appearance, the surgical procedure does not fall within the provisions set forth in this subrule. Surgeries for the purpose of sex reassignment are not considered as restoring bodily function and are excluded from coverage.

a. Coverage under the program is generally not available for cosmetic, reconstructive, or plastic surgery. However, under certain limited circumstances payment for otherwise covered services and supplies may be provided in connection with cosmetic, reconstructive, or plastic surgery as follows:

(1) Correction of a congenital anomaly; or

(2) Restoration of body form following an accidental injury; or

(3) Revision of disfiguring and extensive scars resulting from neoplastic surgery.

(4) Generally, coverage is limited to those cosmetic, reconstructive, or plastic surgery procedures performed no later than 12 months subsequent to the related accidental injury or surgical trauma. However, special consideration for exception will be given to cases involving children who may require a growth period.

b. Cosmetic, reconstructive, or plastic surgery performed in connection with certain conditions is specifically excluded. These conditions are:

(1) Dental congenital anomalies, such as absent tooth buds, malocclusion, and similar conditions.

(2) Procedures related to transsexualism, hermaphroditism, gender identity disorders, or body dysmorphic disorders.

(3) Cosmetic, reconstructive, or plastic surgery procedures performed primarily for psychological reasons or as a result of the aging process.

(4) Breast augmentation mammoplasty, surgical insertion of prosthetic testicles, penile implant procedures, and surgeries for the purpose of sex reassignment.

c. When it is determined that a cosmetic, reconstructive, or plastic surgery procedure does not qualify for coverage under the program, all related services and supplies, including any institutional costs, are also excluded.

d. Following is a partial list of cosmetic, reconstructive, or plastic surgery procedures which are not covered under the program. This list is for example purposes only and is not considered all inclusive.

(1) Any procedure performed for personal reasons, to improve the appearance of an obvious feature or part of the body which would be considered by an average observer to be normal and acceptable for the patient's age or ethnic or racial background.

(2) Cosmetic, reconstructive, or plastic surgical procedures which are justified primarily on the basis of a psychological or psychiatric need.

(3) Augmentation mammoplasties.

(4) Face lifts and other procedures related to the aging process.

(5) Reduction mammoplasties, unless there is medical documentation of intractable pain not amenable to other forms of treatment as the result of increasingly large pendulous breasts.

(6) Panniculectomy and body sculpture procedures.

(7) Repair of sagging eyelids, unless there is demonstrated and medically documented significant impairment of vision.

(8) Rhinoplasties, unless there is evidence of accidental injury occurring within the past six months which resulted in significant obstruction of breathing.

(9) Chemical peeling for facial wrinkles.

(10) Dermabrasion of the face.

(11) Revision of scars resulting from surgery or a disease process, except disfiguring and extensive scars resulting from neoplastic surgery.

(12) Removal of tattoos.

(13) Hair transplants.

(14) Electrolysis.

(15) Sex reassignment.

(16) Penile implant procedures.

(17) Insertion of prosthetic testicles.

e. Coverage is available for otherwise covered services and supplies required in the treatment of complications resulting from a noncovered incident or treatment, but only when the subsequent complications represent a separate medical condition such as systemic infection, cardiac arrest, acute drug reaction, or similar conditions. Coverage shall not be extended for any subsequent care or procedure related to the complication that is essentially similar to the initial noncovered care. An example of a complication similar to the initial period of care would be repair of facial scarring resulting from dermabrasion for acne.

78.1(5) The legally qualified practitioner's prescription for medical equipment, appliances, or prosthetic devices shall include the patient's diagnosis and prognosis, the reason the item is required, and an estimate in months of the duration of the need. Payment will be made in accordance with rule 78.10(249A).

78.1(6) Payment will be approved for the examination to establish the need for orthopedic shoes in accordance with rule 78.15(249A).

78.1(7) No payment shall be made for the services of a private duty nurse.

78.1(8) Payment for mileage shall be the same as that in effect in part B of Medicare.

78.1(9) Payment will be approved for visits to patients in nursing facilities subject to the following conditions:

a. Payment will be approved for only one visit to the same patient in a calendar month. Payment for further visits will be made only when the need for the visits is adequately documented by the physician.

b. When only one patient is seen in a single visit the allowance shall be based on a follow-up home visit. When more than one patient is seen in a single visit, payment shall be based on a follow-up office visit. In the absence of information on the claim, the carrier will assume that more than one patient was seen, and payment approved on that basis.

c. Payment will be approved for mileage in connection with nursing home visits when:

(1) It is necessary for the physician to travel outside the home community, and

(2) There are not physicians in the community in which the nursing home is located.

d. Payment will be approved for tasks related to a resident receiving nursing facility care which are performed by a physician's employee who is a nurse practitioner, clinical nurse specialist, or physician assistant as specified in subrule 81.13(13)*"e."* On-site supervision of the physician is not required for these services.

78.1(10) Payment will be approved in independent laboratory when it has been certified as eligible to participate in Medicare.

78.1(11) Rescinded, effective 8/1/87.

78.1(12) Payment will be made on the same basis as in Medicare for services associated with treatment of chronic renal disease including physician's services, hospital care, renal transplantation, and hemodialysis, whether performed on an inpatient or outpatient basis. Payment will be made for deductibles and coinsurance for those persons eligible for Medicare.

78.1(13) Payment will be made to the physician for services rendered by auxiliary personnel employed by the physician and working under the direct personal supervision of the physician, when such services are performed incident to the physician's professional service.

a. Auxiliary personnel are nurses, physician's assistants, psychologists, social workers, audiologists, occupational therapists and physical therapists.

b. An auxiliary person is considered to be an employee of the physician if the physician:

(1) Is able to control the manner in which the work is performed, i.e., is able to control when, where and how the work is done. This control need not be actually exercised by the physician.

(2) Sets work standards.

(3) Establishes job description.

(4) Withholds taxes from the wages of the auxiliary personnel.

c. Direct personal supervision in the office setting means the physician must be present in the same office suite, not necessarily the same room, and be available to provide immediate assistance and direction.

Direct personal supervision outside the office setting, such as the member's home, hospital, emergency room, or nursing facility, means the physician must be present in the same room as the auxiliary person.

Advanced registered nurse practitioners certified under board of nursing rules 655—Chapter 7 performing services within their scope of practice are exempt from the direct personal supervision requirement for the purpose of reimbursement to the employing physicians. In these exempted circumstances, the employing physicians must still provide general supervision and be available to provide immediate needed assistance by telephone. Advanced registered nurse practitioners who prescribe drugs and medical devices are subject to the guidelines in effect for physicians as specified in rule 441—78.1(249A).

A physician assistant licensed under board of physician assistants' professional licensure rules in 645—Chapter 325 is exempt from the direct personal supervision requirement but the physician must still provide general supervision and be available to provide immediate needed assistance by telephone.

Physician assistants who prescribe drugs and medical devices are subject to the guidelines in effect for physicians as specified in rule 441—78.1(249A).

d. Services incident to the professional services of the physician means the service provided by the auxiliary person must be related to the physician's professional service to the member. If the physician has not or will not perform a personal professional service to the member, the clinical records must document that the physician assigned treatment of the member to the auxiliary person.

78.1(14) Payment will be made for persons aged 20 and under for nutritional counseling provided by a licensed dietitian employed by or under contract with a physician for a nutritional problem or condition of a degree of severity that nutritional counseling beyond that normally expected as part of the standard medical management is warranted. For persons eligible for the WIC program, a WIC referral is required. Medical necessity for nutritional counseling services exceeding those available through WIC shall be documented.

78.1(15) The certification of inpatient hospital care shall be the same as that in effect in part A of Medicare. The hospital admittance record is sufficient for the original certification.

78.1(16) No payment will be made for sterilization of an individual under the age of 21 or who is mentally incompetent or institutionalized. Payment will be made for sterilization performed on an individual who is aged 21 or older at the time the informed consent is obtained and who is mentally competent and not institutionalized when all the conditions in this subrule are met.

a. The following definitions are pertinent to this subrule:

(1) Sterilization means any medical procedure, treatment, or operation performed for the purpose of rendering an individual permanently incapable of reproducing and which is not a necessary part of the treatment of an existing illness or medically indicated as an accompaniment of an operation on the genital urinary tract. Mental illness or retardation is not considered an illness or injury.

(2) Hysterectomy means a medical procedure or operation to remove the uterus.

(3) Mentally incompetent individual means a person who has been declared mentally incompetent by a federal, state or local court of jurisdiction for any purpose, unless the individual has been declared competent for purposes which include the ability to consent to sterilization.

(4) Institutionalized individual means an individual who is involuntarily confined or detained, under a civil or criminal statute, in a correctional or rehabilitative facility, including a mental hospital or other facility for the care and treatment of mental illness, or an individual who is confined under a voluntary commitment in a mental hospital or other facility for the care and treatment of mental illness.

b. The sterilization shall be performed as the result of a voluntary request for the services made by the person on whom the sterilization is performed.

c. The person shall be advised prior to the receipt of consent that no benefits provided under the medical assistance program or other programs administered by the department may be withdrawn or withheld by reason of a decision not to be sterilized.

d. The person shall be informed that the consent can be withheld or withdrawn any time prior to the sterilization without prejudicing future care and without loss of other project or program benefits.

e. The person shall be given a complete explanation of the sterilization. The explanation shall include:

(1) A description of available alternative methods and the effect and impact of the proposed sterilization including the fact that it must be considered to be an irreversible procedure.

(2) A thorough description of the specific sterilization procedure to be performed and benefits expected.

(3) A description of the attendant discomforts and risks including the type and possible effects of any anesthetic to be used.

(4) An offer to answer any inquiries the person to be sterilized may have concerning the procedure to be performed. The individual shall be provided a copy of the informed consent form in addition to the oral presentation.

f. At least 30 days and not more than 180 days shall have elapsed following the signing of the informed consent except in the case of premature delivery or emergency abdominal surgery which occurs not less than 72 hours after the informed consent was signed. The informed consent shall have

been signed at least 30 days prior to the expected delivery date for premature deliveries. Consent shall be obtained on Form 470-0835 or 470-0835(S), Consent Form, and shall be attached to the claim for payment.

g. The information in paragraphs *"b"* through *"f"* shall be effectively presented to a blind, deaf, or otherwise handicapped individual and an interpreter shall be provided when the individual to be sterilized does not understand the language used on the consent form or used by the person obtaining consent. The individual to be sterilized may have a witness of the individual's choice present when consent is obtained.

h. Form 470-0835 or 470-0835(S), Consent Form, shall be signed by the individual to be sterilized, the interpreter, when one was necessary, the physician, and the person who provided the required information.

i. Informed consent shall not be obtained while the individual to be sterilized is:

(1) In labor or childbirth, or

(2) Seeking to obtain or obtaining an abortion, or

(3) Under the influence of alcohol or other substance that affects the individual's state of awareness.

j. Payment will be made for a medically necessary hysterectomy only when it is performed for a purpose other than sterilization and only when one or more of the following conditions is met:

(1) The individual or representative has signed an acknowledgment that she has been informed orally and in writing from the person authorized to perform the hysterectomy that the hysterectomy will make the individual permanently incapable of reproducing, or

(2) The individual was already sterile before the hysterectomy, the physician has certified in writing that the individual was already sterile at the time of the hysterectomy and has stated the cause of the sterility, or

(3) The hysterectomy was performed as a result of a life-threatening emergency situation in which the physician determined that prior acknowledgment was not possible and the physician includes a description of the nature of the emergency.

78.1(17) Abortions. Payment for an abortion or related service is made when Form 470-0836 is completed for the applicable circumstances and is attached to each claim for services. Payment for an abortion is made under one of the following circumstances:

a. The physician certifies that the pregnant woman's life would be endangered if the fetus were carried to term.

b. The physician certifies that the fetus is physically deformed, mentally deficient or afflicted with a congenital illness and the physician states the medical indication for determining the fetal condition.

c. The pregnancy was the result of rape reported to a law enforcement agency or public or private health agency which may include a family physician within 45 days of the date of occurrence of the incident. The report shall include the name, address, and signature of the person making the report. Form 470-0836 shall be signed by the person receiving the report of the rape.

d. The pregnancy was the result of incest reported to a law enforcement agency or public or private health agency including a family physician no later than 150 days after the date of occurrence. The report shall include the name, address, and signature of the person making the report. Form 470-0836 shall be signed by the person receiving the report of incest.

78.1(18) Payment and procedure for obtaining eyeglasses, contact lenses, and visual aids, shall be the same as described in 441—78.6(249A). (Cross-reference 78.28(3))

78.1(19) Preprocedure review by the Iowa Foundation for Medical Care (IFMC) will be required if payment under Medicaid is to be made for certain frequently performed surgical procedures which have a wide variation in the relative frequency the procedures are performed. Preprocedure surgical review applies to surgeries performed in hospitals (outpatient and inpatient) and ambulatory surgical centers. Approval by the IFMC will be granted only if the procedures are determined to be necessary based on the condition of the patient and the published criteria established by the IFMC and the department. If not so approved by the IFMC, payment will not be made under the program to the physician or to the facility in which the surgery is performed. The criteria are available from IFMC, 6000 Westown Parkway, Suite 350E, West Des Moines, Iowa 50265-7771, or in local hospital utilization review offices.

The "Preprocedure Surgical Review List" shall be published by the department in the provider manuals for physicians, hospitals, and ambulatory surgical centers. The "Preprocedure Surgical Review List" shall be developed by the department with advice and consultation from the IFMC and appropriate professional organizations and will list the procedures for which prior review is required and the steps that must be followed in requesting such review. The department shall update the "Preprocedure Surgical Review List" annually. (Cross-reference 78.28(1)*"e."*)

78.1(20) Transplants.

a. Payment will be made only for the following organ and tissue transplant services:

(1) Kidney, cornea, skin, and bone transplants.

(2) Allogeneic bone marrow transplants for the treatment of aplastic anemia, severe combined immunodeficiency disease, Wiskott-Aldrich syndrome, or the following types of leukemia: acute myelocytic leukemia in relapse or remission, chronic myelogenous leukemia, and acute lemphocytic leukemia in remission.

(3) Autologous bone marrow transplants for treatment of the following conditions: acute leukemia in remission with a high probability of relapse when there is no matched donor; resistant non-Hodgkin's lymphomas; lymphomas presenting poor prognostic features; recurrent or refractory neuroblastoma; or advanced Hodgkin's disease when conventional therapy has failed and there is no matched donor.

(4) Liver transplants for persons with extrahepatic biliary artesia or any other form of end-stage liver disease, except that coverage is not provided for persons with a malignancy extending beyond the margins of the liver.

Liver transplants require preprocedure review by the Iowa Foundation for Medical Care. (Cross-reference 78.1(19) and 78.28(1)*"f."*)

Covered liver transplants are payable only when performed in a facility that meets the requirements of 78.3(10).

(5) Heart transplants. Artificial hearts and ventricular assist devices, either as a permanent replacement for a human heart or as a temporary life-support system until a human heart becomes available for transplants, are not covered. Heart-lung transplants are covered where bilateral or unilateral lung transplantation with repair of a congenital cardiac defect is contraindicated.

Heart transplants and heart-lung transplants described above require preprocedure review by the Iowa Foundation for Medical Care. (Cross-reference 78.1(19) and 78.28(1)*"f."*) Covered heart transplants are payable only when performed in a facility that meets the requirements of 78.3(10).

(6) Lung transplants. Lung transplants for persons having end-stage pulmonary disease. Lung transplants require preprocedure review by the Iowa Foundation for Medical Care. (Cross-reference 78.1(19) and 78.28(1)*"f."*) Covered transplants are payable only when performed in a facility that meets the requirements of 78.3(10). Heart-lung transplants are covered consistent with criteria in subparagraph (5) above.

(7) Pancreas transplants for persons with type I diabetes mellitus, as follows:

1. Simultaneous pancreas-kidney transplants and pancreas after kidney transplants are covered.

2. Pancreas transplants alone are covered for persons exhibiting any of the following:

- A history of frequent, acute, and severe metabolic complications (e.g., hypoglycemia, hyperglycemia, or ketoacidosis) requiring medical attention.
- Clinical problems with exogenous insulin therapy that are so severe as to be incapacitating.
- Consistent failure of insulin-based management to prevent acute complications.

The pancreas transplants listed under this subparagraph require preprocedure review by the Iowa Foundation for Medical Care. (Cross-reference 78.1(19) and 78.28(1)*"f."*)

Covered transplants are payable only when performed in a facility that meets the requirements of 78.3(10).

Transplantation of islet cells or partial pancreatic tissue is not covered.

b. Donor expenses incurred directly in connection with a covered transplant are payable. Expenses incurred for complications that arise with respect to the donor are covered only if they are directly and immediately attributed to surgery. Expenses of searching for a donor are not covered.

c. All transplants must be medically necessary and meet other general requirements of this chapter for physician and hospital services.

d. Payment will not be made for any transplant not specifically listed in paragraph *"a."*

78.1(21) Utilization review. Utilization review shall be conducted of Medicaid members who access more than 24 outpatient visits in any 12-month period from physicians, advanced registered nurse practitioners, federally qualified health centers, other clinics, and emergency rooms. For the purposes of utilization review, the term "physician" does not include a psychiatrist. Refer to rule 441—76.9(249A) for further information concerning the member lock-in program.

78.1(22) Risk assessment. Risk assessment, using Form 470-2942, Medicaid Prenatal Risk Assessment, shall be completed at the initial visit during a Medicaid member's pregnancy.

a. If the risk assessment reflects a low-risk pregnancy, the assessment shall be completed again at approximately the twenty-eighth week of pregnancy.

b. If the risk assessment reflects a high-risk pregnancy, referral shall be made for enhanced services. Enhanced services include health education, social services, nutrition education, and a postpartum home visit. Additional reimbursement shall be provided for obstetrical services related to a high-risk pregnancy. (See description of enhanced services at subrule 78.25(3).)

78.1(23) EPSDT care coordination. Rescinded IAB 12/3/08, effective 2/1/09.

78.1(24) Topical fluoride varnish. Payment shall be made for application of an FDA-approved topical fluoride varnish, as defined by the Current Dental Terminology, Third Edition (CDT-3), for the purpose of preventing the worsening of early childhood caries in children aged 0 to 36 months of age, when rendered by physicians acting within the scope of their practice, licensure, and other applicable state law, subject to the following provisions and limitations:

a. Application of topical fluoride varnish must be provided in conjunction with an early and periodic screening, diagnosis, and treatment (EPSDT) examination which includes a limited oral screening.

b. Separate payment shall be available only for application of topical fluoride varnish, which shall be at the same rate of reimbursement paid to dentists for providing this service. Separate payment for the limited oral screening shall not be available, as this service is already part of and paid under the EPSDT screening examination.

c. Parents, legal guardians, or other authorized caregivers of children receiving application of topical fluoride varnish as part of an EPSDT screening examination shall be informed by the physician or auxiliary staff employed by and under the physician's supervision that this application is not a substitute for comprehensive dental care.

d. Physicians rendering the services under this subrule shall make every reasonable effort to refer or facilitate referral of these children for comprehensive dental care rendered by a dental professional.

This rule is intended to implement Iowa Code section 249A.4.

441—78.2(249A) Prescribed outpatient drugs. Payment will be made for "covered outpatient drugs" as defined in 42 U.S.C. Section 1396r-8(k)(2)-(4) subject to the conditions and limitations specified in this rule.

78.2(1) *Qualified prescriber.* All drugs are covered only if prescribed by a legally qualified practitioner (physician, dentist, podiatrist, therapeutically certified optometrist, physician assistant, or advanced registered nurse practitioner).

78.2(2) *Prescription required.* As a condition of payment for all drugs, including "nonprescription" or "over-the-counter" drugs that may otherwise be dispensed without a prescription, a prescription shall be transmitted as specified in Iowa Code sections 124.308 and 155A.27, subject to the provisions of Iowa Code section 155A.29 regarding refills. All prescriptions shall be available for audit by the department.

78.2(3) *Qualified source.* All drugs are covered only if marketed by manufacturers that have signed a Medicaid rebate agreement with the Secretary of Health and Human Services in accordance with Public Law 101-508 (Omnibus Budget Reconciliation Act of 1990).

78.2(4) *Prescription drugs.* Drugs that may be dispensed only upon a prescription are covered subject to the following limitations.

a. Prior authorization is required as specified in the preferred drug list published by the department pursuant to Iowa Code section 249A.20A. For drugs requiring prior authorization, reimbursement will be made for a 72-hour supply dispensed in an emergency when a prior authorization request cannot be submitted.

b. Payment is not made for:

(1) Drugs whose prescribed use is not for a medically accepted indication as defined by Section 1927(k)(6) of the Social Security Act.

(2) Drugs used to cause anorexia, weight gain, or weight loss, except for lipase inhibitor drugs prescribed for weight loss with prior authorization as provided in paragraph *"a."*

(3) Drugs used for cosmetic purposes or hair growth.

(4) Drugs used to promote smoking cessation, except for varenicline with prior authorization as provided in paragraph *"a"* above and generic, sustained-release bupropion products that are indicated for smoking cessation by the U.S. Food and Drug Administration.

(5) Otherwise covered outpatient drugs if the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or the manufacturer's designee.

(6) Drugs described in Section 107(c)(3) of the Drug Amendments of 1962 and identical, similar, or related drugs (within the meaning of Section 310.6(b)(1) of Title 21 of the Code of Federal Regulations (drugs identified through the Drug Efficacy Study Implementation (DESI) review)).

(7) "Covered Part D drugs" as defined by 42 U.S.C. Section 1395w-102(e)(1)-(2) for any "Part D eligible individual" as defined by 42 U.S.C. Section 1395w-101(a)(3)(A), including a member who is not enrolled in a Medicare Part D plan.

(8) Drugs prescribed for fertility purposes, except when prescribed for a medically accepted indication other than infertility, as defined in subparagraph (1).

(9) Drugs used for the treatment of sexual or erectile dysfunction, except when used to treat a condition other than sexual or erectile dysfunction for which the drug has been approved by the U.S. Food and Drug Administration.

(10) Prescription drugs for which the prescription was executed in written (and nonelectronic) form unless the prescription was executed on a tamper-resistant pad, as required by Section 1903(i)(23) of the Social Security Act (42 U.S.C. Section 1396b(i)(23)).

78.2(5) *Nonprescription drugs.* The following drugs that may otherwise be dispensed without a prescription are covered subject to the prior authorization requirements stated below and as specified in the preferred drug list published by the department pursuant to Iowa Code section 249A.20A:

Acetaminophen tablets 325 mg, 500 mg
Acetaminophen elixir 160 mg/5 ml
Acetaminophen solution 100 mg/ml
Acetaminophen suppositories 120 mg
Artificial tears ophthalmic solution
Artificial tears ophthalmic ointment
Aspirin tablets 325 mg, 650 mg, 81 mg (chewable)
Aspirin tablets, enteric coated 325 mg, 650 mg, 81 mg
Aspirin tablets, buffered 325 mg
Bacitracin ointment 500 units/gm
Benzoyl peroxide 5%, gel, lotion
Benzoyl peroxide 10%, gel, lotion
Calcium carbonate chewable tablets 1250 mg (500 mg elemental calcium)
Calcium carbonate suspension 1250 mg/5 ml
Calcium carbonate tablets 600 mg
Calcium carbonate-vitamin D tablets 500 mg-200 units
Calcium carbonate-vitamin D tablets 600 mg-200 units
Calcium citrate tablets 950 mg (200 mg elemental calcium)
Calcium gluconate tablets 650 mg

Calcium lactate tablets 650 mg
Cetirizine hydrochloride liquid 1 mg/ml
Cetirizine hydrochloride tablets 5 mg
Cetirizine hydrochloride tablets 10 mg
Chlorpheniramine maleate tablets 4 mg
Clotrimazole vaginal cream 1%
Diphenhydramine hydrochloride capsules 25 mg
Diphenhydramine hydrochloride elixir, liquid, and syrup 12.5 mg/5 ml
Epinephrine racemic solution 2.25%
Ferrous sulfate tablets 325 mg
Ferrous sulfate elixir 220 mg/5 ml
Ferrous sulfate drops 75 mg/0.6 ml
Ferrous gluconate tablets 325 mg
Ferrous fumarate tablets 325 mg
Guaifenesin 100 mg/5 ml with dextromethorphan 10 mg/5 ml liquid
Ibuprofen suspension 100 mg/5 ml
Ibuprofen tablets 200 mg
Insulin
Lactic acid (ammonium lactate) lotion 12%
Loperamide hydrochloride liquid 1 mg/5 ml
Loperamide hydrochloride tablets 2 mg
Loratadine syrup 5 mg/5 ml
Loratadine tablets 10 mg
Magnesium hydroxide suspension 400 mg/5 ml
Magnesium oxide capsule 140 mg (85 mg elemental magnesium)
Magnesium oxide tablets 400 mg
Meclizine hydrochloride tablets 12.5 mg, 25 mg oral and chewable
Miconazole nitrate cream 2% topical and vaginal
Miconazole nitrate vaginal suppositories, 100 mg
Multiple vitamin and mineral products with prior authorization
Neomycin-bacitracin-polymyxin ointment
Niacin (nicotinic acid) tablets 50 mg, 100 mg, 250 mg, 500 mg
Nicotine gum 2 mg, 4 mg
Nicotine patch 7 mg/day, 14 mg/day and 21 mg/day
Pediatric oral electrolyte solutions
Permethrin liquid 1%
Pseudoephedrine hydrochloride tablets 30 mg, 60 mg
Pseudoephedrine hydrochloride liquid 30 mg/5 ml
Pseudoephedrine/dextromethorphan 15 mg/7.5 mg/5 mL liquid
Pseudoephedrine/dextromethorphan 20 mg/10 mg/5 mL liquid
Pseudoephedrine/dextromethorphan 30 mg/15 mg/5 mL liquid
Pseudoephedrine/dextromethorphan 20 mg/10 mg/5 mL elixir
Pseudoephedrine/dextromethorphan 15 mg/7.5 mg/5 mL syrup
Pseudoephedrine/dextromethorphan 30 mg/15 mg/5 mL syrup
Pseudoephedrine/dextromethorphan 7.5 mg/2.5 mg/0.8 mL solution
Pyrethrins-piperonyl butoxide liquid 0.33-4%
Pyrethrins-piperonyl butoxide shampoo 0.3-3%
Pyrethrins-piperonyl butoxide shampoo 0.33-4%
Salicylic acid liquid 17%
Senna tablets 187 mg
Sennosides-docusate sodium tablets 8.6 mg-50 mg
Sennosides syrup 8.8 mg/5 ml

Sennosides tablets 8.6 mg
Sodium bicarbonate tablets 325 mg
Sodium bicarbonate tablets 650 mg
Sodium chloride hypertonic ophthalmic ointment 5%
Sodium chloride hypertonic ophthalmic solution 5%
Tolnaftate 1% cream, solution, powder

Other nonprescription drugs listed as preferred in the preferred drug list published by the department pursuant to Iowa Code section 249A.20A.

78.2(6) *Quantity prescribed and dispensed.*

a. When it is not therapeutically contraindicated, the legally qualified practitioner shall prescribe a quantity of prescription medication sufficient for up to a 31-day supply. Oral contraceptives may be prescribed in 90-day quantities.

b. Oral solid forms of covered nonprescription items shall be prescribed and dispensed in a minimum quantity of 100 units per prescription or the currently available consumer package size except when dispensed via a unit-dose system.

78.2(7) *Lowest cost item.* The pharmacist shall dispense the lowest cost item in stock that meets the requirements of the practitioner as shown on the prescription.

78.2(8) *Consultation.* In accordance with Public Law 101-508 (Omnibus Budget Reconciliation Act of 1990), a pharmacist shall offer to discuss information regarding the use of the medication with each Medicaid member or the caregiver of a member presenting a prescription. The consultation is not required if the person refuses the consultation. Standards for the content of the consultation shall be found in rules of the Iowa board of pharmacy.

This rule is intended to implement Iowa Code section 249A.4.

[**ARC 8097B**, IAB 9/9/09, effective 11/1/09]

441—78.3(249A) Inpatient hospital services. Payment for inpatient hospital admission is approved when it meets the criteria for inpatient hospital care as determined by the Iowa Foundation for Medical Care (IFMC). All cases are subject to random retrospective review and may be subject to a more intensive retrospective review if abuse is suspected. In addition, transfers, outliers, and readmissions within 31 days are subject to random review. Readmissions to the same facility due to premature discharge shall not be paid a new DRG. Selected admissions and procedures are subject to a 100 percent review before the services are rendered. Medicaid payment for inpatient hospital admissions and continued stays are approved when the admissions and continued stays are determined to meet the criteria for inpatient hospital care. (Cross-reference 78.28(5)) The criteria are available from IFMC, 6000 Westown Parkway, Suite 350E, West Des Moines, Iowa 50265-7771, or in local hospital utilization review offices. No payment will be made for waiver days.

See rule 441—78.31(249A) for policies regarding payment of hospital outpatient services.

If the recipient is eligible for inpatient or outpatient hospital care through the Medicare program, payment will be made for deductibles and coinsurance as set out in 441—subrule 79.1(22).

The DRG payment calculations include any special services required by the hospital, including a private room.

78.3(1) Payment for Medicaid-certified physical rehabilitation units will be approved for the day of admission but not the day of discharge or death.

78.3(2) No payment will be approved for private duty nursing.

78.3(3) Certification of inpatient hospital care shall be the same as that in effect in part A of Medicare. The hospital admittance records are sufficient for the original certification.

78.3(4) Services provided for intestinal or gastric bypass surgery for treatment of obesity requires prior approval, which must be obtained by the attending physician before surgery is performed.

78.3(5) Payment will be approved for drugs provided inpatients subject to the same provisions specified in 78.2(1) and 78.2(4)*"b"*(1) to (10) except for 78.2(4)*"b"*(7). The basis of payment for drugs administered to inpatients is through the DRG reimbursement.

a. Payment will be approved for drugs and supplies provided outpatients subject to the same provisions specified in 78.2(1) through 78.2(4) except for 78.2(4)*"b"*(7). The basis of payment for drugs provided outpatients is through a combination of Medicaid-determined fee schedules and ambulatory payment classification, pursuant to 441—subrule 79.1(16).

b. Hospitals that wish to administer vaccines which are available through the Vaccines for Children program to Medicaid members shall enroll in the Vaccines for Children program. In lieu of payment, vaccines available through the Vaccines for Children program shall be accessed from the department of public health for Medicaid members.

78.3(6) Payment for nursing care provided by a hospital shall be made to those hospitals which have been certified by the department of inspections and appeals as meeting the standards for a nursing facility.

78.3(7) Payment for inpatient hospital tests for purposes of diagnosis and treatment shall be made only when the tests are specifically ordered for the diagnosis and treatment of a particular patient's condition by the attending physician or other licensed practitioner acting within the scope of practice as defined by law, who is responsible for that patient's diagnosis or treatment.

78.3(8) Rescinded IAB 2/6/91, effective 4/1/91.

78.3(9) Payment will be made for sterilizations in accordance with 78.1(16).

78.3(10) Payment will be approved for organ and tissue transplant services, as specified in subrule 78.1(20). Kidney, cornea, skin, bone, allogeneic bone marrow, autologous bone marrow, heart, liver, and lung transplants are covered as specified in subrule 78.1(20). Lung transplants are payable at Medicare-designated lung transplant centers only. Heart and liver transplants are payable when performed at facilities that meet the following criteria:

a. Recipient selection and education.

(1) *Selection.* The transplant center must have written criteria based on medical need for transplantation for final facility selection of recipients. These criteria should include an equitable, consistent and practical protocol for selection of recipients. The criteria must be at least as strict as those specified by Medicare.

(2) *Education.* The transplant center will provide a written plan for recipient education. It shall include educational plans for recipient, family and significant others during all phases of the program. These phases shall include:

Intake.

Preparation and waiting period.

Preadmission.

Hospitalization.

Discharge planning.

Follow-up.

b. Staffing and resource commitment.

(1) *Transplant surgeon.* The transplant center must have on staff a qualified transplant surgeon.

The surgeon must have received at least one year of training at a transplant center approved by the American Society of Transplant Surgeons under the direction of an experienced transplant surgeon and must have had at least two years of experience in all facets of transplant surgery specific to the surgeon's specialty. This experience must include management of recipients' presurgical and postsurgical care and actual experience as a member of a transplant team at the institution. The transplant surgeon will have an understanding of the principles of and demonstrated expertise in the use of immunosuppressive therapy.

The transplant surgeon will be certified by the American Board of Thoracic Surgery or equivalent for heart transplants and the American Board of Surgery or equivalent for liver transplants.

The transplant surgeon will be the defined leader of a stable, established transplant team that has a strong commitment to the transplant program.

(2) *Transplant team.* The transplant team will be clearly defined with leadership and corresponding responsibilities of all team members identified.

The team should consist of:

A surgeon director.

A board-certified internist or pediatrician with training and expertise in organ transplantation medicine and clinical use of immunosuppressive regimens.

The transplant center will assume responsibility for initial training and continuing education of the transplant team and ancillary personnel. The center will maintain records that demonstrate competency in achieving, maintaining and improving skills in the distinct areas of expertise of each of the team members.

(3) *Physicians.* The transplant center will have on staff or available for consultation physicians with the following areas of expertise:

Anesthesiology.

Cardiology.

Dialysis.

Gastroenterology.

Hepatology.

Immunology.

Infectious diseases.

Nephrology.

Neurology.

Pathology.

Pediatrics.

Psychiatry.

Pulmonary medicine.

Radiology.

Rehabilitation medicine.

Liaison with the recipient's permanent physician is established for the purpose of providing continuity and management of the recipient's long-term care.

(4) *Support personnel and resources.* The center must have a commitment of sufficient resources and planning for implementation and operation of the transplant program. Indicators of the commitment will include the following:

Persons with expertise in the following areas available at the transplant center:

Anesthesiology.

Blood bank services.

Cardiology.

Cardiovascular surgery.

Dialysis.

Dietary services.

Gastroenterology.

Infection control.

Laboratory services (pathology, microbiology, immunology, tissue typing, and monitoring of immunosuppressive drugs).

Legal counsel familiar with transplantation laws and regulations.

Nursing service department with staff available who have expertise in the care of transplant recipients, especially in managing immunosuppressed patients and hemodynamic support.

Respiratory therapy.

Pharmaceutical services.

Physical therapy.

Psychiatry.

Psycho-social.

The center will have active cardiovascular, medical, and surgical programs with the ability and willingness to perform diagnostic and evaluative procedures appropriate to transplants on an emergency and ongoing basis.

The center will have designated an adequate number of intensive care and general service beds to support the transplant center.

(5) *Laboratory.* Each transplant center must have direct local 24-hour per day access to histocompatibility testing facilities. These facilities must meet the Standards for Histocompatibility Testing set forth by the Committee on Quality Assurance and Standards of the American Society for Histocompatibility and Immunogenetics (ASHI). As specified by ASHI, the director of the facility shall hold a doctoral degree in biological science, or be a physician, and subsequent to graduation shall have had four years' experience in immunology, two of which were devoted to formal training in human histocompatibility testing, documented to be professionally competent by external measures such as national proficiency testing, participation in national or international workshops or publications in peer-reviewed journals. The laboratory must successfully participate in a regional or national testing program.

c. Experience and survival rates.

(1) *Experience.* Centers will be given a minimum volume requirement of 12 heart or 12 liver transplants that should be met within one year. Due to special considerations such as patient case mix or donor availability, an additional one year conditional approval may be given if the minimum volume is not met the first year.

For approval of an extrarenal organ transplant program it is highly desirable that the institution: 1. has available a complete team of surgeons, physicians, and other specialists with specific experience in transplantation of that organ, or 2. has an established approved renal transplant program at that institution and personnel with expertise in the extrarenal organ system itself.

(2) *Survival rates.* The transplant center will achieve a record of acceptable performance consistent with the performance and outcomes at other successful designated transplant centers. The center will collect and maintain recipient and graft survival and complication rates. A level of satisfactory success and safety will be demonstrated with bases for substantial probability of continued performance at an acceptable level.

To encourage a high level of performance, transplant programs must achieve and maintain a minimum one-year patient survival rate of 70 percent for heart transplants and 50 percent for liver transplants.

d. Organ procurement. The transplant center will participate in a nationwide organ procurement and typing network.

Detailed plans must exist for organ procurement yielding viable transplantable organs in reasonable numbers, meeting established legal and ethical criteria.

The transplant center must be a member of the National Organ Procurement and Transplant Network.

e. Maintenance of data, research, review and evaluation.

(1) *Maintenance of data.* The transplant center will collect and maintain data on the following:

Risk and benefit.

Morbidity and mortality.

Long-term survival.

Quality of life.

Recipient demographic information.

These data should be maintained in the computer at the transplant center monthly.

The transplant center will submit the above data to the United Network of Organ Sharing yearly.

(2) *Research.* The transplant center will have a plan for and a commitment to research.

Ongoing research regarding the transplanted organs is required.

The transplant center will have a program in graduate medical education or have a formal agreement with a teaching institution for affiliation with a graduate medical education program.

(3) *Review and evaluation.* The transplant center will have a plan for ongoing evaluation of the transplantation program.

The transplant center will have a detailed plan for review and evaluation of recipient selection, preoperative, operative, postoperative and long-term management of the recipient.

The transplant center will conduct concurrent ongoing studies to ensure high quality services are provided in the transplantation program.

The transplant center will provide information to members of the transplant team and ancillary staff regarding the findings of the quality assurance studies. This information will be utilized to provide education geared toward interventions to improve staff performance and reduce complications occurring in the transplant process.

The transplant center will maintain records of all quality assurance and peer review activities concerning the transplantation program to document identification of problems or potential problems, intervention, education and follow-up.

f. Application procedure. A Medicare-designated heart, liver, or lung transplant facility needs only to submit evidence of this designation to the Iowa Medicaid enterprise provider services unit. The application procedure for other heart and liver facilities is as follows:

(1) An original and two copies of the application must be submitted on 8½ by 11 inch paper, signed by a person authorized to do so. The facility must be a participating hospital under Medicaid and must specify its provider number, and the name and telephone number of a contact person should there be questions regarding the application.

(2) Information and data must be clearly stated, well organized and appropriately indexed to aid in its review against the criteria specified in this rule. Each page must be numbered.

(3) To the extent possible, the application should be organized into five sections corresponding to each of the five major criteria and addressing, in order, each of the subcriteria identified.

(4) The application should be mailed to the Iowa Medicaid enterprise provider services unit.

g. Review and approval of facilities. An organized review committee will be established to evaluate performance and survival statistics and make recommendations regarding approval as a designated transplant center based on acceptable performance standards established by the review organization and approved by the Medicaid agency.

There will be established protocol for the systematic evaluation of patient outcome including survival statistics.

Once a facility applies for approval and is approved as a heart or liver transplant facility for Medicaid purposes, it is obliged to report immediately to the department any events or changes which would affect its approved status. Specifically, a facility must report any significant decrease in its experience level or survival rates, the transplantation of patients who do not meet its patient selection criteria, the loss of key members of the transplant team, or any other major changes that could affect the performance of heart or liver transplants at the facility. Changes from the terms of approval may lead to withdrawal of approval for Medicaid coverage of heart or liver transplants performed at the facility.

78.3(11) Payment will be approved for inpatient hospital care rendered a patient in connection with dental treatment only when the mental, physical, or emotional condition of the patient prevents the dentist from providing this necessary care in the office.

78.3(12) Payment will be approved for an assessment fee as specified in 441—paragraphs 79.1(16)*"a"* and *"r"* to determine if a medical emergency exists.

Medical emergency is defined as a sudden or unforeseen occurrence or combination of circumstances presenting a substantial risk to an individual's health unless immediate medical treatment is given.

The determination of whether a medical emergency exists will be based on the patient's medical condition including presenting symptoms and medical history prior to treatment or evaluation.

78.3(13) Payment for patients in acute hospital beds who are determined by IFMC to require the skilled nursing care level of care shall be made at an amount equal to the sum of the direct care rate component limit for Medicare-certified hospital-based nursing facilities pursuant to 441—subparagraph 81.6(16)*"f"*(3) plus the non-direct care rate component limit for Medicare-certified hospital-based nursing facilities pursuant to 441—subparagraph 81.6(16)*"f"*(3), with the rate component limits being revised July 1, 2001, and every second year thereafter. This rate is effective *(a)* as of the date of notice by IFMC that the lower level of care is required or *(b)* for the days IFMC determines in an outlier review that the lower level of care was required.

78.3(14) Payment for patients in acute hospital beds who are determined by IFMC to require nursing facility level of care shall be made at an amount equal to the sum of the direct care rate component limit for Medicaid nursing facilities pursuant to 441—subparagraph 81.6(16)*"f"*(1) plus the non-direct

care rate component limit for Medicaid nursing facilities pursuant to 441—subparagraph 81.6(16)*"f"*(1), with the rate component limits being revised July 1, 2001, and every second year thereafter. This rate is effective *(a)* as of the date of notice by IFMC that the lower level of care is required or *(b)* for the days IFMC determines in an outlier review that the lower level of care was required.

78.3(15) Payment for inpatient hospital charges associated with surgical procedures on the "Outpatient/Same Day Surgery List" produced by the Iowa Foundation for Medical Care shall be made only when attending physician has secured approval from the hospital's utilization review department prior to admittance to the hospital. Approval shall be granted when inpatient care is deemed to be medically necessary based on the condition of the patient or when the surgical procedure is not performed as a routine, primary, independent procedure. The "Outpatient/Same Day Surgery List" shall be published by the department in the provider manuals for hospitals and physicians. The "Outpatient/Same Day Surgery List" shall be developed by the Iowa Foundation for Medical Care, and shall include procedures which can safely and effectively be performed in a doctor's office or on an outpatient basis in a hospital. The Iowa Foundation for Medical Care may add, delete or modify entries on the "Outpatient/Same Day Surgery List."

78.3(16) Payment will be made for medically necessary skilled nursing care when provided by a hospital participating in the swing-bed program certified by the department of inspections and appeals and approved by the U.S. Department of Health and Human Services. Payment shall be at an amount equal to the sum of the direct care rate component limit for Medicare-certified hospital-based nursing facilities pursuant to 441—subparagraph 81.6(16)*"f"*(3) and the non-direct care rate component limit for Medicare-certified hospital-based nursing facilities pursuant to 441—subparagraph 81.6(16)*"f"*(3), with the rate component limits being revised July 1, 2001, and every second year thereafter.

78.3(17) Rescinded IAB 8/9/89, effective 10/1/89.

78.3(18) Preprocedure review by the IFMC is required if hospitals are to be reimbursed for certain frequently performed surgical procedures as set forth under subrule 78.1(19). Criteria are available from IFMC, 6000 Westown Parkway, Suite 350E, West Des Moines, Iowa 50265-7771, or in local hospital utilization review offices. (Cross-reference 78.28(5))

78.3(19) Rescinded IAB 10/8/97, effective 12/1/97.

This rule is intended to implement Iowa Code section 249A.4.

441—78.4(249A) Dentists. Payment will be made for medical and surgical services furnished by a dentist to the extent these services may be performed under state law either by doctors of medicine, osteopathy, dental surgery or dental medicine and would be covered if furnished by doctors of medicine or osteopathy. Payment will also be made for the following dental procedures subject to the exclusions for services to adults 21 years of age and older set forth in subrule 78.4(14):

78.4(1) *Preventive services.* Payment shall be made for the following preventive services:

a. Oral prophylaxis, including necessary scaling and polishing, is payable only once in a six-month period except for persons who, because of physical or mental disability, need more frequent care. Documentation supporting the need for oral prophylaxis performed more than once in a six-month period must be maintained.

b. Topical application of fluoride is payable once in a six-month period except for people who need more frequent applications because of physical or mental disability. (This does not include the use of fluoride prophylaxis paste as fluoride treatment.)

c. Pit and fissure sealants are payable for placement on deciduous and permanent posterior teeth only. Reimbursement for sealants is restricted to work performed on members through 18 years of age and on members who have a physical or mental disability that impairs their ability to maintain adequate oral hygiene. Replacement sealants are covered when medically necessary, as documented in the patient record.

78.4(2) *Diagnostic services.* Payment shall be made for the following diagnostic services:

a. A comprehensive oral evaluation is payable once per patient per dentist in a three-year period when the patient has not seen that dentist during the three-year period.

b. A periodic oral examination is payable once in a six-month period.

c. A complete mouth radiograph survey consisting of a minimum of 14 periapical films and bite-wing films is a payable service once in a five-year period, except when medically necessary to evaluate development, and to detect anomalies, injuries and diseases. Complete mouth radiograph surveys are not payable under the age of six. A panographic-type radiography with bitewings is considered the same as a complete mouth radiograph survey.

d. Supplemental bitewing films are payable only once in a 12-month period.

e. Single periapical films are payable when necessary.

f. Intraoral radiograph, occlusal.

g. Extraoral radiograph.

h. Posterior-anterior and lateral skull and facial bone radiograph, survey film.

i. Temporomandibular joint radiograph.

j. Cephalometric film.

k. Diagnostic casts are payable only for orthodontic cases or when requested by the Iowa Medicaid enterprise medical services unit's dental consultant.

78.4(3) *Restorative services.* Payment shall be made for the following restorative services:

a. Treatment of dental caries is payable in those areas which require immediate attention. Restoration of incipient or nonactive carious lesions are not payable. Carious activity may be considered incipient when there is no penetration of the dento-enamel junction as demonstrated in diagnostic radiographs.

b. Amalgam alloy and composite resin-type filling materials are reimbursable only once for the same restoration in a two-year period.

c. Rescinded IAB 5/1/02, effective 7/1/02.

d. Two laboratory-fabricated crowns using nonprecious materials, other than stainless steel, are payable per member in a 12-month period. Additional laboratory-fabricated crowns using nonprecious materials, other than stainless steel, are payable when prior authorization has been obtained. Noble metals are payable for crowns when members are allergic to all other restorative materials. Stainless steel crowns are payable when a more conservative procedure would not be serviceable. (Cross-reference 78.28(2)*"e"*)

e. Cast post and core, steel post and composite or amalgam in addition to a crown is payable when a tooth is functional and the integrity of the tooth would be jeopardized by no post support.

f. Payment as indicated will be made for the following restorative procedures:

(1) Amalgam or acrylic buildups are considered part of the preparation for the completed restoration.

(2) One, two, or more restorations on one surface of a tooth shall be paid as a one-surface restoration, i.e., mesial occlusal pit and distal occlusal pit of a maxillary molar or mesial and distal occlusal pits of a lower bicuspid.

(3) Occlusal lingual groove of a maxillary molar that extends from the distal occlusal pit and down the distolingual groove will be paid as a two-surface restoration. This restoration and a mesial occlusal pit restoration on the same tooth will be paid as one, two-surface restoration.

(4) Rescinded IAB 5/1/02, effective 7/1/02.

(5) A two-surface anterior composite restoration will be payable as a one-surface restoration if it involved the lingual surface.

(6) Tooth preparation, temporary restorations, cement bases, pulp capping, impressions, local anesthesia and inhaled anesthesia are included in the restorative fee and may not be billed separately.

(7) Pin retention will be paid on a per-tooth basis and in addition to the final restoration.

(8) More than four surfaces on an amalgam restoration will be reimbursed as a "four-surface" amalgam.

(9) An amalgam restoration is not payable following a sedative filling in the same tooth unless the sedative filling was placed more than 30 days previously.

78.4(4) *Periodontal services.* Payment may be made for the following periodontal services:

a. Full-mouth debridement to enable comprehensive periodontal evaluation and diagnosis is payable once every 24 months. This procedure is not payable on the same date of service when other prophylasix or periodontal services are performed.

b. Periodontal scaling and root planing is payable when prior approval has been received. A request for approval must be accompanied by a plan for treatment, a completed copy of a periodontal probe chart that exhibits pocket depths, history and radiograph(s). Payment for periodontal scaling and root planing will be approved when interproximal and subgingival calculus is evident in X-rays or when justified and documented that curettage, scaling or root planing is required in addition to routine prophylaxis. (Cross-reference 78.28(2)*"a"*(1))

c. Periodontal surgical procedures which include gingivoplasty, osseous surgery, and osseous allograft are payable services when prior approval has been received. A request for approval must be accompanied by a plan for treatment, a completed copy of a periodontal probe chart that exhibits pocket depths, history and radiograph(s). Payment for these surgical procedures will be approved after periodontal scaling and root planing has been provided, a reevaluation examination has been completed, and the patient has demonstrated reasonable oral hygiene, unless the patient is unable to demonstrate reasonable oral hygiene because of physical or mental disability or in cases which demonstrate gingival hyperplasia resulting from drug therapy. (Cross-reference 78.28(2)*"a"*(2))

d. Pedicle soft tissue graft and free soft tissue graft are payable services with prior approval based on a written narrative describing medical necessity. (Cross-reference 78.28(2)*"a"*(3))

e. Periodontal maintenance therapy which includes oral prophylaxis, measurement of pocket depths and limited root planing and scaling is a payable service when prior approval has been received. A request for approval must be accompanied by a periodontal treatment plan, a completed copy of a periodontal probe chart which exhibits pocket depths, periodontal history and radiograph(s). Payment for periodontal maintenance therapy may be approved after periodontal scaling and root planing or periodontal surgical procedures have been provided. Periodontal maintenance therapy may be approved once per three-month interval for moderate to advanced cases if the condition would deteriorate without treatment. (Cross-reference 78.28(2)*"a"*(4))

f. Payment as indicated will be made for the following periodontal services:

(1) Periodontal scaling and root planing, gingivoplasty, osseous surgery will be paid per quadrant.

(2) Gingivoplasty will be paid per tooth.

(3) Osseous allograft will be paid as a single site if one site is involved, or if more than one site is involved, payment will be made for multiple sites.

78.4(5) *Endodontic services.* Payment shall be made for the following endodontic services:

a. Root canal treatments on permanent anterior and posterior teeth when extensive posttreatment restorative procedures are not necessary and when missing teeth do not jeopardize the integrity or function of the dental arches.

b. Vital pulpotomies. Cement bases, pulp capping, and insulating liners are considered part of the restoration and may not be billed separately.

c. Surgical endodontic treatment is payable when prior approval has been received. Payment for an apicoectomy, performed as a separate surgical procedure; an apicoectomy, performed in conjunction with endodontic procedure; an apical curettage; a root resection; or excision of hyperplastic tissue will be approved when nonsurgical treatment has been attempted and a reasonable time has elapsed after which failure has been demonstrated. Surgical endodontic procedures may be indicated when:

(1) Conventional root canal treatment cannot be successfully completed because canals cannot be negotiated, debrided or obturated due to calcifications, blockages, broken instruments, severe curvatures, and dilacerated roots.

(2) Correction of problems resulting from conventional treatment including gross underfilling, perforations, and canal blockages with restorative materials. (Cross-reference 78.28(2)*"d"*)

d. Endodontic retreatment when prior authorization has been received. Authorization for retreatment of a tooth with previous endodontic treatment shall be granted when the conventional treatment has been completed, a reasonable time has elapsed, and failure has been demonstrated with a radiograph and narrative history.

78.4(6) *Oral surgery—medically necessary.* Payment shall be made for medically necessary oral surgery services furnished by dentists to the extent that these services may be performed under state law either by doctors of medicine, osteopathy, dental surgery or dental medicine and would be covered if furnished by doctors of medicine or osteopathy, as defined in rule 441—78.1(249A). These services will be reimbursed in a manner consistent with the physician's reimbursement policy. The following surgical procedures are also payable when performed by a dentist:

a. Extractions, both surgical and nonsurgical.

b. Impaction (soft tissue impaction, upper or lower) that requires an incision of overlying soft tissue and the removal of the tooth.

c. Impaction (partial bony impaction, upper or lower) that requires incision of overlying soft tissue, elevation of a flap, removal of bone and removal of the tooth.

d. Impaction (complete bony impaction, upper or lower) that requires incision of overlying soft tissue, elevation of a flap, removal of bone and section of the tooth for removal.

e. Root recovery (surgical removal of residual root).

f. Oral antral fistula closure (or antral root recovery).

g. Surgical exposure of impacted or unerupted tooth for orthodontic reasons, including ligation when indicated.

h. Surgical exposure of impacted or unerupted tooth to aid eruption.

i. General anesthesia, intravenous sedation, and non-intravenous conscious sedation are payable services when the extensiveness of the procedure indicates it or there is a concomitant disease or impairment which warrants its use.

j. Routine postoperative care is considered part of the fee for surgical procedures and may not be billed separately.

k. Payment may be made for postoperative care where need is shown to be beyond normal follow-up care or for postoperative care where the original service was performed by another dentist.

78.4(7) *Prosthetic services.* Payment may be made for the following prosthetic services:

a. An immediate denture and a first-time complete denture including six months' postdelivery care. An immediate denture and a first-time complete denture are payable when the denture is provided to establish masticatory function. An immediate denture or a first-time complete denture is payable only once following the removal of teeth it replaces. A complete denture is payable only once in a five-year period except when the denture is broken beyond repair, lost or stolen, or no longer fits due to growth or changes in jaw structure and is required to prevent significant dental problems. Replacement of complete dentures due to resorption in less than a five-year period is not payable.

b. A removable partial denture replacing anterior teeth, including six months' postdelivery care. A removable partial denture replacing anterior teeth is payable only once in a five-year period unless the removable partial denture is broken beyond repair, lost or stolen, or no longer fits due to growth or changes in jaw structure and is required to prevent significant dental problems. Replacement of a removable partial denture replacing anterior teeth due to resorption in less than a five-year period is not payable.

c. A removable partial denture replacing posterior teeth including six months' postdelivery care when prior approval has been received. A removable partial denture replacing posterior teeth shall be approved when the member has fewer than eight posterior teeth in occlusion or the member has a full denture in one arch, and a partial denture replacing posterior teeth is required in the opposing arch to balance occlusion. When one removable partial denture brings eight posterior teeth in occlusion, no additional removable partial denture will be approved. A removable partial denture replacing posterior teeth is payable only once in a five-year period unless the removable partial denture is broken beyond repair, lost or stolen, or no longer fits due to growth or changes in jaw structure and is required to prevent significant dental problems. Replacement of a removable partial denture replacing posterior teeth due to resorption in less than a five-year period is not payable. (Cross-reference 78.28(2)*"c"*(1))

d. A fixed partial denture (including an acid etch fixed partial denture) replacing anterior teeth when prior approval has been received. A fixed partial denture (including an acid etch fixed partial denture) replacing anterior teeth shall be approved for members whose medical condition precludes the

use of a removable partial denture. High noble or noble metals shall be approved only when the member is allergic to all other restorative materials. A fixed partial denture replacing anterior teeth is payable only once in a five-year period unless the fixed partial denture is broken beyond repair. (Cross-reference 78.28(2)*"c"*(2))

e. A fixed partial denture (including an acid etch fixed partial denture) replacing posterior teeth when prior approval has been received. A fixed partial denture (including an acid etch fixed partial denture) replacing posterior teeth shall be approved for the member whose medical condition precludes the use of a removable partial denture and who has fewer than eight posterior teeth in occlusion or if the member has a full denture in one arch and a partial denture replacing posterior teeth is required in the opposing arch to balance occlusion. When one fixed partial denture brings eight posterior teeth in occlusion, no additional fixed partial denture will be approved. High noble or noble metals will be approved only when the member is allergic to all other restorative materials. A fixed partial denture replacing posterior teeth is payable only once in a five-year period unless the fixed partial denture is broken beyond repair. (Cross-reference 78.28(2)*"c"*(3))

f. Obturator for surgically excised palatal tissue or deficient velopharyngeal function of cleft palate patients.

g. Chairside relines are payable only once per prosthesis every 12 months.

h. Laboratory processed relines are payable only once per prosthesis every 12 months.

i. Tissue conditioning is a payable service twice per prosthesis in a 12-month period.

j. Two repairs per prosthesis in a 12-month period are payable.

k. Adjustments to a complete or removable partial denture are payable when medically necessary after six months' postdelivery care. An adjustment consists of removal of acrylic material or adjustment of teeth to eliminate a sore area or to make the denture fit better. Warming dentures and massaging them for better fit or placing them in a sonic device does not constitute an adjustment.

l. Dental implants and related services when prior authorization has been received. Prior authorization shall be granted when the member is missing significant oral structures due to cancer, traumatic injuries, or developmental defects such as cleft palate and cannot use a conventional denture.

78.4(8) *Orthodontic procedures.* Payment may be made for the following orthodontic procedures:

a. When prior approval has been given for orthodontic services to treat the most handicapping malocclusions in a manner consistent with "Handicapping Malocclusion Assessment to Establish Treatment Priority," by J.A. Salzmann, D.D.S., American Journal of Orthodontics, October 1968.

A handicapping malocclusion is a condition that constitutes a hazard to the maintenance of oral health and interferes with the well-being of the patient by causing impaired mastication, dysfunction of the temporomandibular articulation, susceptibility to periodontal disease, susceptibility to dental caries, and impaired speech due to malpositions of the teeth. Treatment of handicapping malocclusions will be approved only for the severe and the most handicapping. Assessment of the most handicapping malocclusion is determined by the magnitude of the following variables: degree of malalignment, missing teeth, angle classification, overjet and overbite, openbite, and crossbite.

A request to perform an orthodontic procedure must be accompanied by an interpreted cephalometric radiograph and study models trimmed so that the models simulate centric occlusion of the patient. A written plan of treatment must accompany the diagnostic aids. Posttreatment records must be furnished upon request of the Iowa Medicaid enterprise.

Approval may be made for eight units of a three-month active treatment period. Additional units may be approved by the Iowa Medicaid enterprise's orthodontic consultant if found to be medically necessary. (Cross-reference 78.28(2)*"d"*)

b. Space management services shall be payable when there is too little dental ridge to accommodate either the number or the size of teeth and if not corrected significant dental disease will result.

c. Tooth guidance for a limited number of teeth or interceptive orthodontics is a payable service when extensive treatment is not required. Pretreatment records are not required.

78.4(9) *Treatment in a hospital.* Payment will be approved for dental treatment rendered a hospitalized patient only when the mental, physical, or emotional condition of the patient prevents the dentist from providing necessary care in the office.

78.4(10) *Treatment in a nursing facility.* Payment will be approved for dental treatment provided in a nursing facility. When more than one patient is examined during the same nursing home visit, payment will be made by the Medicaid program for only one visit to the nursing home.

78.4(11) *Office visit.* Payment will be approved for an office visit for care of injuries or abnormal conditions of the teeth or supporting structure when treatment procedures or exams are not billed for that visit.

78.4(12) *Office calls after hours.* Payment will be approved for office calls after office hours in emergency situations. The office call will be paid in addition to treatment procedures.

78.4(13) *Drugs.* Payment will be made for drugs dispensed by a dentist only if there is no licensed retail pharmacy in the community where the dentist's office is located. If eligible to dispense drugs, the dentist should request a copy of the Prescribed Drugs Manual from the Iowa Medicaid enterprise provider services unit. Payment will not be made for writing prescriptions.

78.4(14) *Services to members 21 years of age or older.* Orthodontic procedures are not covered for members 21 years of age or older.

This rule is intended to implement Iowa Code section 249A.4.

441—78.5(249A) Podiatrists. Payment will be approved only for certain podiatric services.

78.5(1) Payment will be approved for the following orthotic appliances and treatment of nail pathologies:

a. Durable plantar foot orthotic.

b. Plaster impressions for foot orthotic.

c. Molded digital orthotic.

d. Shoe padding when appliances are not practical.

e. Custom molded space shoes for rheumatoid arthritis, congenital defects and deformities, neurotropic, diabetic and ischemic intractable ulcerations and deformities due to injuries.

f. Rams horn (hypertrophic) nails.

g. Onychomycosis (mycotic) nails.

78.5(2) Payment will be made for the same scope of podiatric services available through Part B of Title XVIII (Medicare) except as listed below:

a. Treatment of flatfoot. The term "flatfoot" is defined as a condition in which one or more arches have flattened out.

b. Treatment of subluxations of the foot are defined as partial dislocations or displacements of joint surfaces, tendons, ligaments, or muscles of the foot. Surgical or nonsurgical treatments undertaken for the sole purpose of correcting a subluxated structure in the foot as an isolated entity are not covered.

Reasonable and necessary diagnosis of symptomatic conditions that result from or are associated with partial displacement of foot structures is a covered service. Surgical correction in the subluxated foot structure that is an integral part of the treatment of a foot injury or is undertaken to improve the function of the foot or to alleviate an induced or associated symptomatic condition is a covered service.

c. Routine foot care. Routine foot care includes the cutting or removal of corns or callouses, the trimming of nails and other hygienic and preventive maintenance care in the realm of self-care such as cleaning and soaking the feet, the use of skin creams to maintain skin tone of both ambulatory and bedfast patients and any services performed in the absence of localized illness, injury, or symptoms involving the foot.

d. Orthopedic shoes. Payment will not be made for orthopedic shoes or for any device to be worn in or attached to orthopedic shoes or other types of shoes when provided by the podiatrist. Payment will be made to the podiatrist for the examination including tests to establish the need for orthopedic shoes.

78.5(3) Prescriptions are required for drugs and supplies as specified in rule 78.1(2)*"c."* Payment shall be made for drugs dispensed by a podiatrist only if there is no licensed retail pharmacy in the community where the podiatrist's office is located. If eligible to dispense drugs, the podiatrist should

request a copy of the Prescribed Drugs Manual from the Iowa Medicaid enterprise provider services unit. Payment will not be made for writing prescriptions.

This rule is intended to implement Iowa Code section 249A.4.

441—78.6(249A) Optometrists. Payment will be approved for medically necessary services and supplies provided by the optometrist within the scope of practice of optometry and the limitations of state law, subject to the following limitations and exclusions. Covered optometric services include a professional component and materials.

78.6(1) *Payable professional services are:*

a. Eye examinations. The coverage of eye examinations depends on the purpose of the examination. Services are covered if the examination is the result of a complaint or symptom of an eye disease or injury. Routine eye examinations are covered once in a 12-month period. These services are rendered in the optometrist's office or clinic, the home, a nursing facility, or other appropriate setting. Payment for mileage shall be subject to the same approval and payment criteria as those in effect for Medicare Part B. The following levels of service are recognized for optometric examinations:

(1) Intermediate examination. A level of optometric or ophthalmological services pertaining to medical examination and evaluation, with initiation or continuation of a diagnostic and treatment program.

(2) Comprehensive examination. A level of optometric or ophthalmological services pertaining to medical examination and evaluation, with initiation or continuation of a diagnostic and treatment program, and a general evaluation of the complete visual system.

b. Medical services. Payment will be approved for medically necessary services and supplies within the scope of practice of the optometrist, including services rendered in the optometrist's office or clinic, the home, a nursing facility, or other appropriate setting. Payment for mileage shall be subject to the same approval and payment criteria as those in effect for Medicare Part B.

c. Auxiliary procedures. The following auxiliary procedures and special tests are payable when performed by an optometrist. Auxiliary procedures and special tests are reimbursed as a separate procedure only when warranted by case history or diagnosis.

(1) Serial tonometry. Single tonometry is part of the intermediate and comprehensive exams and is not payable as a separate procedure as is serial tonometry.

(2) Gonioscopy.

(3) Extended ophthalmoscopy. Routine ophthalmoscopy is part of the intermediate and comprehensive examination and is not payable as a separate procedure. Generally, extended ophthalmoscopy is considered to be part of the comprehensive examination and, if performed in conjunction with that level of service, is not payable as a separate procedure.

(4) Visual fields. Gross visual field testing is part of general optometric services and is not reported separately.

(5) External photography.

(6) Fundus photography.

(7) Retinal integrity evaluation.

d. Single vision and multifocal lens service, verification and subsequent service. When lenses are necessary, the following enumerated professional and technical optometric services are to be provided:

(1) When lenses are necessary, the following enumerated professional and technical optometric services are to be provided:

1. Ordering of corrective lenses.
2. Verification of lenses after fabrication.
3. Adjustment and alignment of completed lens order.

(2) New lenses are subject to the following limitations:

1. Up to three times for children up to one year of age.
2. Up to four times per year for children one through three years of age.
3. Once every 12 months for children four through seven years of age.
4. Once every 24 months after eight years of age when there is a change in the prescription.

(3) Protective lenses are allowed for:

1. Children through seven years of age.

2. Members with vision in only one eye.

3. Members with a diagnosis-related illness or disability where regular lenses would pose a safety risk.

e. Rescinded IAB 4/3/02, effective 6/1/02.

f. Frame service.

(1) When a new frame is necessary, the following enumerated professional and technical optometric services are to be provided:

1. Selection and styling.

2. Sizing and measurements.

3. Fitting and adjustment.

4. Readjustment and servicing.

(2) New frames are subject to the following limitations:

1. One frame every six months is allowed for children through three years of age.

2. One frame every 12 months is allowed for children four through six years of age.

3. When there is a prescribed lens change and the new lenses cannot be accommodated by the current frame.

(3) Safety frames are allowed for:

1. Children through seven years of age.

2. Members with a diagnosis-related disability or illness where regular frames would pose a safety risk.

g. Rescinded IAB 4/3/02, effective 6/1/02.

h. Repairs or replacement of frames, lenses or component parts. Payment shall be made for service in addition to materials. The service fee shall not exceed the dispensing fee for a replacement frame. Payment shall be made for replacement of glasses when the original glasses have been lost or damaged beyond repair. Replacement of lost or damaged glasses is limited to once every 12 months for adults aged 21 and over, except for people with a mental or physical disability.

i. Fitting of contact lenses when required following cataract surgery, documented keratoconus, aphakia, or for treatment of acute or chronic eye disease. Up to eight pairs of contact lenses are allowed for children up to one year of age with aphakia. Up to four pairs of contact lenses per year are allowed for children one to three years of age with aphakia.

78.6(2) *Ophthalmic materials.* Ophthalmic materials which are provided in connection with any of the foregoing professional optometric services shall provide adequate vision as determined by the optometrist and meet the following standards:

a. Corrected curve lenses, unless clinically contraindicated, manufactured by reputable American manufacturers.

b. Standard plastic, plastic and metal combination, or metal frames manufactured by reputable American manufacturers, if available.

c. Prescription standards according to the American National Standards Institute (ANSI) standards and tolerance.

78.6(3) *Reimbursement.* The reimbursement for allowed ophthalmic material is subject to a fee schedule established by the department or to actual laboratory cost as evidenced by an attached invoice.

a. Materials payable by fee schedule are:

(1) Lenses, single vision and multifocal.

(2) Frames.

(3) Case for glasses.

b. Materials payable at actual laboratory cost as evidenced by an attached invoice are:

(1) Contact lenses.

(2) Schroeder shield.

(3) Ptosis crutch.

(4) Protective lenses and safety frames.

(5) Subnormal visual aids.

78.6(4) *Prior authorization.* Prior authorization is required for the following:

a. A second lens correction within a 24-month period for members eight years of age and older. Approval shall be given when the member's vision has at least a five-tenths diopter of change in sphere or cylinder or ten-degree change in axis in either eye.

b. Visual therapy may be authorized when warranted by case history or diagnosis for a period of time not greater than 90 days. Should continued therapy be warranted, the prior approval process shall be reaccomplished, accompanied by a report showing satisfactory progress. Approved diagnoses are convergence insufficiency and amblyopia. Visual therapy is not covered when provided by opticians.

c. Subnormal visual aids where near visual acuity is better than 20/100 at 16 inches, 2M print. Prior authorization is not required if near visual acuity as described above is less than 20/100. Subnormal visual aids include, but are not limited to, hand magnifiers, loupes, telescopic spectacles, or reverse Galilean telescope systems. Payment shall be actual laboratory cost as evidenced by an attached invoice.

(Cross-reference 78.28(3))

78.6(5) *Noncovered services.* Noncovered services include, but are not limited to, the following services:

a. Glasses with cosmetic gradient tint lenses or other eyewear for cosmetic purposes.

b. Glasses for protective purposes including glasses for eye safety, sunglasses, or glasses with photogray lenses. An exception to this is in 78.6(3)*"b"*(4).

c. A second pair of glasses or spare glasses.

d. Cosmetic surgery and experimental medical and surgical procedures.

e. Contact lenses if vision is correctable with noncontact lenses except as found at paragraph 78.6(1)*"i."*

78.6(6) *Therapeutically certified optometrists.* Therapeutically certified optometrists may provide services and employ pharmaceutical agents in accordance with Iowa Code chapter 154 regulating the practice of optometry. A therapeutically certified optometrist is an optometrist who is licensed to practice optometry in this state and who is certified by the board of optometry to employ the agents and perform the procedures provided by the Iowa Code.

This rule is intended to implement Iowa Code section 249A.4.

[**ARC 7548B**, IAB 2/11/09, effective 4/1/09]

441—78.7(249A) Opticians. Payment will be approved only for certain services and supplies provided by opticians when prescribed by a physician (MD or DO) or an optometrist. Payment and procedure for obtaining services and supplies shall be the same as described in rule 441—78.6(249A). (Cross-reference 78.28(3))

78.7(1) to **78.7(3)** Rescinded IAB 4/3/02, effective 6/1/02.

This rule is intended to implement Iowa Code section 249A.4.

441—78.8(249A) Chiropractors. Payment will be made for the same chiropractic procedures payable under Title XVIII of the Social Security Act (Medicare).

78.8(1) *Covered services.* Chiropractic manipulative therapy (CMT) eligible for reimbursement is specifically limited by Medicaid to the manual manipulation (i.e., by use of the hands) of the spine for the purpose of correcting a subluxation demonstrated by X-ray. Subluxation means an incomplete dislocation, off-centering, misalignment, fixation, or abnormal spacing of the vertebrae.

78.8(2) *Indications and limitations of coverage.*

a. The subluxation must have resulted in a neuromusculoskeletal condition set forth in the table below for which CMT is appropriate treatment. The symptoms must be directly related to the subluxation that has been diagnosed. The mere statement or diagnosis of "pain" is not sufficient to support the medical necessity of CMT. CMT must have a direct therapeutic relationship to the patient's condition. No other diagnostic or therapeutic service furnished by a chiropractor is covered under the Medicaid program.

ICD-9	CATEGORY I	ICD-9	CATEGORY II	ICD-9	CATEGORY III
307.81	Tension headache	353.0	Brachial plexus lesions	721.7	Traumatic spondylopathy
721.0	Cervical spondylosis without myelopathy	353.1	Lumbosacral plexus lesions	722.0	Displacement of cervical intervertebral disc without myelopathy
721.2	Thoracic spondylosis without myelopathy	353.2	Cervical root lesions, NEC	722.10	Displacement of lumbar intervertebral disc without myelopathy
721.3	Lumbosacral spondylosis without myelopathy	353.3	Thoracic root lesions, NEC	722.11	Displacement of thoracic intervertebral disc without myelopathy
723.1	Cervicalgia	353.4	Lumbosacral root lesions, NEC	722.4	Degeneration of cervical intervertebral disc
724.1	Pain in thoracic spine	353.8	Other nerve root and plexus disorders	722.51	Degeneration of thoracic or thoracolumbar intervertebral disc
724.2	Lumbago	719.48	Pain in joint (other specified sites, must specify site)	722.52	Degeneration of lumbar or lumbosacral intervertebral disc
724.5	Backache, unspecified	720.1	Spinal enthesopathy	722.81	Post laminectomy syndrome, cervical region
784.0	Headache	722.91	Calcification of intervertebral cartilage or disc, cervical region	722.82	Post laminectomy syndrome, thoracic region
		722.92	Calcification of intervertebral cartilage or disc, thoracic region	722.83	Post laminectomy syndrome, lumbar region
		722.93	Calcification of intervertebral cartilage or disc, lumbar region	724.3	Sciatica
		723.0	Spinal stenosis in cervical region		
		723.2	Cervicocranial syndrome		
		723.3	Cervicobrachial syndrome		
		723.4	Brachial neuritis or radiculitis, NOC		
		723.5	Torticollis, unspecified		
		724.01	Spinal stenosis, thoracic region		
		724.02	Spinal stenosis, lumbar region		
		724.4	Thoracic or lumbosacral neuritis or radiculitis		
		724.6	Disorders of sacrum, ankylosis		
		724.79	Disorders of coccyx, coccygodynia		
		724.8	Other symptoms referable to back, facet syndrome		
		729.1	Myalgia and myositis, unspecified		
		729.4	Fascitis, unspecified		
		738.40	Acquired spondylolisthesis		
		756.12	Spondylolisthesis		

ICD-9	CATEGORY I	ICD-9	CATEGORY II	ICD-9	CATEGORY III
		846.0	Sprains and strains of sacroiliac region, lumbosacral (joint; ligament)		
		846.1	Sprains and strains of sacroiliac region, sacroiliac ligament		
		846.2	Sprains and strains of sacroiliac region, sacrospinatus (ligament)		
		846.3	Sprains and strains of sacroiliac region, sacrotuberous (ligament)		
		846.8	Sprains and strains of sacroiliac region, other specified sites of sacroiliac region		
		847.0	Sprains and strains, neck		
		847.1	Sprains and strains, thoracic		
		847.2	Sprains and strains, lumbar		
		847.3	Sprains and strains, sacrum		
		847.4	Sprains and strains, coccyx		

b. The neuromusculoskeletal conditions listed in the table in paragraph *"a"* generally require short-, moderate-, or long-term CMT. A diagnosis or combination of diagnoses within Category I generally requires short-term CMT of 12 per 12-month period. A diagnosis or combination of diagnoses within Category II generally requires moderate-term CMT of 18 per 12-month period. A diagnosis or combination of diagnoses within Category III generally requires long-term CMT of 24 per 12-month period. For diagnostic combinations between categories, 28 CMTs are generally required per 12-month period. If the CMT utilization guidelines are exceeded, documentation supporting the medical necessity of additional CMT must be submitted with the Medicaid claim form or the claim will be denied for failure to provide information.

c. CMT is not a covered benefit when:

(1) The maximum therapeutic benefit has been achieved for a given condition.

(2) There is not a reasonable expectation that the continuation of CMT would result in improvement of the patient's condition.

(3) The CMT seeks to prevent disease, promote health and prolong and enhance the quality of life.

78.8(3) *Documenting X-ray.* An X-ray must document the primary regions of subluxation being treated by CMT.

a. The documenting X-ray must be taken at a time reasonably proximate to the initiation of CMT. An X-ray is considered to be reasonably proximate if it was taken no more than 12 months prior to or 3 months following the initiation of CMT. X-rays need not be repeated unless there is a new condition and no payment shall be made for subsequent X-rays, absent a new condition, consistent with paragraph *"c"* of this subrule. No X-ray is required for pregnant women and for children aged 18 and under.

b. The X-ray films shall be labeled with the patient's name and date the X-rays were taken and shall be marked right or left. The X-ray shall be made available to the department or its duly authorized representative when requested. A written and dated X-ray report, including interpretation and diagnosis, shall be present in the patient's clinical record.

c. Chiropractors shall be reimbursed for documenting X-rays at the physician fee schedule rate. Payable X-rays shall be limited to those Current Procedural Terminology (CPT) procedure codes that are appropriate to determine the presence of a subluxation of the spine. Criteria used to determine payable X-ray CPT codes may include, but are not limited to, the X-ray CPT codes for which major commercial payors reimburse chiropractors. The Iowa Medicaid enterprise shall publish in the

Chiropractic Services Provider Manual the current list of payable X-ray CPT codes. Consistent with CPT, chiropractors may bill the professional, technical, or professional and technical components for X-rays, as appropriate. Payment for documenting X-rays shall be further limited to one per condition, consistent with the provisions of paragraph *"a"* of this subrule. A claim for a documenting X-ray related to the onset of a new condition is only payable if the X-ray is reasonably proximate to the initiation of CMT for the new condition, as defined in paragraph *"a"* of this subrule. A chiropractor is also authorized to order a documenting X-ray whether or not the chiropractor owns or possesses X-ray equipment in the chiropractor's office. Any X-rays so ordered shall be payable to the X-ray provider, consistent with the provisions in this paragraph.

This rule is intended to implement Iowa Code section 249A.4.

441—78.9(249A) Home health agencies. Payment shall be approved for medically necessary home health agency services prescribed by a physician in a plan of home health care provided by a Medicare-certified home health agency.

The number of hours of home health agency services shall be reasonable and appropriate to meet an established medical need of the member that cannot be met by a family member, significant other, friend, or neighbor. Services must be medically necessary in the individual case and be related to a diagnosed medical impairment or disability.

The member need not be homebound to be eligible for home health agency services; however, the services provided by a home health agency shall only be covered when provided in the member's residence with the following exception. Private duty nursing and personal care services for persons aged 20 and under as described at 78.9(10)*"a"* may be provided in settings other than the member's residence when medically necessary.

Medicaid members of home health agency services need not first require skilled nursing care to be entitled to home health aide services.

Further limitations related to specific components of home health agency services are noted in subrules 78.9(3) to 78.9(10).

Payment shall be made on an encounter basis. An encounter is defined as separately identifiable hours in which home health agency staff provide continuous service to a member.

Payment for supplies shall be approved when the supplies are incidental to the patient's care, e.g., syringes for injections, and do not exceed $15 per month. Dressings, durable medical equipment, and other supplies shall be obtained from a durable medical equipment dealer or pharmacy. Payment of supplies may be made to home health agencies when a durable medical equipment dealer or pharmacy is not available in the member's community.

Payment may be made for restorative and maintenance home health agency services.

Payment may be made for teaching, training, and counseling in the provision of health care services.

Treatment plans for these services shall additionally reflect: to whom the services are to be provided (patient, family member, etc.); prior teaching training, or counseling provided; medical necessity for the rendered service; identification of specific services and goals; date of onset of the teaching, training, or counseling; frequency of services; progress of member in response to treatment; and estimated length of time these services will be needed.

The following are not covered: services provided in the home health agency office, homemaker services, well child care and supervision, and medical equipment rental or purchase.

Services shall be authorized by a physician, evidenced by the physician's signature and date on a plan of treatment.

78.9(1) *Treatment plan.* A plan of treatment shall be completed prior to the start of care and at a minimum reviewed every 62 days thereafter. The plan of care shall support the medical necessity and intensity of services to be provided by reflecting the following information:

a. Place of service.

b. Type of service to be rendered and the treatment modalities being used.

c. Frequency of the services.

d. Assistance devices to be used.

e. Date home health services were initiated.
f. Progress of member in response to treatment.
g. Medical supplies to be furnished.
h. Member's medical condition as reflected by the following information, if applicable:
(1) Dates of prior hospitalization.
(2) Dates of prior surgery.
(3) Date last seen by a physician.
(4) Diagnoses and dates of onset of diagnoses for which treatment is being rendered.
(5) Prognosis.
(6) Functional limitations.
(7) Vital signs reading.
(8) Date of last episode of instability.
(9) Date of last episode of acute recurrence of illness or symptoms.
(10) Medications.
i. Discipline of the person providing the service.
j. Certification period (no more than 62 days).
k. Estimated date of discharge from the hospital or home health agency services, if applicable.
l. Physician's signature and date. The date of the signature shall be within the certification period.

78.9(2) *Supervisory visits.* Payment shall be made for supervisory visits two times a month when a registered nurse acting in a supervisory capacity provides supervisory visits of services provided by a home health aide under a home health agency plan of treatment or when services are provided by an in-home health care provider under the department's in-home health-related care program as set forth in 441—Chapter 177.

78.9(3) *Skilled nursing services.* Skilled nursing services are services that when performed by a home health agency require a licensed registered nurse or licensed practical nurse to perform. Situations when a service can be safely performed by the member or other nonskilled person who has received the proper training or instruction or when there is no one else to perform the service are not considered a "skilled nursing service." Skilled nursing services shall be available only on an intermittent basis. Intermittent services for skilled nursing services shall be defined as a medically predictable recurring need requiring a skilled nursing service at least once every 60 days, not to exceed five days per week (except as provided below), with an attempt to have a predictable end. Daily visits (six or seven days per week) that are reasonable and necessary and show an attempt to have a predictable end shall be covered for up to three weeks. Coverage of additional daily visits beyond the initial anticipated time frame may be appropriate for a short period of time, based on the medical necessity of service. Medical documentation shall be submitted justifying the need for continued visits, including the physician's estimate of the length of time that additional visits will be necessary. Daily skilled nursing visits or multiple daily visits for wound care or insulin injections shall be covered when ordered by a physician and included in the plan of care. Other daily skilled nursing visits which are ordered for an indefinite period of time and designated as daily skilled nursing care do not meet the intermittent definition and shall be denied.

Skilled nursing services shall be evaluated based on the complexity of the service and the condition of the patient.

Private duty nursing for persons aged 21 and over is not a covered service. See subrule 78.9(10) for guidelines for private duty nursing for persons aged 20 or under.

78.9(4) *Physical therapy services.* Payment shall be made for physical therapy services when the services relate directly to an active written treatment plan, follow a treatment plan established by the physician after any needed consultation with the qualified physical therapist, are reasonable and necessary to the treatment of the patient's illness or injury, and meet the guidelines defined for restorative, maintenance, or trial therapy as set forth in subrule 78.19(1), paragraphs *"a"* and *"b."*

For physical therapy services, the treatment plan shall additionally reflect goals, modalities of treatment, date of onset of conditions being treated, restorative potential, and progress notes.

78.9(5) *Occupational therapy services.* Payment shall be made for occupational therapy services when the services relate directly to an active written treatment plan, follow a treatment plan established

by the physician, are reasonable and necessary to the treatment of the patient's illness or injury, and meet the guidelines defined for restorative, maintenance, or trial therapy as set forth in subrule 78.19(1), paragraphs *"a"* and *"c."*

For occupational therapy services, the treatment plan shall additionally reflect goals, modalities of treatment, date of onset of conditions being treated, restorative potential, and progress notes.

78.9(6) *Speech therapy services.* Payment shall be made for speech therapy services when the services relate directly to an active written treatment plan, follow a treatment plan established by the physician, are reasonable and necessary to the treatment of the patient's illness or injury, and meet the guidelines defined for restorative, maintenance, or trial therapy as set forth in subrule 78.19(1), paragraphs *"a"* and *"d."*

For speech therapy services, the treatment plan shall additionally reflect goals, modalities of treatment, date of onset of conditions being treated, restorative potential, and progress notes.

78.9(7) *Home health aide services.* Payment shall be made for unskilled services provided by a home health aide if the following conditions are met:

a. The service as well as the frequency and duration are stated in a written plan of treatment established by a physician. The home health agency is encouraged to collaborate with the member, or in the case of a child with the child's caregiver, in the development and implementation of the plan of treatment.

b. The member requires personal care services as determined by a registered nurse or other appropriate therapist. The services shall be given under the supervision of a registered nurse, physical, speech, or occupational therapist and the registered nurse or therapist shall assign the aide who will provide the care.

c. Services shall be provided on an intermittent basis. "Intermittent basis" for home health agency services is defined as services that are usually two to three times a week for two to three hours at a time. Services provided for four to seven days per week, not to exceed 28 hours per week, when ordered by a physician and included in a plan of care shall be allowed as intermittent services. Increased services provided when medically necessary due to unusual circumstances on a short-term basis of two to three weeks may also be allowed as intermittent services when the home health agency documents the need for the excessive time required for home health aide services.

Home health aide daily care may be provided for persons employed or attending school whose disabling conditions require the persons to be assisted with morning and evening activities of daily living in order to support their independent living.

Personal care services include the activities of daily living, e.g., helping the member to bathe, get in and out of bed, care for hair and teeth, exercise, and take medications specifically ordered by the physician, but ordinarily self-administered, and retraining the member in necessary self-help skills.

Certain household services may be performed by the aide in order to prevent or postpone the member's institutionalization when the primary need of the member for home health aide services furnished is for personal care. If household services are incidental and do not substantially increase the time spent by the aide in the home, the entire visit is considered a covered service. Domestic or housekeeping services which are not related to patient care are not a covered service if personal care is not rendered during the visit.

For home health aide services, the treatment plan shall additionally reflect the number of hours per visit and the living arrangement of the member, e.g., lives alone or with family.

78.9(8) *Medical social services.*

a. Payment shall be made for medical social work services when all of the following conditions are met and the problems are not responding to medical treatment and there does not appear to be a medical reason for the lack of response. The services:

(1) Are reasonable and necessary to the treatment of a member's illness or injury.

(2) Contribute meaningfully to the treatment of the member's condition.

(3) Are under the direction of a physician.

(4) Are provided by or under the supervision of a qualified medical or psychiatric social worker.

(5) Address social problems that are impeding the member's recovery.

b. Medical social services directed toward minimizing the problems an illness may create for the member and family, e.g., encouraging them to air their concerns and providing them with reassurance, are not considered reasonable and necessary to the treatment of the patient's illness or injury.

78.9(9) *Home health agency care for maternity patients and children.* The intent of home health agency services for maternity patients and children shall be to provide services when the members are unable to receive the care outside of their home and require home health care due to a high-risk factor. Routine prenatal, postpartum, or child health care is a covered service in a physician's office or clinic and, therefore, is not covered by Medicaid when provided by a home health agency.

a. Treatment plans for maternity patients and children shall identify:

(1) The potential risk factors,

(2) The medical factor or symptom which verifies the child is at risk,

(3) The reason the member is unable to obtain care outside of the home,

(4) The medically related task of the home health agency,

(5) The member's diagnosis,

(6) Specific services and goals, and

(7) The medical necessity for the services to be rendered. A single high-risk factor does not provide sufficient documentation of the need for services.

b. The following list of potential high-risk factors may indicate a need for home health services to prenatal maternity patients:

(1) Aged 16 or under.

(2) First pregnancy for a woman aged 35 or over.

(3) Previous history of prenatal complications such as fetal death, eclampsia, C-section delivery, psychosis, or diabetes.

(4) Current prenatal problems such as hypertensive disorders of pregnancy, diabetes, cardiac disease, sickle cell anemia, low hemoglobin, mental illness, or drug or alcohol abuse.

(5) Sociocultural or ethnic problems such as language barriers, lack of family support, insufficient dietary practices, history of child abuse or neglect, or single mother.

(6) Preexisting disabilities such as sensory deficits, or mental or physical disabilities.

(7) Second pregnancy in 12 months.

(8) Death of a close family member or significant other within the previous year.

c. The following list of potential high-risk factors may indicate a need for home health services to postpartum maternity patients:

(1) Aged 16 or under.

(2) First pregnancy for a woman aged 35 or over.

(3) Major postpartum complications such as severe hemorrhage, eclampsia, or C-section delivery.

(4) Preexisting mental or physical disabilities such as deaf, blind, hemaplegic, activity-limiting disease, sickle cell anemia, uncontrolled hypertension, uncontrolled diabetes, mental illness, or mental retardation.

(5) Drug or alcohol abuse.

(6) Symptoms of postpartum psychosis.

(7) Special sociocultural or ethnic problems such as lack of job, family problems, single mother, lack of support system, or history of child abuse or neglect.

(8) Demonstrated disturbance in maternal and infant bonding.

(9) Discharge or release from hospital against medical advice before 36 hours postpartum.

(10) Insufficient antepartum care by history.

(11) Multiple births.

(12) Nonhospital delivery.

d. The following list of potential high-risk factors may indicate a need for home health services to infants:

(1) Birth weight of five pounds or under or over ten pounds.

(2) History of severe respiratory distress.

(3) Major congenital anomalies such as neonatal complications which necessitate planning for long-term follow-up such as postsurgical care, poor prognosis, home stimulation activities, or periodic development evaluation.

(4) Disabling birth injuries.

(5) Extended hospitalization and separation from other family members.

(6) Genetic disorders, such as Down's syndrome, and phenylketonuria or other metabolic conditions that may lead to mental retardation.

(7) Noted parental rejection or indifference toward baby such as never visiting or calling the hospital about the baby's condition during the infant's extended stay.

(8) Family sociocultural or ethnic problems such as low education level or lack of knowledge of child care.

(9) Discharge or release against medical advice before 36 hours of age.

(10) Nutrition or feeding problems.

e. The following list of potential high-risk factors may indicate a need for home health services to preschool or school-age children:

(1) Child or sibling victim of child abuse or neglect.

(2) Mental retardation or other physical disabilities necessitating long-term follow-up or major readjustments in family lifestyle.

(3) Failure to complete the basic series of immunizations by 18 months, or boosters by 6 years.

(4) Chronic illness such as asthma, cardiac, respiratory or renal disease, diabetes, cystic fibrosis, or muscular dystrophy.

(5) Malignancies such as leukemia or carcinoma.

(6) Severe injuries necessitating treatment or rehabilitation.

(7) Disruption in family or peer relationships.

(8) Suspected developmental delay.

(9) Nutritional deficiencies.

78.9(10) *Private duty nursing or personal care services for persons aged 20 and under.* Payment for private duty nursing or personal care services for persons aged 20 and under shall be approved if determined to be medically necessary. Payment shall be made on an hourly unit of service.

a. Definitions.

(1) Private duty nursing services are those services which are provided by a registered nurse or a licensed practical nurse under the direction of the member's physician to a member in the member's place of residence or outside the member's residence, when normal life activities take the member outside the place of residence. Place of residence does not include nursing facilities, intermediate care facilities for the mentally retarded, or hospitals.

Services shall be provided according to a written plan of care authorized by a licensed physician. The home health agency is encouraged to collaborate with the member, or in the case of a child with the child's caregiver, in the development and implementation of the plan of treatment. These services shall exceed intermittent guidelines as defined in subrule 78.9(3). Private duty nursing and personal care services shall be inclusive of all home health agency services personally provided to the member. Enhanced payment under the interim fee schedule shall be made available for services to children who are technology dependent, i.e., ventilator dependent or whose medical condition is so unstable as to otherwise require intensive care in a hospital.

Private duty nursing or personal care services do not include:

1. Respite care, which is a temporary intermission or period of rest for the caregiver.

2. Nurse supervision services including chart review, case discussion or scheduling by a registered nurse.

3. Services provided to other persons in the member's household.

4. Services requiring prior authorization that are provided without regard to the prior authorization process.

5. Transportation services.

6. Homework assistance.

(2) Personal care services are those services provided by a home health aide or certified nurse's aide and which are delegated and supervised by a registered nurse under the direction of the member's physician to a member in the member's place of residence or outside the member's residence, when normal life activities take the member outside the place of residence. Place of residence does not include nursing facilities, intermediate care facilities for the mentally retarded, or hospitals. Payment for personal care services for persons aged 20 and under that exceed intermittent guidelines may be approved if determined to be medically necessary as defined in subrule 78.9(7). These services shall be in accordance with the member's plan of care and authorized by a physician. The home health agency is encouraged to collaborate with the member, or in the case of a child with the child's caregiver, in the development and implementation of the plan of treatment.

Medical necessity means the service is reasonably calculated to prevent, diagnose, correct, cure, alleviate or prevent the worsening of conditions that endanger life, cause pain, result in illness or infirmity, threaten to cause or aggravate a disability or chronic illness, and no other equally effective course of treatment is available or suitable for the member requesting a service.

b. Requirements.

(1) Private duty nursing or personal care services shall be ordered in writing by a physician as evidenced by the physician's signature on the plan of care.

(2) Private duty nursing or personal care services shall be authorized by the department or the department's designated review agent prior to payment.

(3) Prior authorization shall be requested at the time of initial submission of the plan of care or at any time the plan of care is substantially amended and shall be renewed with the department or the department's designated review agent. Initial request for and request for renewal of prior authorization shall be submitted to the department's designated review agent. The provider of the service is responsible for requesting prior authorization and for obtaining renewal of prior authorization.

The request for prior authorization shall include a nursing assessment, the plan of care, and supporting documentation. The request for prior authorization shall include all items previously identified as required treatment plan information and shall further include: any planned surgical interventions and projected time frame; information regarding caregiver's desire to become involved in the member's care, to adhere to program objectives, to work toward treatment plan goals, and to work toward maximum independence; and identify the types and service delivery levels of all other services to the member whether or not the services are reimbursable by Medicaid. Providers shall indicate the expected number of private duty nursing RN hours, private duty nursing LPN hours, or home health aide hours per day, the number of days per week, and the number of weeks or months of service per discipline. If the member is currently hospitalized, the projected date of discharge shall be included.

Prior authorization approvals shall not be granted for treatment plans that exceed 16 hours of home health agency services per day. (Cross-reference 78.28(9))

78.9(11) *Vaccines.* Home health agencies which wish to administer vaccines which are available through the Vaccines for Children program to Medicaid members shall enroll in the Vaccines for Children program. In lieu of payment, vaccines available through the Vaccines for Children program shall be accessed from the department of public health for Medicaid members. Home health agencies may provide Vaccines for Children clinics and be reimbursed for vaccine administration to provide Vaccines for Children program vaccines to Medicaid children in other than the home setting.

This rule is intended to implement Iowa Code section 249A.4.

[**ARC 7548B**, IAB 2/11/09, effective 4/1/09]

441—78.10(249A) Durable medical equipment (DME), prosthetic devices and medical supplies.

78.10(1) *General payment requirements.* Payment will be made for items of DME, prosthetic devices and medical supplies, subject to the following general requirements and the requirements of subrule 78.10(2), 78.10(3), or 78.10(4), as applicable:

a. DME, prosthetic devices, and medical supplies must be required by the member because of the member's medical condition.

b. The item shall be necessary and reasonable either for the treatment of an illness or injury, or to improve the functioning of a malformed body part. Determination will be made by the Iowa Medicaid enterprise medical services unit.

(1) An item is necessary when it can be expected to make a meaningful contribution to the treatment of a specific illness or injury or to the improvement in function of a malformed body part.

(2) Although an item may be necessary, it must also be a reasonable expenditure for the Medicaid program. The following considerations enter into the determination of reasonableness: Whether the expense of the item to the program would be clearly disproportionate to the therapeutic benefits which could ordinarily be derived from use of the item; whether the item would be substantially more costly than a medically appropriate and realistically feasible alternative pattern of care; and whether the item serves essentially the same purpose as an item already available to the beneficiary.

c. A physician's (doctor of medicine, osteopathy, or podiatry), physician assistant's, or advanced registered nurse practitioner's prescription is required to establish medical necessity. The prescription shall state the diagnosis, prognosis, and length of time the item is to be required.

For items requiring prior approval, a request shall include a physician's, physician assistant's, or advanced registered nurse practitioner's written order or prescription and sufficient medical documentation to permit an independent conclusion that the requirements for the equipment or device are met and the item is medically necessary and reasonable. A request for prior approval is made on Form 470-0829, Request for Prior Authorization. See rule 441—78.28(249A) for prior approval requirements.

d. Nonmedical items will not be covered. These include but are not limited to:

(1) Physical fitness equipment, e.g., an exercycle, weights.

(2) First-aid or precautionary-type equipment, e.g., preset portable oxygen units.

(3) Self-help devices, e.g., safety grab bars, raised toilet seats.

(4) Training equipment, e.g., speech teaching machines, braille training texts.

(5) Equipment used for environmental control or to enhance the environmental setting, e.g., room heaters, air conditioners, humidifiers, dehumidifiers, and electric air cleaners.

(6) Equipment which basically serves comfort or convenience functions, or is primarily for the convenience of a person caring for the patient, e.g., elevators, stairway elevators and posture chairs.

e. The amount payable is based on the least expensive item which meets the patient's medical needs. Payment will not be approved for duplicate items.

f. Consideration will be given to rental or purchase based on the price of the item and the length of time it would be required. The decision on rental or purchase shall be made by the Iowa Medicaid enterprise, and be based on the most reasonable method to provide the equipment.

(1) The provider shall monitor rental payments up to 100 percent of the purchase price. At the point that total rent paid equals 100 percent of the purchase allowance, the member will be considered to own the item and no further rental payments will be made to the provider.

(2) Payment may be made for the purchase of an item even though rental payments may have been made for prior months. The rental of the equipment may be necessary for a period of time to establish that it will meet the identified need before the purchase of the equipment. When a decision is made to purchase after renting an item, all of the rental payments will be applied to the purchase allowance.

(3) EXCEPTION: Ventilators will be maintained on a rental basis for the duration of use.

g. Payment may be made for necessary repair, maintenance, and supplies for member-owned equipment. No payment may be made for repairs, maintenance, or supplies when the member is renting the item.

h. Replacement of member-owned equipment is covered in cases of loss or irreparable damage or when required because of a change in the member's condition.

i. No allowance will be made for delivery, freight, postage, or other provider operating expenses for DME, prosthetic devices or medical supplies.

78.10(2) *Durable medical equipment.* DME is equipment which can withstand repeated use, is primarily and customarily used to serve a medical purpose, is generally not useful to a person in the absence of an illness or injury, and is appropriate for use in the home.

a. Durable medical equipment will not be provided in a hospital, nursing facility, or intermediate care facility for the mentally retarded except when a Medicaid-eligible resident of a nursing facility medically needs oxygen for 12 or more hours per day for at least 30 days or more. Medicaid will provide payment to medical equipment and supply dealers to provide oxygen services in a nursing facility when all of the following requirements and conditions have been met:

(1) A physician's, physician assistant's, or advanced registered nurse practitioner's prescription documents that a resident of a nursing facility requires oxygen for 12 hours or more per day and the provider and physician, physician assistant, or advanced registered nurse practitioner jointly submit Certificate of Medical Necessity, Form CMS-484, from Medicare or a reasonable facsimile to the Iowa Medicaid enterprise with the monthly billing. The documentation submitted must contain the following:

1. The number of hours oxygen is required per day;
2. The diagnosis of the disease requiring continuous oxygen, prognosis, and length of time the oxygen will be needed;
3. The oxygen flow rate and concentration; the type of system ordered, i.e., cylinder gas, liquid gas, or concentrator;
4. A specific estimate of the frequency and duration of use; and
5. The initial reading on the time meter clock on each concentrator, where applicable.

Oxygen prescribed "PRN" or "as necessary" is not allowed.

(2) The maximum Medicaid payment shall be based on the least costly method of oxygen delivery.

(3) Medicaid payment shall be made for the rental of equipment only. All accessories and disposable supplies related to the oxygen delivery system, servicing and repairing of equipment are included in the Medicaid payment.

(4) Oxygen logs must be maintained by the provider. When random postpayment review of these logs indicates less than an average of 12 hours per day of oxygen was provided over a 30-day period, recoupment of the overpayment may occur.

(5) Payment will be made for only one mode of oxygen even if the physician's, physician assistant's, or advanced registered nurse practitioner's prescription allows for multiple modes of delivery.

(6) Payment will not be made for oxygen that is not documented according to department of inspections and appeals 481—subrule 58.21(8).

b. Only the following types of durable medical equipment can be covered through the Medicaid program:

Alternating pressure pump.

Automated medication dispenser. See 78.10(2)*"d"* for prior authorization requirements.

Bedpan.

Blood glucose monitors, subject to the limitation in 78.10(2)*"e."*

Blood pressure cuffs.

Cane.

Cardiorespiratory monitor (rental and supplies).

Commode.

Commode pail.

Crutches.

Decubitus equipment.

Dialysis equipment.

Diaphragm (contraceptive device).

Enclosed bed. See 78.10(2)*"d"* for prior authorization requirements.

Enuresis alarm system (bed-wetting alarm device) for members five years of age or older.

Hospital bed.

Hospital bed accessories.

Inhalation equipment.

Insulin infusion pump. See 78.10(2)*"d"* for prior authorization requirements.

Lymphedema pump.

Neuromuscular stimulator.
Oximeter.
Oxygen, subject to the limitations in 78.10(2)*"a"* and 78.10(2)*"c."*
Patient lift (Hoyer).
Phototherapy bilirubin light.
Pressure unit.
Protective helmet.
Respirator.
Resuscitator bags and pressure gauge.
Seat lift chair.
Suction machine.
Traction equipment.
Urinal (portable).
Vaporizer.
Ventilator.
Vest airway clearance system. See 78.10(2)*"d"* for prior authorization requirements.
Walker.
Wheelchair—standard and adaptive.
Whirlpool bath.

c. Coverage of home oxygen equipment and oxygen will be considered reasonable and necessary only for members with significant hypoxemia, as shown by medical documentation. The physician's, physician assistant's, or advanced registered nurse practitioner's prescription shall document that other forms of treatment have been tried and have not been successful, and that oxygen therapy is required.

(1) To identify the medical necessity for oxygen therapy, the supplier and a physician, physician assistant, or advanced registered nurse practitioner shall jointly submit Medicare Form B-7401, Physician's Certification for Durable Medical Equipment, or a reasonable facsimile. The following information is required:

1. A diagnosis of the disease requiring home use of oxygen;
2. The oxygen flow rate and concentration;
3. The type of system ordered, i.e., cylinder gas, liquid gas, or concentrator;
4. A specific estimate of the frequency and duration of use; and
5. The initial reading on the time meter clock on each concentrator, where applicable.

Oxygen prescribed "PRN" or "as necessary" is not allowed.

(2) If the patient's condition or need for oxygen services changes, the attending physician, physician assistant, or advanced registered nurse practitioner must adjust the documentation accordingly.

(3) A second oxygen system is not covered by Medicaid when used as a backup for oxygen concentrators or as a standby in case of emergency. Members may be provided with a portable oxygen system to complement a stationary oxygen system, or to be used by itself, with documentation from the physician (doctor of medicine or osteopathy), physician assistant, or advanced registered nurse practitioner of the medical necessity for portable oxygen for specific activities.

(4) Payment for concentrators shall be made only on a rental basis.

(5) All accessories, disposable supplies, servicing, and repairing of concentrators are included in the monthly Medicaid payment for concentrators.

d. Prior authorization is required for the following medical equipment and supplies (Cross-reference 78.28(1)):

(1) Enclosed beds. Payment for an enclosed bed will be approved when prescribed for a patient who meets all of the following conditions:

1. The patient has a diagnosis-related cognitive or communication impairment that results in risk to safety.
2. The patient's mobility puts the patient at risk for injury.
3. The patient has suffered injuries when getting out of bed.
4. The patient has had a successful trial with an enclosed bed.

(2) External insulin infusion pumps. Payment will be approved according to Medicare coverage criteria.

(3) Vest airway clearance systems. Payment will be approved for a vest airway clearance system when prescribed by a pulmonologist for a patient with a diagnosis of a lung disorder if all of the following conditions are met:

1. Pulmonary function tests for the 12 months before the initiation of the vest demonstrate an overall significant decrease of lung function.

2. The patient resides in an independent living situation or has a medical condition that precludes the caregiver from administering traditional chest physiotherapy.

3. Treatment by flutter device failed or is contraindicated.

4. Treatment by intrapulmonary percussive ventilation failed or is contraindicated.

5. All other less costly alternatives have been tried.

(4) Automated medication dispenser. Payment will be approved for an automated medication dispenser when prescribed for a member who meets all of the following conditions:

1. The member has a diagnosis indicative of cognitive impairment or age-related factors that affect the member's ability to remember to take medications.

2. The member is on two or more medications prescribed to be administered more than one time a day.

3. The availability of a caregiver to administer the medications or perform setup is limited or nonexistent.

4. Less costly alternatives, such as medisets or telephone reminders, have failed.

(5) Blood glucose monitors and diabetic test strips produced by a manufacturer that does not have a current agreement to provide a rebate to the department for monitors or test strips provided through the Medicaid program. Prior approval shall be granted when the member's medical condition necessitates use of a blood glucose monitor or diabetic test strips produced by a manufacturer that does not have a current rebate agreement with the department.

e. Blood glucose monitors are covered through the Medicaid program only if:

(1) The monitor is produced by a manufacturer that has a current agreement to provide a rebate to the department for monitors provided through the Medicaid program; or

(2) Prior authorization based on medical necessity is received pursuant to rule 441—79.8(249A) for a monitor produced by a manufacturer that does not have a current rebate agreement with the department.

78.10(3) *Prosthetic devices.* Prosthetic devices mean replacement, corrective, or supportive devices prescribed by a physician (doctor of medicine, osteopathy or podiatry), physician assistant, or advanced registered nurse practitioner within the scope of practice as defined by state law to artificially replace a missing portion of the body, prevent or correct a physical deformity or malfunction, or support a weak or deformed portion of the body. This does not require a determination that there is no possibility that the patient's condition may improve sometime in the future.

a. Prosthetic devices are not covered when dispensed to a patient prior to the time the patient undergoes a procedure which will make necessary the use of the device.

b. Only the following types of prosthetic devices shall be covered through the Medicaid program:

Artificial eyes.

Artificial limbs.

Augmentative communications systems provided for members unable to communicate their basic needs through oral speech or manual sign language. Payment will be made for the most cost-effective item that meets basic communication needs commensurate with the member's cognitive and language abilities. See 78.10(3)*"c"* for prior approval requirements.

Enteral delivery supplies and products. See 78.10(3)*"c"* for prior approval requirements.

Hearing aids. See rule 441—78.14(249A).

Oral nutritional products. See 78.10(3)*"c"* for prior approval requirements.

Orthotic devices. See 78.10(3)*"d"* for limitations on coverage of cranial orthotic devices.

Ostomy appliances.

Parenteral delivery supplies and products. Daily parenteral nutrition therapy is considered necessary and reasonable for a member with severe pathology of the alimentary tract that does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the member's general condition.

Prosthetic shoes. See rule 441—78.15(249A).

Tracheotomy tubes.

Vibrotactile aids. Vibrotactile aids are payable only once in a four-year period unless the original aid is broken beyond repair or lost. (Cross-reference 78.28(8))

c. Prior approval is required for the following prosthetic devices:

(1) Augmentative communication systems. Form 470-2145, Augmentative Communication System Selection, completed by a speech pathologist and a physician's, physician assistant's, or advanced registered nurse practitioner's prescription for a particular device shall be submitted to the Iowa Medicaid enterprise medical services unit to request prior approval. Information requested on the prior approval form includes a medical history, diagnosis, and prognosis completed by a physician, physician assistant, or advanced registered nurse practitioner. In addition, a speech or language pathologist needs to describe current functional abilities in the following areas: communication skills, motor status, sensory status, cognitive status, social and emotional status, and language status. Also needed from the speech or language pathologist is information on educational ability and needs, vocational potential, anticipated duration of need, prognosis regarding oral communication skills, prognosis with a particular device, and recommendations. The department's consultants with expertise in speech pathology will evaluate the prior approval requests and make recommendations to the department. (Cross-reference 78.28(1)*"c"*)

(2) Enteral products and enteral delivery pumps and supplies. Daily enteral nutrition therapy shall be approved as medically necessary only for a member who either has a metabolic or digestive disorder that prevents the member from obtaining the necessary nutritional value from usual foods in any form and cannot be managed by avoidance of certain food products or has a severe pathology of the body that does not allow ingestion or absorption of sufficient nutrients from regular food to maintain weight and strength commensurate with the member's general condition.

A request for prior approval shall include a physician's, physician assistant's, or advanced registered nurse practitioner's written order or prescription and documentation to establish the medical necessity for enteral products and enteral delivery pumps and supplies pursuant to the above standards. The documentation shall include:

1. A statement of the member's total medical condition that includes a description of the member's metabolic or digestive disorder or pathology.

2. Documentation of the medical necessity for commercially prepared products. The information submitted must identify other methods attempted to support the member's nutritional status and indicate that the member's nutritional needs were not or could not be met by regular food in pureed form.

3. Documentation of the medical necessity for an enteral pump, if the request includes an enteral pump. The information submitted must identify the medical reasons for not using a gravity feeding set.

Examples of conditions that will not justify approval of enteral nutrition therapy are: weight-loss diets, wired-shut jaws, diabetic diets, milk or food allergies (unless the member is under five years of age and coverage through the Women, Infant and Children's program is not available), and the use of enteral products for convenience reasons when regular food in pureed form would meet the medical need of the member.

Basis of payment for nutritional therapy supplies shall be the least expensive method of delivery that is reasonable and medically necessary based on the documentation submitted.

(3) Oral nutritional products. Payment for oral nutritional products shall be approved as medically necessary only when the member is not able to ingest or absorb sufficient nutrients from regular food due to a metabolic, digestive, or psychological disorder or pathology, to the extent that supplementation is necessary to provide 51 percent or more of the daily caloric intake, or when the use of oral nutritional products is otherwise determined medically necessary in accordance with evidence-based guidelines for treatment of the member's condition.

A request for prior approval shall include a physician's, physician assistant's, or advanced registered nurse practitioner's written order or prescription and documentation to establish the medical necessity for oral supplementation pursuant to these standards. The documentation shall include:

1. A statement of the member's total medical condition that includes a description of the member's metabolic, digestive, or psychological disorder or pathology.

2. Documentation of the medical necessity for commercially prepared products. The information submitted must identify other methods attempted to support the member's nutritional status and indicate that the member's nutritional needs were not or could not be met by regular food in pureed form.

3. Documentation to support the fact that regular foods will not provide sufficient nutritional value to the member.

Examples of conditions that will not justify approval of oral supplementation are: weight-loss diets, wired-shut jaws, diabetic diets, milk or food allergies (unless the member is under five years of age and coverage through the Women, Infant and Children's program is not available), supplementation to boost calorie or protein intake by less than 51 percent of the daily intake, and the absence of severe pathology of the body or psychological pathology or disorder.

d. Cranial orthotic device. Payment shall be approved for cranial orthotic devices when the device is medically necessary for the postsurgical treatment of synostotic plagiocephaly. Payment shall also be approved when there is photographic evidence supporting moderate to severe nonsynostotic positional plagiocephaly and either:

(1) The member is between 3 and 5 months of age and has failed to respond to a two-month trial of repositioning therapy; or

(2) The member is between 6 and 18 months of age and there is documentation of either of the following conditions:

1. Cephalic index at least two standard deviations above the mean for the member's gender and age; or

2. Asymmetry of 12 millimeters or more in the cranial vault, skull base, or orbitotragial depth.

78.10(4) *Medical supplies.* Medical supplies are nondurable items consumed in the process of giving medical care, for example, nebulizers, gauze, bandages, sterile pads, adhesive tape, and sterile absorbent cotton. Medical supplies are payable for a specific medicinal purpose. This does not include food or drugs. Medical supplies are not to be dispensed at any one time for quantities exceeding a three-month supply. After the initial dispensing of medical supplies, the provider must document a refill request from the Medicaid member or the member's caregiver for each refill.

a. Only the following types of medical supplies and supplies necessary for the effective use of a payable item can be purchased through the medical assistance program:

Catheter (indwelling Foley).

Colostomy and ileostomy appliances.

Colostomy and ileostomy care dressings, liquid adhesive, and adhesive tape.

Diabetic blood glucose test strips, subject to the limitation in 78.10(4)*"c."*

Diabetic supplies, other than blood glucose test strips (needles, syringes, and diabetic urine test supplies).

Dialysis supplies.

Diapers (for members aged four and above).

Disposable catheterization trays or sets (sterile).

Disposable irrigation trays or sets (sterile).

Disposable saline enemas (e.g., sodium phosphate type).

Disposable underpads.

Dressings.

Elastic antiembolism support stocking.

Enema.

Hearing aid batteries.

Respirator supplies.

Surgical supplies.

Urinary collection supplies.

b. Only the following types of medical supplies will be approved for payment for members receiving care in a nursing facility or an intermediate care facility for the mentally retarded when prescribed by the physician, physician assistant, or advanced registered nurse practitioner:

Catheter (indwelling Foley).

Colostomy and ileostomy appliances.

Colostomy and ileostomy care dressings, liquid adhesive and adhesive tape.

Diabetic supplies (needles and syringes, blood glucose test strips and diabetic urine test supplies).

Disposable catheterization trays or sets (sterile).

Disposable irrigation trays or sets (sterile).

Disposable saline enemas (e.g., sodium phosphate type).

c. Diabetic blood glucose test strips are covered through the Medicaid program only if:

(1) The strips are produced by a manufacturer that has a current agreement to provide a rebate to the department for test strips provided through the Medicaid program, or

(2) Prior authorization is received pursuant to rule 441—79.8(249A) for test strips produced by a manufacturer that does not have a current rebate agreement with the department, based on medical necessity.

This rule is intended to implement Iowa Code sections 249A.3, 249A.4 and 249A.12.

[**ARC 7548B**, IAB 2/11/09, effective 4/1/09; **ARC 8344B**, IAB 12/2/09, effective 12/1/09; **ARC 8643B**, IAB 4/7/10, effective 3/11/10]

441—78.11(249A) Ambulance service. Payment will be approved for ambulance service if it is required by the recipient's condition and the recipient is transported to the nearest hospital with appropriate facilities or to one in the same locality, from one hospital to another, to the patient's home or to a nursing facility. Payment for ambulance service to the nearest hospital for outpatient service will be approved only for emergency treatment. Ambulance service must be medically necessary and not merely for the convenience of the patient.

78.11(1) Partial payment may be made when an individual is transported beyond the destinations specified, and is limited to the amount that would have been paid had the individual been transported to the nearest institution with appropriate facilities. When transportation is to the patient's home, partial payment is limited to the amount that would have been paid from the nearest institution with appropriate facilities. When a recipient who is a resident of a nursing care facility is hospitalized and later discharged from the hospital, payment will be made for the trip to the nursing care facility where the recipient resides even though it may not in fact be the nearest nursing care facility.

78.11(2) The Iowa Medicaid enterprise medical services unit shall determine that the ambulance transportation was medically necessary and that the condition of the patient precluded any other method of transportation. Payment can be made without the physician's confirmation when:

a. The individual is admitted as a hospital inpatient or in an emergency situation.

b. Previous information on file relating to the patient's condition clearly indicates ambulance service was necessary.

78.11(3) When a patient is transferred from one nursing home to another because of the closing of a facility or from a nursing home to a custodial home because the recipient no longer requires nursing care, the conditions of medical necessity and the distance requirements shall not be applicable. Approval for transfer shall be made by the local office of the department of human services prior to the transfer. When such a transfer is made, the following rate schedule shall apply:

One patient - normal allowance

Two patients - 3/4 normal allowance per patient

Three patients - 2/3 normal allowance per patient

Four patients - 5/8 normal allowance per patient

78.11(4) Transportation of hospital inpatients. When an ambulance service provides transport of a hospital inpatient to a provider and returns the recipient to the same hospital (the recipient continuing to be an inpatient of the hospital), the ambulance service shall bill the hospital for reimbursement as the

hospital's DRG reimbursement system includes all costs associated with providing inpatient services as stated in 79.1(5)*"j."*

78.11(5) In the event that more than one ambulance service is called to provide ground ambulance transport, payment shall be made only to one ambulance company. When a paramedic from one ambulance service joins a ground ambulance company already in transport, coverage is not available for the services and supplies provided by the paramedic.

This rule is intended to implement Iowa Code section 249A.4.

441—78.12(249A) Remedial services. Payment will be made for remedial services not otherwise covered under this chapter that are designed to minimize or, if possible, eliminate the symptoms or causes of a psychological disorder, subject to the limitations in this rule.

78.12(1) *Covered services.* Medicaid covers the following remedial services:

a. Community psychiatric supportive treatment, which offers intensive interventions to modify psychological, behavioral, emotional, cognitive, and social factors affecting a member's functioning when less intensive remedial services do not meet the member's needs.

(1) Interventions must focus on the member's remedial needs to minimize or eliminate psychological barriers to a member's ability to effectively manage symptoms associated with a psychological disorder in an age-appropriate manner.

(2) Interventions may assist the member in skills such as conflict resolution, problem solving, social skills, interpersonal relationship skills, and communication.

(3) Community psychiatric supportive treatment is covered only for Medicaid members who are aged 20 or under.

(4) Community psychiatric supportive treatment is not intended for members in congregate care.

(5) Community psychiatric supportive treatment is not intended to be provided in a group.

b. Crisis intervention to de-escalate situations in which a risk to self, others, or property exists.

(1) Services shall assist a member to regain self-control and reestablish effective management of behavioral symptoms associated with a psychological disorder in an age-appropriate manner.

(2) Crisis intervention is covered only for Medicaid members who are aged 20 or under and shall be provided as outlined in a written treatment plan.

c. Health or behavior intervention, used to modify the psychological, behavioral, emotional, cognitive, and social factors affecting a member's functioning.

(1) Interventions may address the following skills for effective functioning with family, peers, and community: conflict resolution skills, problem-solving skills, social skills, interpersonal relationship skills, and communication skills.

(2) The purpose of intervention shall be to minimize or eliminate psychological barriers to the member's ability to effectively manage symptoms associated with a psychological disorder in an age-appropriate manner.

(3) Health or behavior intervention is covered only for Medicaid members aged 20 or under.

d. Rehabilitation program, which consists of interventions to enhance a member's independent living, social, and communication skills; to minimize or eliminate psychological barriers to a member's ability to effectively manage symptoms associated with a psychological disorder; and to maximize the member's ability to live and participate in the community.

(1) Interventions may address the following skills for effective functioning with family, peers, and community: communication skills, conflict resolution skills, problem-solving skills, social skills, interpersonal relationship skills, and employment-related skills.

(2) Rehabilitation program services are covered only for Medicaid members who are aged 18 or over.

e. Skills training and development, which consists of interventions to enhance independent living, social, and communication skills; to minimize or eliminate psychological barriers to a member's ability to effectively manage symptoms associated with a psychological disorder; and to maximize a member's ability to live and participate in the community.

(1) Interventions may include the following skills for effective functioning with family, peers, and community: communication skills, conflict resolution skills, problem-solving skills, social skills, interpersonal relationship skills, and employment-related skills.

(2) Skills training and development services are covered only for Medicaid members aged 18 or over.

78.12(2) *Excluded services.* Services that are habilitative in nature are not covered as remedial services. For purposes of this subrule, "habilitative services" means services that are designed to assist individuals in acquiring skills that they never had, as well as associated training to acquire self-help, socialization, and adaptive skills necessary to reside successfully in a home or community setting.

78.12(3) *Coverage requirements.* Medicaid covers remedial services only when the following conditions are met:

a. A licensed practitioner of the healing arts acting within the practitioner's scope of practice under state law has diagnosed the member with a psychological disorder. For example, licensed practitioners of the healing arts include physicians (M.D. or D.O.), advanced registered nurse practitioners (ARNP), psychologists (Ph.D. or Psy.D.), independent social workers (LISW), marital and family therapists (LMFT), and mental health counselors (LMHC). For purposes of this rule, the licensed practitioner of the healing arts must be:

(1) Enrolled in the Iowa Plan pursuant to 441—Chapter 88, Division IV; and

(2) Qualified to provide clinical assessment services under the Iowa Plan pursuant to 441—Chapter 88, Division IV (Current Procedural Terminology code 90801).

b. The licensed practitioner of the healing arts has recommended the remedial services as part of a plan of treatment designed to treat the member's psychological disorder. Diagnosis and treatment plan development provided in connection with this rule for members enrolled in the Iowa Plan are covered services under the Iowa Plan pursuant to 441— Chapter 88, Division IV.

c. For a member under the age of 21, the licensed practitioner of the healing arts:

(1) Has, in cooperation with the managed care contractor, selected a standardized assessment instrument appropriate for baseline measurement of the member's current skill level in managing mental health needs;

(2) Has completed an initial formal assessment of the member using the instrument selected; and

(3) Completes a formal assessment using the same instrument every six months thereafter if continued services are ordered.

d. The remedial services provider has prepared a written remedial services implementation plan that has been approved by:

(1) The member or the member's parent or guardian; and

(2) The medical services unit of the Iowa Medicaid enterprise.

78.12(4) *Approval of plan.* The remedial services provider shall submit the treatment plan, the results of the formal assessment, and the remedial services implementation plan to the Iowa Medicaid enterprise (IME) medical services unit for approval before providing the services.

a. *Initial plan.* The IME medical services unit shall approve the provider's initial remedial services implementation plan if:

(1) The plan conforms to the medical necessity requirements in subrule 78.12(3);

(2) The plan is consistent with the written diagnosis and treatment recommendations made by the licensed practitioner of the healing arts;

(3) The plan is sufficient in amount, duration, and scope to reasonably achieve its purpose;

(4) The provider can demonstrate that the provider possesses the skills and resources necessary to implement the plan, as required in rule 441—77.12(249A);

(5) The plan does not exceed six months' duration; and

(6) The plan requires that written progress notes be submitted no less often than every six weeks to the IME medical services unit.

b. *Subsequent plans.* The IME medical services unit may approve a subsequent remedial services implementation plan according to the conditions in paragraph *"a"* if the services are recommended by a licensed practitioner of the healing arts who has:

(1) Reexamined the member;

(2) Reviewed the original diagnosis and treatment plan;

(3) Evaluated the member's progress, including a formal assessment as required by 78.12(3)*"c"*(3); and

(4) Submitted the results of the formal assessment with the recommendation for continued services.

c. *Quality review.* The IME medical services unit will establish a quality review process. Reviews will evaluate:

(1) The time elapsed from referral to remedial plan development;

(2) The continuity of treatment;

(3) The affiliation of the licensed practitioner of the healing arts with the remedial services provider;

(4) Gaps in service;

(5) The results achieved; and

(6) Member satisfaction.

78.12(5) *Medical necessity.* Nothing in this rule shall be deemed to exempt coverage of remedial services from the requirement that services be medically necessary. "Medically necessary" means that the service is:

a. Consistent with the diagnosis and treatment of the member's condition;

b. Required to meet the medical needs of the member and is needed for reasons other than the convenience of the member or the member's caregiver;

c. The least costly type of service that can reasonably meet the medical needs of the member; and

d. In accordance with the standards of good medical practice. The standards of good practice for each field of medical and remedial care covered by the Iowa Medicaid program are those standards of good practice identified by:

(1) Knowledgeable Iowa clinicians practicing or teaching in the field; and

(2) The professional literature regarding best practices in the field.

This rule is intended to implement Iowa Code section 249A.4.

[**ARC 8504B**, IAB 2/10/10, effective 3/22/10]

441—78.13(249A) Transportation to receive medical care. Payment will be approved for transportation to receive services covered under the program, including transportation to obtain prescribed drugs, when all of the following conditions are met.

78.13(1) Transportation costs are reimbursable only when:

a. The source of the care is located outside the city limits of the community in which the member resides; or

b. The member resides in a rural area and must travel to a city to receive necessary care.

78.13(2) Transportation costs are reimbursable only when:

a. The type of care is not available in the community in which the member resides; or

b. The member has been referred by the attending physician to a specialist in another community.

78.13(3) Transportation costs are reimbursable only when there is no resource available to the member through which necessary transportation might be secured free of charge. EXCEPTION: Costs of transportation to obtain prescribed drugs may be reimbursed irrespective of whether free delivery is offered when the prescription drug is needed immediately.

78.13(4) Transportation is reimbursable only to the nearest institution or practitioner having appropriate facilities for the care of the member.

78.13(5) Transportation may be of any type and may be provided from any source.

a. When transportation is by car, the maximum payment that may be made will be the actual charge made by the provider for transportation to and from the source of medical care, but not in excess of 30 cents per mile.

b. When public transportation is utilized, the basis of payment will be the actual charge made by the provider of transportation, not to exceed $1.40 per mile.

c. In all cases where public transportation is reasonably available to or from the source of care and the member's condition does not preclude its use, public transportation must be utilized. When the

member's condition precludes the use of public transportation, a statement to the effect shall be included in the case record.

78.13(6) In the case of a child too young to travel alone, or an adult or child who because of physical or mental incapacity is unable to travel alone, payment subject to the above conditions shall be made for the transportation costs of an escort. The worker is responsible for making a decision concerning the necessity of an escort and recording the basis for the decision in the case record.

78.13(7) When meals and lodging or other travel expenses are required in connection with transportation, payment will be subject to the same conditions as for a state employee and the maximum amount payable shall not exceed the maximum payable to a state employee for the same expenses in connection with official travel within the state of Iowa.

78.13(8) When the services of an escort are required subject to the conditions in subrule 78.13(6), payment may be made for the escort's meals and lodging, when required, on the same basis as for the member.

78.13(9) Payment will not be made in advance to a member or a provider of medical transportation.

78.13(10) Payment for transportation to receive medical care is made to the member with the following exceptions:

a. Payment may be made to the agency that provided transportation if the agency is certified by the department of transportation and requests direct payment. Reimbursement for transportation shall be based on a fee schedule by mile or by trip.

b. In cases where the local office has established that the member has persistently failed to reimburse a provider of medical transportation, payment may be made directly to the provider.

c. In all situations where one of the department's volunteers is the provider of transportation.

78.13(11) Form 470-0386, Medical Transportation Claim, shall be completed by the member and the medical provider and submitted to the local office for each trip for which payment is requested. All trips to the same provider in a calendar month may, at the member's option, be submitted on the same form.

78.13(12) No claim shall be paid if presented after the lapse of 365 days from its accrual unless it is to correct payment on a claim originally submitted within the required period.

This rule is intended to implement Iowa Code section 249A.4.

[**ARC 8344B**, IAB 12/2/09, effective 12/1/09; **ARC 8643B**, IAB 4/7/10, effective 3/11/10]

441—78.14(249A) Hearing aids. Payment shall be approved for a hearing aid and examinations subject to the following conditions:

78.14(1) *Physician examination.* The member shall have an examination by a physician to determine that the member has no condition which would contraindicate the use of a hearing aid. This report shall be documented in the patient record. The requirement for a physician evaluation shall be waived for members 18 years of age or older when the member has signed an informed consent statement acknowledging that the member:

a. Has been advised that it may be in the member's best health interest to receive a medical evaluation from a licensed physician before purchase of a hearing aid.

b. Does not wish to receive a medical evaluation prior to purchase of a hearing aid.

78.14(2) *Audiological testings.* A physician or an audiologist shall perform audiological testing as a part of making a determination that a member could benefit from the use of a hearing aid. The department shall cover vestibular testing performed by an audiologist only when prescribed by a physician.

78.14(3) *Hearing aid evaluation.* A physician or an audiologist shall perform a hearing aid evaluation to establish if a member could benefit from a hearing aid. When a hearing aid is recommended for a member, the physician or audiologist recommending the hearing aid shall see the member at least one time within 30 days after purchase of the hearing aid to determine that the aid is adequate.

78.14(4) *Hearing aid selection.* A physician or audiologist may recommend a specific brand or model appropriate to the member's condition. When a physician or an audiologist makes a general hearing aid recommendation, a hearing aid dispenser may perform the tests to determine the specific brand or model appropriate to the member's condition.

78.14(5) *Travel.* When a member is unable to travel to the physician or audiologist because of health reasons, the department shall make payment for travel to the member's place of residence or other suitable location. The department shall make payment to physicians as specified in 78.1(8) and payment to audiologists at the same rate it reimburses state employees for travel.

78.14(6) *Purchase of hearing aid.* The department shall pay for the type of hearing aid recommended when purchased from an eligible licensed hearing aid dispenser pursuant to rule 441—77.13(249A). The department shall pay for binaural amplification when:

a. A child needs the aid for speech development,

b. The aid is needed for educational or vocational purposes,

c. The aid is for a blind member,

d. The member's hearing loss has caused marked restriction of daily activities and constriction of interests resulting in seriously impaired ability to relate to other people, or

e. Lack of binaural amplification poses a hazard to a member's safety.

78.14(7) *Payment for hearing aids.*

a. Payment for hearing aids shall be acquisition cost plus a dispensing fee covering the fitting and service for six months. The department shall make payment for routine service after the first six months. Dispensing fees and payment for routine service shall not exceed the fee schedule appropriate to the place of service. Shipping and handling charges are not allowed.

b. Payment for ear mold and batteries shall be at the current audiologist's fee schedule.

c. Payment for repairs shall be made to the dealer for repairs made by the dealer. Payment for in-house repairs shall be made at the current fee schedule. Payment shall also be made to the dealer for repairs when the hearing aid is repaired by the manufacturer or manufacturer's depot. Payment for out-of-house repairs shall be at the amount shown on the manufacturer's invoice. payment shall be allowed for a service or handling charge when it is necessary for repairs to be performed by the manufacturer or manufacturer's depot and this charge is made to the general public.

d. Prior approval. When prior approval is required, Form 470-4767, Examiner Report of Need for a Hearing Aid, shall be submitted along with the forms required by 441—paragraph 79.8(1)*"a."*

(1) Payment for the replacement of a hearing aid less than four years old shall require prior approval except when the member is under 21 years of age. The department shall approve payment when the original hearing aid is lost or broken beyond repair or there is a significant change in the member's hearing that would require a different hearing aid. (Cross-reference 78.28(4)*"a"*)

(2) Payment for a hearing aid costing more than $650 shall require prior approval. The department shall approve payment for either of the following purposes (Cross-reference 78.28(4)*"b"*):

1. Educational purposes when the member is participating in primary or secondary education or in a postsecondary academic program leading to a degree and an in-office comparison of an analog aid and a digital aid matched (+/− 5dB) for gain and output shows a significant improvement in either speech recognition in quiet or speech recognition in noise or an in-office comparison of two aids, one of which is single channel, shows significantly improved audibility.

2. Vocational purposes when documentation submitted indicates the necessity, such as varying amounts of background noise in the work environment and a need to converse in order to do the job, and an in-office comparison of an analog aid and a digital aid matched (+/- 5dB) for gain and output shows a significant improvement in either speech recognition in quiet or speech recognition in noise or an in-office comparison of two aids, one of which is single channel, shows significantly improved audibility.

This rule is intended to implement Iowa Code section 249A.4.

[**ARC 8008B**, IAB 7/29/09, effective 8/1/09]

441—78.15(249A) Orthopedic shoes. Payment shall be approved only for depth or custom-molded orthopedic shoes, inserts, and modifications, subject to the following definitions and conditions.

78.15(1) *Definitions.*

"Custom-molded shoe" means a shoe that:

1. Has been constructed over a cast or model of the recipient's foot;

2. Is made of leather or another suitable material of equal quality;

3. Has inserts that can be removed, altered, or replaced according to the recipient's conditions and needs; and

4. Has some form of closure.

"Depth shoe" means a shoe that:

1. Has a full length, heel-to-toe filler that when removed provides a minimum of 3/16 inch of additional depth used to accommodate custom-molded or customized inserts;

2. Is made from leather or another suitable material of equal quality;

3. Has some form of closure; and

4. Is available in full and half sizes with a minimum of three widths, so that the sole is graded to the size and width of the upper portions of the shoe according to the American Standard last sizing schedule or its equivalent.

"Insert" means a foot mold or orthosis constructed of more than one layer of a material that:

1. Is soft enough and firm enough to take and hold an impression during use, and

2. Is molded to the recipient's foot or is made over a model of the foot.

78.15(2) *Prescription.* The recipient shall present to the provider a written prescription by a physician, a podiatrist, a physician assistant, or an advanced registered nurse practitioner that includes all of the following:

1. The date.

2. The patient's diagnosis.

3. The reason orthopedic shoes are needed.

4. The probable duration of need.

5. A specific description of any required modification of the shoes.

78.15(3) *Diagnosis.* The recipient shall have a diagnosis of an orthopedic, neuromuscular, vascular, or insensate foot condition, supported by applicable codes from the current version of the International Classification of Diseases (ICD). A diagnosis of flat feet is not covered.

a. A recipient with diabetes must meet the Medicare criteria for therapeutic depth and custom-molded shoes.

b. Custom-molded shoes are covered only when the recipient has a foot deformity and the provider has documentation of all of the following:

(1) The reasons the recipient cannot be fitted with a depth shoe.

(2) Pain.

(3) Tissue breakdown or a high probability of tissue breakdown.

(4) Any limitation on walking.

78.15(4) *Frequency.* Only two pairs of orthopedic shoes are allowed per recipient in a 12-month period unless documentation of change in size or evidence of excessive wear is submitted. EXCEPTION: School-aged children under the age of 21 may obtain athletic shoes in addition to the two pairs of shoes in a 12-month period.

This rule is intended to implement Iowa Code section 249A.4.

441—78.16(249A) Community mental health centers. Payment will be approved for all reasonable and necessary services provided by a psychiatrist on the staff of a community mental health center. Payment will be approved for services provided by a clinical psychologist, social worker or psychiatric nurse on the staff of the center, subject to the following conditions:

78.16(1) Payment to a community mental health center will be approved for reasonable and necessary services provided to members by a psychiatrist, psychologist, social worker or psychiatric nurse on the staff of the center under the following conditions:

a. Services must be rendered under the supervision of a board-eligible or board-certified psychiatrist. All services must be performed under the supervision of a board-eligible or board-certified psychiatrist subject to the conditions set forth in 78.16(1)*"b"* with the following exceptions:

(1) Services by staff psychiatrists, or

(2) Services rendered by psychologists meeting the requirements of the National Register of Health Service Providers in Psychology, or

(3) Services provided by a staff member listed in this subrule performing the preliminary diagnostic evaluation of a member for voluntary admission to one of the state mental health institutes.

b. Supervisory process.

(1) Each patient shall have an initial evaluation completed which shall include at least one personal evaluation interview with a mental health professional, as defined under Iowa Code section 228.1. If the evaluation interview results indicate a need for an interview with a board-eligible or board-certified psychiatrist, then such referral shall be made. This must be accomplished before submission of the first claim for services rendered to that patient.

(2) Ongoing review and assessment of patients' treatment needs, treatment plans, and the appropriateness of services rendered shall be assured through the peer review process in effect for community mental health centers, as directed by 2002 Iowa Acts, chapter 1120, section 13.

(3) and (4) Rescinded IAB 2/5/03, effective 2/1/03.

78.16(2) The treatment plans for and services rendered to patients of the center shall be evaluated and revised as necessary and appropriate, consistent with the standards of the peer review process described in subparagraph 78.16(1)*"b"*(1).

78.16(3) The peer review process and related activities, as described under subparagraph 78.16(1)*"b"*(1), are not payable as separate services under the Medicaid program. The center shall maintain the results of and information related to the peer review process, and these records shall be subject to audit by the department of human services or department designees, as necessary and appropriate.

78.16(4) Clinical records of medical assistance patients shall be available to the carrier on request. All these records shall be held confidential.

78.16(5) At the time of application for participation in the program the center will be provided with a form on which to list its professional staff. The center shall report acquisitions or losses of professional staff to the carrier within ten days.

78.16(6) Payment to a community mental health center will be approved for day treatment services for persons aged 21 or over if the center is certified by the department for day treatment services, the services are provided on the premises of the community mental health center or satellite office of the community mental health center, and the services meet the standards outlined herein.

a. Community mental health centers providing day treatment services for persons aged 21 or over shall have available a written narrative providing the following day treatment information:

(1) Documented need for day treatment services for persons aged 21 and over in the area served by the program, including studies, needs assessments, and consultations with other health care professionals.

(2) Goals and objectives of the day treatment program for persons aged 21 and over that meet the day treatment program guidelines noted in 78.16(6)*"b."*

(3) Organization and staffing including how the day treatment program for persons aged 21 and over fits with the rest of the community mental health center, the number of staff, staff credentials, and the staff's relationship to the program, e.g., employee, contractual, or consultant.

(4) Policies and procedures for the program including admission criteria, patient assessment, treatment plan, discharge plan, postdischarge services, and the scope of services provided.

(5) Any accreditations or other types of approvals from national or state organizations.

(6) The physical facility and any equipment to be utilized.

b. Day treatment services for persons aged 21 and over shall be structured, long-term services designed to assist in restoring, maintaining or increasing levels of functioning, minimizing regression, and preventing hospitalization.

(1) Service components include training in independent functioning skills necessary for self-care, emotional stability and psychosocial interactions and training in medication management.

(2) Services are structured with an emphasis on program variation according to individual need.

(3) Services are provided for a period of three to five hours per day, three or four times per week.

c. Payment will be approved for day treatment services provided by or under the general supervision of a mental health professional as defined in rule 441—33.1(225C,230A). When services are provided by an employee or consultant of the community mental health center who is not a mental health professional, the employee or consultant shall be supervised by a mental health professional who gives professional direction and active guidance to the employee or consultant and who retains responsibility for consumer care. The supervision shall be timely, regular, and documented. The employee or consultant shall meet the following minimum requirements:

(1) Have a bachelor's degree in a human services related field from an accredited college or university; or

(2) Have an Iowa license to practice as a registered nurse with two years of experience in the delivery of nursing or human services.

d. Persons aged 18 through 20 with chronic mental illness as defined by rule 441—24.1(225C) can receive day treatment services under this subrule or subrule 78.16(7).

78.16(7) Payment to a community mental health center will be approved for day treatment services for persons aged 20 or under if the center is certified by the department for day treatment services and the services are provided on the premises of the community mental health center or satellite office of the community mental health center. Exception: Field trips away from the premises are a covered service when the trip is therapeutic and integrated into the day treatment program's description and milieu plan.

Day treatment coverage will be limited to a maximum of 15 hours per week. Day treatment services for persons aged 20 or under shall be outpatient services provided to persons who are not inpatients in a medical institution or residents of a group care facility licensed under 441—Chapter 114.

a. Program documentation. Community mental health centers providing day treatment services for persons aged 20 or under shall have available a written narrative which provides the following day treatment program information:

(1) Documented need for day treatment services for persons aged 20 or under in the area served by the program, including studies, needs assessments, and consultations with other health care professionals.

(2) Goals and objectives of the day treatment program for persons aged 20 or under that meet the guidelines noted in paragraphs *"c"* to *"h"* below.

(3) Organization and staffing including how the day treatment program for persons aged 20 or under fits with the rest of the community mental health center, the number of staff, staff credentials, and the staff's relationship to the program, e.g., employee, contractual, or consultant.

(4) Policies and procedures for the program including admission criteria, patient assessment, treatment plan, discharge plan, postdischarge services, and the scope of services provided.

(5) Any accreditations or other types of approvals from national or state organizations.

(6) The physical facility and any equipment to be utilized.

b. Program standards. Medicaid day treatment program services for persons aged 20 and under shall meet the following standards:

(1) Staffing shall:

1. Be sufficient to deliver program services and provide stable, consistent, and cohesive milieu with a staff-to-patient ratio of no less than one staff for each eight participants. Clinical, professional, and paraprofessional staff may be counted in determining the staff-to-patient ratio. Professional or clinical staff are those staff who are either mental health professionals as defined in rule 441—33.1(225C,230A) or persons employed for the purpose of providing offered services under the supervision of a mental health professional. All other staff (administrative, adjunctive, support, nonclinical, clerical, and consulting staff or professional clinical staff) when engaged in administrative or clerical activities shall not be counted in determining the staff-to-patient ratio or in defining program staffing patterns. Educational staff may be counted in the staff-to-patient ratio.

2. Reflect how program continuity will be provided.

3. Reflect an interdisciplinary team of professionals and paraprofessionals.

4. Include a designated director who is a mental health professional as defined in rule 441—33.1(225C,230A). The director shall be responsible for direct supervision of the individual treatment plans for participants and the ongoing assessment of program effectiveness.

5. Be provided by or under the general supervision of a mental health professional as defined in rule 441—33.1(225C,230A). When services are provided by an employee or consultant of the community mental health center who is not a mental health professional, the employee or consultant shall be supervised by a mental health professional who gives direct professional direction and active guidance to the employee or consultant and who retains responsibility for consumer care. The supervision shall be timely, regular and documented. The employee or consultant shall have a bachelor's degree in a human services related field from an accredited college or university or have an Iowa license to practice as a registered nurse with two years of experience in the delivery of nursing or human services. Exception: Other certified or licensed staff, such as certified addiction counselors or certified occupational and recreational therapy assistants, are eligible to provide direct services under the general supervision of a mental health professional, but they shall not be included in the staff-to-patient ratio.

(2) There shall be written policies and procedures addressing the following: admission criteria; patient assessment; patient evaluation; treatment plan; discharge plan; community linkage with other psychiatric, mental health, and human service providers; a process to review the quality of care being provided with a quarterly review of the effectiveness of the clinical program; postdischarge services; and the scope of services provided.

(3) The program shall have hours of operation available for a minimum of three consecutive hours per day, three days or evenings per week.

(4) The length of stay in a day treatment program for persons aged 20 or under shall not exceed 180 treatment days per episode of care, unless the rationale for a longer stay is documented in the patient's case record and treatment plan every 30 calendar days after the first 180 treatment days.

(5) Programming shall meet the individual needs of the patient. A description of services provided for patients shall be documented along with a schedule of when service activities are available including the days and hours of program availability.

(6) There shall be a written plan for accessing emergency services 24 hours a day, seven days a week.

(7) The program shall maintain a community liaison with other psychiatric, mental health, and human service providers. Formal relationships shall exist with hospitals providing inpatient programs to facilitate referral, communication, and discharge planning. Relationships shall also exist with appropriate school districts and educational cooperatives. Relationships with other entities such as physicians, hospitals, private practitioners, halfway houses, the department, juvenile justice system, community support groups, and child advocacy groups are encouraged. The provider's program description will describe how community links will be established and maintained.

(8) Psychotherapeutic treatment services and psychosocial rehabilitation services shall be available. A description of the services shall accompany the application for certification.

(9) The program shall maintain a distinct clinical record for each patient admitted. Documentation, at a minimum, shall include: the specific services rendered, the date and actual time services were rendered, who rendered the services, the setting in which the services were rendered, the amount of time it took to deliver the services, the relationship of the services to the treatment regimen described in the plan of care, and updates describing the patient's progress.

c. Program services. Day treatment services for persons aged 20 or under shall be a time-limited, goal-oriented active treatment program that offers therapeutically intensive, coordinated, structured clinical services within a stable therapeutic milieu. Time-limited means that the patient is not expected to need services indefinitely or lifelong, and that the primary goal of the program is to improve the behavioral functioning or emotional adjustment of the patient in order that the service is no longer necessary. Day treatment services shall be provided within the least restrictive therapeutically appropriate context and shall be community-based and family focused. The overall expected outcome is clinically adaptive behavior on the part of the patient and the family.

At a minimum, day treatment services will be expected to improve the patient's condition, restore the condition to the level of functioning prior to onset of illness, control symptoms, or establish and maintain a functional level to avoid further deterioration or hospitalization. Services are expected to be age-appropriate forms of psychosocial rehabilitation activities, psychotherapeutic services, social

skills training, or training in basic care activities to establish, retain or encourage age-appropriate or developmentally appropriate psychosocial, educational, and emotional adjustment.

Day treatment programs shall use an integrated, comprehensive and complementary schedule of therapeutic activities and shall have the capacity to treat a wide array of clinical conditions.

The following services shall be available as components of the day treatment program. These services are not separately billable to Medicaid, as day treatment reimbursement includes reimbursement for all day treatment components.

(1) Psychotherapeutic treatment services (examples would include individual, group, and family therapy).

(2) Psychosocial rehabilitation services. Active treatment examples include, but are not limited to, individual and group therapy, medication evaluation and management, expressive therapies, and theme groups such as communication skills, assertiveness training, other forms of community skills training, stress management, chemical dependency counseling, education, and prevention, symptom recognition and reduction, problem solving, relaxation techniques, and victimization (sexual, emotional, or physical abuse issues).

Other program components may be provided, such as personal hygiene, recreation, community awareness, arts and crafts, and social activities designed to improve interpersonal skills and family mental health. Although these other services may be provided, they are not the primary focus of treatment.

(3) Evaluation services to determine need for day treatment prior to program admission. For persons for whom clarification is needed to determine whether day treatment is an appropriate therapy approach, or for persons who do not clearly meet admission criteria, an evaluation service may be performed. Evaluation services shall be individual and family evaluation activities made available to courts, schools, other agencies, and individuals upon request, who assess, plan, and link individuals with appropriate services. This service must be completed by a mental health professional. An evaluation from another source performed within the previous 12 months or sooner if there has not been a change may be substituted. Medicaid will not make separate payment for these services under the day treatment program.

(4) Assessment services. All day treatment patients will receive a formal, comprehensive biopsychosocial assessment of day treatment needs including, if applicable, a diagnostic impression based on the current Diagnostic and Statistical Manual of Mental Disorders. An assessment from another source performed within the previous 12 months may be used if the symptomatology is the same as 12 months ago. If not, parts of the assessment which reflect current functioning may be used as an update. Using the assessment, a comprehensive summation will be produced, including the findings of all assessments performed. The summary will be used in forming a treatment plan including treatment goals. Indicators for discharge planning, including recommended follow-up goals and provision for future services, should also be considered, and consistently monitored.

(5) The day treatment program may include an educational component as an additional service. The patient's educational needs shall be served without conflict from the day treatment program. Hours in which the patient is involved in the educational component of the day treatment program are not included in the day treatment hours billable to Medicaid.

d. Admission criteria. Admission criteria for day treatment services for persons aged 20 or under shall reflect the following clinical indicators:

(1) The patient is at risk for exclusion from normative community activities or residence.

(2) The patient exhibits psychiatric symptoms, disturbances of conduct, decompensating conditions affecting mental health, severe developmental delays, psychological symptoms, or chemical dependency issues sufficiently severe to bring about significant or profound impairment in day-to-day educational, social, vocational, or interpersonal functioning.

(3) Documentation is provided that the traditional outpatient setting has been considered and has been determined not to be appropriate.

(4) The patient's principal caretaker (family, guardian, foster family or custodian) must be able and willing to provide the support and monitoring of the patient, to enable adequate control of the patient's

behavior, and must be involved in the patient's treatment. Persons aged 20 or under who have reached the age of majority, either by age or emancipation, are exempt from family therapy involvement.

(5) The patient has the capacity to benefit from the interventions provided.

e. Individual treatment plan. Each patient receiving day treatment services shall have a treatment plan prepared. A preliminary treatment plan should be formulated within 3 days of participation after admission, and replaced within 30 calendar days by a comprehensive, formalized plan utilizing the comprehensive assessment. This individual treatment plan should reflect the patient's strengths and weaknesses and identify areas of therapeutic focus. The treatment goals which are general statements of consumer outcomes shall be related to identified strengths, weaknesses, and clinical needs with time-limited, measurable objectives. Objectives shall be related to the goal and have specific anticipated outcomes. Methods that will be used to pursue the objectives shall be stated. The plan should be reviewed and revised as needed, but shall be reviewed at least every 30 calendar days. The treatment plan shall be developed or approved by a board-eligible or board-certified psychiatrist, a staff psychiatrist, physician, or a psychologist registered either on the "National Register of Health Service Providers in Psychology" or the "Iowa Register of Health Service Providers for Psychology." Approval will be evidenced by a signature of the physician or health service provider.

f. Discharge criteria. Discharge criteria for the day treatment program for persons aged 20 or under shall incorporate at least the following indicators:

(1) In the case of patient improvement:

1. The patient's clinical condition has improved as shown by symptom relief, behavioral control, or indication of mastery of skills at the patient's developmental level. Reduced interference with and increased responsibility with social, vocational, interpersonal, or educational goals occurs sufficient to warrant a treatment program of less supervision, support, and therapeutic intervention.

2. Treatment goals in the individualized treatment plan have been achieved.

3. An aftercare plan has been developed that is appropriate to the patient's needs and agreed to by the patient and family, custodian, or guardian.

(2) If the patient does not improve:

1. The patient's clinical condition has deteriorated to the extent that the safety and security of inpatient or residential care is necessary.

2. Patient, family, or custodian noncompliance with treatment or with program rules exists.

g. Coordination of services. Programming services shall be provided in accordance with the individual treatment plan developed by appropriate day treatment staff, in collaboration with the patient and appropriate caretaker figure (parent, guardian, or principal caretaker), and under the supervision of the program director, coordinator, or supervisor.

The program for each patient will be coordinated by primary care staff of the community mental health center. A coordinated, consistent array of scheduled therapeutic services and activities shall comprise the day treatment program. These may include counseling or psychotherapy, theme groups, social skills development, behavior management, and other adjunctive therapies. At least 50 percent of scheduled therapeutic program hours exclusive of educational hours for each patient shall consist of active treatment that specifically addresses the targeted problems of the population served. Active treatment shall be defined as treatment in which the program staff assume significant responsibility and often intervene.

Family, guardian, or principal caretaker shall be involved with the program through family therapy sessions or scheduled family components of the program. They will be encouraged to adopt an active role in treatment. Medicaid will not make separate payment for family therapy services. Persons aged 20 or under who have reached the age of majority, either by age or emancipation, are exempt from family therapy involvement.

Therapeutic activities will be scheduled according to the needs of the patients, both individually and as a group.

Scheduled therapeutic activities, which may include other program components as described above, shall be provided at least 3 hours per week up to a maximum of 15 hours per week.

h. *Stable milieu.* The program shall formally seek to provide a stable, consistent, and cohesive therapeutic milieu. In part this will be encouraged by scheduling attendance such that a stable core of patients exists as much as possible. The milieu will consider the developmental and social stage of the participants such that no patient will be significantly involved with other patients who are likely to contribute to retardation or deterioration of the patient's social and emotional functioning. To help establish a sense of program identity, the array of therapeutic interventions shall be specifically identified as the day treatment program. Program planning meetings shall be held at least quarterly to evaluate the effectiveness of the clinical program. In the program description, the provider shall state how milieu stability will be provided.

i. *Chronic mental illness.* Persons aged 18 through 20 with chronic mental illness as defined by rule 441—24.1(225C) can receive day treatment services under this subrule or subrule 78.16(6).

This rule is intended to implement Iowa Code section 249A.4.

441—78.17(249A) Physical therapists. Payment will be approved for the same services payable under Title XVIII of the Social Security Act (Medicare).

This rule is intended to implement Iowa Code section 249A.4.

441—78.18(249A) Screening centers. Payment will be approved for health screening as defined in 441—subrule 84.1(1) for Medicaid members under 21 years of age.

78.18(1) Vaccines available through the Vaccines for Children program under Section 1928 of the Social Security Act are not covered as screening center services. Screening centers that wish to administer those vaccines to Medicaid members shall enroll in the Vaccines for Children program and obtain the vaccines from the department of public health. Screening centers shall receive reimbursement for the administration of vaccines to Medicaid members.

78.18(2) Payment will be approved for necessary laboratory service related to an element of screening when performed by the screening center and billed as a separate item.

78.18(3) Periodicity schedules for health, hearing, vision, and dental screenings.

a. Payment will be approved for health, vision, and hearing screenings as follows:

(1) Six screenings in the first year of life.

(2) Four screenings between the ages of 1 and 2.

(3) One screening a year at ages 3, 4, 5, and 6.

(4) One screening a year at ages 8, 10, 12, 14, 16, 18, and 20.

b. Payment for dental screenings will be approved in conjunction with the health screenings up to age 12 months. Screenings will be approved at ages 12 months and 24 months and thereafter at six-month intervals up to age 21.

c. Interperiodic screenings will be approved as medically necessary.

78.18(4) When it is established by the periodicity schedule in 78.18(3) that an individual is in need of screening the individual will receive a notice that screening is due.

78.18(5) When an individual is screened, a member of the screening center shall complete a medical history. The medical history shall become part of the individual's medical record.

78.18(6) Rescinded IAB 12/3/08, effective 2/1/09.

78.18(7) Payment will be made for persons aged 20 and under for nutritional counseling provided by a licensed dietitian employed by or under contract with a screening center for a nutritional problem or condition of a degree of severity that nutritional counseling beyond that normally expected as part of the standard medical management is warranted. For persons eligible for the WIC program, a WIC referral is required. Medical necessity for nutritional counseling services exceeding those available through WIC shall be documented.

78.18(8) Payment shall be made for dental services provided by a dental hygienist employed by or under contract with a screening center.

This rule is intended to implement Iowa Code section 249A.4.

441—78.19(249A) Rehabilitation agencies.

78.19(1) *Coverage of services.*

a. General provisions regarding coverage of services.

(1) Services are provided in the recipient's home or in a care facility (other than a hospital) by a speech therapist, physical therapist, or occupational therapist employed by or contracted by the agency. Services provided a recipient residing in a nursing facility or residential care facility are payable when a statement is submitted signed by the facility that the facility does not have these services available. The statement need only be submitted at the start of care unless the situation changes. Payment will not be made to a rehabilitation agency for therapy provided to a recipient residing in an intermediate care facility for the mentally retarded since these facilities are responsible for providing or paying for services required by recipients.

(2) All services must be determined to be medically necessary, reasonable, and meet a significant need of the recipient that cannot be met by a family member, friend, medical staff personnel, or other caregiver; must meet accepted standards of medical practice; and must be a specific and effective treatment for a patient's medical or disabling condition.

(3) In order for a service to be payable, a licensed therapist must complete a plan of treatment every 30 days and indicate the type of service required. The plan of treatment must contain the information noted in subrule 78.19(2).

(4) There is no specific limitation on the number of visits for which payment through the program will be made so long as that amount of service is medically necessary in the individual case, is related to a diagnosed medical impairment or disabling condition, and meets the current standards of practice in each related field. Documentation must be submitted with each claim to support the need for the number of services being provided.

(5) Payments will be made both for restorative service and also for maintenance types of service. Essentially, maintenance services means services to a patient whose condition is stabilized and who requires observation by a therapist of conditions defined by the physician as indicating a possible deterioration of health status. This would include persons with long-term illnesses or a disabling condition whose status is stable rather than posthospital. Refer to 78.19(1)*"b"*(7) and (8) for guidelines under restorative and maintenance therapy.

(6) Restorative or maintenance therapy sessions must meet the following criteria:

1. There must be face-to-face patient contact interaction.

2. Services must be provided primarily on an individual basis. Group therapy is covered, but total units of service in a month shall not exceed total units of individual therapy. Family members receiving therapy may be included as part of a group.

3. Treatment sessions may be no less than 15 minutes of service and no more than 60 minutes of service per date unless more than 60 minutes of service is required for a treatment session due to the patient's specific condition. If more than 60 minutes of service is required for a treatment session, additional documentation of the specific condition and the need for the longer treatment session shall be submitted with the claim. A unit of treatment shall be considered to be 15 minutes in length.

4. Progress must be documented in measurable statistics in the progress notes in order for services to be reimbursed. Refer to 78.19(1)*"b"*(7) and (8) for guidelines under restorative and maintenance therapy.

(7) Payment will be made for an appropriate period of diagnostic therapy or trial therapy (up to two months) to determine a patient's rehabilitation potential and establish appropriate short-term and long-term goals. Documentation must be submitted with each plan to support the need for diagnostic or trial therapy. Refer to 78.19(1)*"b"*(16) for guidelines under diagnostic or trial therapy.

b. Physical therapy services.

(1) To be covered under rehabilitation agency services, physical therapy services must relate directly and specifically to an active written treatment plan, follow a treatment plan established by the licensed therapist after consultation with the physician, be reasonable and necessary to the treatment of the person's illness, injury, or disabling condition, be specific and effective treatment for the patient's medical or disabling condition, and be of such a level of complexity and sophistication, or the condition

of the patient must be such that the services required can be safely and effectively performed only by a qualified physical therapist or under the supervision of the therapist.

(2) A qualified physical therapist assistant may provide any restorative services performed by a licensed physical therapist under supervision of the therapist as set forth in the department of public health, professional licensure division, 645—subrule 200.20(7).

(3) The initial physical therapy evaluation must be provided by a licensed physical therapist.

(4) There must be an expectation that there will be a significant, practical improvement in the patient's condition in a reasonable amount of time based on the patient's restorative potential assessed by the physician.

(5) It must be demonstrated there is a need to establish a safe and effective maintenance program related to a specific disease state, illness, injury, or disabling condition.

(6) The amount, frequency, and duration of the services must be reasonable.

(7) Restorative therapy must be reasonable and necessary to the treatment of the patient's injury or disabling condition. The expected restorative potential must be practical and in relation to the extent and duration of the treatment. There must be an expectation that the patient's medical or disabling condition will show functional improvement in a reasonable period of time. Functional improvement means that demonstrable measurable increases have occurred in the patient's level of independence outside the therapeutic environment.

(8) Generally, maintenance therapy means services to a patient whose condition is stabilized and who requires observation by a therapist of conditions defined by the physician as indicating a possible deterioration of health status. This includes persons with long-term illnesses or disabling conditions whose status is stable rather than posthospital. Maintenance therapy is also appropriate for individuals whose condition is such that a professionally established program of activities, exercises, or stimulation is medically necessary to prevent deterioration or maintain present functioning levels.

Where a maintenance program is appropriate, the initial evaluation and the instruction of the patient, family members, home health aides, facility personnel, or other caregivers to carry out the program are considered a covered physical therapy service. Payment shall be made for a maximum of three visits to establish a maintenance program and instruct the caregivers. Payment for supervisory visits to monitor the program is limited to two per month for a maximum period of 12 months. The plan of treatment must specify the anticipated monitoring activity of the supervisor.

Beyond evaluation, instruction, and monitoring, maintenance therapy is not reimbursable.

After 12 months of maintenance therapy, a reevaluation is a covered service, if medically necessary. A reevaluation will be considered medically necessary only if there is a significant change in residential or employment situation or the patient exhibits an increase or decrease in functional ability or motivation, clearing of confusion, or the remission of some other medical condition which previously contraindicated restorative therapy. A statement by the interdisciplinary team of a person with developmental disabilities recommending a reevaluation and stating the basis for medical necessity will be considered as supporting the necessity of a reevaluation and may expedite approval.

(Restorative and maintenance therapy definitions also apply to speech and occupational therapy.)

When a patient is under a restorative physical therapy program, the patient's condition is regularly reevaluated and the program adjusted by the physical therapist. It is expected that prior to discharge, a maintenance program has been designed by the physical therapist. Consequently, where a maintenance program is not established until after the restorative program has been completed, it would not be considered reasonable and necessary to the treatment of the patient's condition and would be excluded from coverage.

(9) Hot packs, hydrocollator, infrared treatments, paraffin baths, and whirlpool baths do not ordinarily require the skills of a qualified physical therapist. These are covered when the patient's condition is complicated by other conditions such as a circulatory deficiency or open wounds or if the service is an integral part of a skilled physical therapy procedure.

(10) Gait training and gait evaluation and training constitute a covered service if the patient's ability to walk has been impaired by a neurological, muscular or skeletal condition or illness. The gait training must be expected to significantly improve the patient's ability to walk or level of independence.

Repetitious exercise to increase endurance of weak or unstable patients can be safely provided by supportive personnel, e.g., aides, nursing personnel. Therefore, it is not a covered physical therapy service.

(11) Ultrasound, shortwave, and microwave diathermy treatments are considered covered services.

(12) Range of motion tests must be performed by a qualified physical therapist. Range of motion exercises require the skills of a qualified physical therapist only when they are part of the active treatment of a specific disease or disabling condition which has resulted in a loss or restriction of mobility.

Documentation must reflect the degree of motion lost, the normal range of motion, and the degree to be restored.

Range of motion to unaffected joints only does not constitute a covered physical therapy service.

(13) Reconditioning programs after surgery or prolonged hospitalization are not covered as physical therapy.

(14) Therapeutic exercises would constitute a physical therapy service due either to the type of exercise employed or to the condition of the patient.

(15) Use of isokinetic or isotonic type equipment in physical therapy is covered when normal range of motion of a joint is affected due to bone, joint, ligament or tendon injury or postsurgical trauma. Billing can only be made for the time actually spent by the therapist in instructing the patient and assessing the patient's progress.

(16) When recipients do not meet restorative or maintenance therapy criteria, diagnostic or trial therapy may be utilized. When the initial evaluation is not sufficient to determine whether there are rehabilitative goals that should be addressed, diagnostic or trial therapy to establish goals shall be considered appropriate. Diagnostic or trial therapy may be appropriate for recipients who need evaluation in multiple environments in order to adequately determine their rehabilitative potential. Diagnostic or trial therapy consideration may be appropriate when there is a need to assess the patient's response to treatment in the recipient's environment.

When during diagnostic or trial therapy a recipient has been sufficiently evaluated to determine potential for restorative or maintenance therapy, or lack of therapy potential, diagnostic or trial therapy ends. When as a result of diagnostic or trial therapy, restorative or maintenance therapy is found appropriate, claims shall be submitted noting restorative or maintenance therapy (instead of diagnostic or trial therapy).

At the end of diagnostic or trial therapy, the rehabilitation provider shall recommend continuance of services under restorative therapy, recommend continuance of services under maintenance therapy, or recommend discontinuance of services. Continuance of services under restorative or maintenance therapy will be reviewed based on the criteria in place for restorative or maintenance therapy.

Trial therapy shall not be granted more often than once per year for the same issue. If the recipient has a previous history of rehabilitative services, trial therapy for the same type of services generally would be payable only when a significant change has occurred since the last therapy. Requests for subsequent diagnostic or trial therapy for the same issue would require documentation reflecting a significant change. See number 4 below for guidelines under a significant change. Further diagnostic or trial therapy for the same issue would not be considered appropriate when progress was not achieved, unless the reasons which blocked change previously are listed and the reasons the new diagnostic or trial therapy would not have these blocks are provided.

The number of diagnostic or trial therapy hours authorized in the initial treatment period shall not exceed 12 hours per month. Documentation of the medical necessity and the plan for services under diagnostic trial therapy are required as they will be reviewed in the determination of the medical necessity of the number of hours of service provided.

Diagnostic or trial therapy standards also apply to speech and occupational therapy.

The following criteria additionally must be met:

1. There must be face-to-face interaction with a licensed therapist. (An aide's services will not be payable.)

2. Services must be provided on an individual basis. (Group diagnostic or trial therapy will not be payable.)

3. Documentation of the diagnostic therapy or trial therapy must reflect the provider's plan for therapy and the recipient's response.

4. If the recipient has a previous history of rehabilitative services, trial therapy for the same type of services generally would be payable only when a significant change has occurred since the last therapy. A significant change would be considered as having occurred when any of the following exist: new onset, new problem, new need, new growth issue, a change in vocational or residential setting that requires a reevaluation of potential, or surgical intervention that may have caused new rehabilitative potentials.

5. For persons who received previous rehabilitative treatment, consideration of trial therapy generally should occur only if the person has incorporated any regimen recommended during prior treatment into the person's daily life to the extent of the person's abilities.

6. Documentation should include any previous attempts to resolve problems using nontherapy personnel (i.e., residential group home staff, family members, etc.) and whether follow-up programs from previous therapy have been carried out.

7. Referrals from residential, vocational or other rehabilitation personnel that do not meet present evaluation, restorative or maintenance criteria shall be considered for trial therapy. Documentation of the proposed service, the medical necessity and the current medical or disabling condition, including any secondary rehabilitative diagnosis, will need to be submitted with the claim.

8. Claims for diagnostic or trial therapy shall reflect the progress being made toward the initial diagnostic or trial therapy plan.

c. Occupational therapy services.

(1) To be covered under rehabilitation agency services, occupational therapy services must be included in a plan of treatment, improve or restore practical functions which have been impaired by illness, injury, or disabling condition, or enhance the person's ability to perform those tasks required for independent functioning, be prescribed by a physician under a plan of treatment, be performed by a qualified licensed occupational therapist or a qualified licensed occupational therapist assistant under the general supervision of a qualified licensed occupational therapist as set forth in the department of public health, professional licensure division, rule 645—201.9(148B), and be reasonable and necessary for the treatment of the person's illness, injury, or disabling condition.

(2) Restorative therapy is covered when an expectation exists that the therapy will result in a significant practical improvement in the person's condition.

However, in these cases where there is a valid expectation of improvement met at the time the occupational therapy program is instituted, but the expectation goal is not realized, services would only be covered up to the time one would reasonably conclude the patient would not improve.

The guidelines under restorative therapy, maintenance therapy, and diagnostic or trial therapy for physical therapy in 78.19(1)*"b"*(7), (8), and (16) apply to occupational therapy.

(3) Maintenance therapy, or any activity or exercise program required to maintain a function at the restored level, is not a covered service. However, designing a maintenance program in accordance with the requirements of 78.19(1)*"b"*(8) and monitoring the progress would be covered.

(4) The selection and teaching of tasks designed to restore physical function are covered.

(5) Planning and implementing therapeutic tasks, such as activities to restore sensory-integrative functions are covered. Other examples include providing motor and tactile activities to increase input and improve responses for a stroke patient.

(6) The teaching of activities of daily living and energy conservation to improve the level of independence of a patient which require the skill of a licensed therapist and meet the definition of restorative therapy is covered.

(7) The designing, fabricating, and fitting of orthotic and self-help devices are considered covered services if they relate to the patient's condition and require occupational therapy. A maximum of 13 visits is reimbursable.

(8) Vocational and prevocational assessment and training are not payable by Medicaid. These include services which are related solely to specific employment opportunities, work skills, or work settings.

d. Speech therapy services.

(1) To be covered by Medicaid as rehabilitation agency services, speech therapy services must be included in a plan of treatment established by the licensed, skilled therapist after consultation with the physician, relate to a specific medical diagnosis which will significantly improve a patient's practical, functional level in a reasonable and predictable time period, and require the skilled services of a speech therapist. Services provided by a speech aide are not reimbursable.

(2) Speech therapy activities which are considered covered services include: restorative therapy services to restore functions affected by illness, injury, or disabling condition resulting in a communication impairment or to develop functions where deficiencies currently exist. Communication impairments fall into the general categories of disorders of voice, fluency, articulation, language, and swallowing disorders resulting from any condition other than mental impairment. Treatment of these conditions is payable if restorative criteria are met.

(3) Aural rehabilitation, the instruction given by a qualified speech pathologist in speech reading or lip reading to patients who have suffered a hearing loss (input impairment), constitutes a covered service if reasonable and necessary to the patient's illness or injury. Group treatment is not covered. Audiological services related to the use of a hearing aid are not reimbursable.

(4) Teaching a patient to use sign language and to use an augmentative communication device is reimbursable. The patient must show significant progress outside the therapy sessions in order for these services to be reimbursable.

(5) Where a maintenance program is appropriate, the initial evaluation, the instruction of the patient and caregivers to carry out the program, and supervisory visits to monitor progress are covered services. Beyond evaluation, instruction, and monitoring, maintenance therapy is not reimbursable. However, designing a maintenance program in accordance with the requirements of maintenance therapy and monitoring the progress are covered.

(6) The guidelines and limits on restorative therapy, maintenance therapy, and diagnostic or trial therapy for physical therapy in 78.19(1)*"b"*(7), (8), and (16) apply to speech therapy. If the only goal of prior rehabilitative speech therapy was to learn the prerequisite speech components, then number "5" under 78.19(1)*"b"*(16) will not apply to trial therapy.

78.19(2) *General guidelines for plans of treatment.*

a. The minimum information to be included on medical information forms and treatment plans includes:

(1) The patient's current medical condition and functional abilities, including any disabling condition.

(2) The physician's signature and date (within the certification period).

(3) Certification period.

(4) Patient's progress in measurable statistics. (Refer to 78.19(1)*"b"*(16).)

(5) The place services are rendered.

(6) Dates of prior hospitalization (if applicable or known).

(7) Dates of prior surgery (if applicable or known).

(8) The date the patient was last seen by the physician (if available).

(9) A diagnosis relevant to the medical necessity for treatment.

(10) Dates of onset of any diagnoses for which treatment is being rendered (if applicable).

(11) A brief summary of the initial evaluation or baseline.

(12) The patient's prognosis.

(13) The services to be rendered.

(14) The frequency of the services and discipline of the person providing the service.

(15) The anticipated duration of the services and the estimated date of discharge (if applicable).

(16) Assistive devices to be used.

(17) Functional limitations.

(18) The patient's rehabilitative potential and the extent to which the patient has been able to apply the skills learned in the rehabilitation setting to everyday living outside the therapy sessions.

(19) The date of the last episode of instability or the date of the last episode of acute recurrence of illness or symptoms (if applicable).

(20) Quantitative, measurable, short-term and long-term functional goals.
(21) The period of time of a session.
(22) Prior treatment (history related to current diagnosis) if available or known.

b. The information to be included when developing plans for teaching, training, and counseling include:

(1) To whom the services were provided (patient, family member, etc.).
(2) Prior teaching, training, or counseling provided.
(3) The medical necessity of the rendered services.
(4) The identification of specific services and goals.
(5) The date of the start of the services.
(6) The frequency of the services.
(7) Progress in response to the services.
(8) The estimated length of time the services are needed.

This rule is intended to implement Iowa Code section 249A.4.

441—78.20(249A) Independent laboratories. Payment will be made for medically necessary laboratory services provided by laboratories that are independent of attending and consulting physicians' offices, hospitals, and critical access hospitals and that are certified to participate in the Medicare program.

This rule is intended to implement Iowa Code section 249A.4.

441—78.21(249A) Rural health clinics. Payment will be made to rural health clinics for the same services payable under the Medicare program (Title XVIII of the Social Security Act). Payment will be made for sterilization in accordance with 78.1(16).

78.21(1) *Utilization review.* Utilization review shall be conducted of Medicaid members who access more than 24 outpatient visits in any 12-month period from physicians, advanced registered nurse practitioners, federally qualified health centers, other clinics, and emergency rooms. Refer to rule 441—76.9(249A) for further information concerning the member lock-in program.

78.21(2) *Risk assessment.* Risk assessment, using Form 470-2942, Medicaid Prenatal Risk Assessment, shall be completed at the initial visit during a Medicaid member's pregnancy.

a. If the risk assessment reflects a low-risk pregnancy, the assessment shall be completed again at approximately the twenty-eighth week of pregnancy.

b. If the risk assessment reflects a high-risk pregnancy, referral shall be made for enhanced services. (See description of enhanced services at subrule 78.25(3).)

78.21(3) *Vaccines.* Vaccines available through the Vaccines for Children program under Section 1928 of the Social Security Act are not covered as rural health center services. Rural health clinics that wish to administer those vaccines to Medicaid members shall enroll in the Vaccines for Children program and obtain the vaccines from the department of public health. However, the administration of vaccines is a covered service.

This rule is intended to implement Iowa Code section 249A.4.

441—78.22(249A) Family planning clinics. Payments will be made on a fee schedule basis for services provided by family planning clinics.

78.22(1) Payment will be made for sterilization in accordance with 78.1(16).

78.22(2) Vaccines available through the Vaccines for Children program under Section 1928 of the Social Security Act are not covered as family planning clinic services. Family planning clinics that wish to administer those vaccines for Medicaid members who receive services at the clinic shall enroll in the Vaccines for Children program and obtain the vaccines from the department of public health. Family planning clinics shall receive reimbursement for the administration of vaccines to Medicaid members.

This rule is intended to implement Iowa Code section 249A.4.

441—78.23(249A) Other clinic services. Payment will be made on a fee schedule basis to facilities not part of a hospital, funded publicly or by private contributions, which provide medically necessary treatment by or under the direct supervision of a physician or dentist to outpatients.

78.23(1) *Sterilization.* Payment will be made for sterilization in accordance with 78.1(16).

78.23(2) *Utilization review.* Utilization review shall be conducted of Medicaid members who access more than 24 outpatient visits in any 12-month period from physicians, advanced registered nurse practitioners, federally qualified health centers, other clinics, and emergency rooms. Refer to rule 441—76.9(249A) for further information concerning the member lock-in program.

78.23(3) *Risk assessment.* Risk assessment, using Form 470-2942, Medicaid Prenatal Risk Assessment, shall be completed at the initial visit during a Medicaid member's pregnancy.

a. If the risk assessment reflects a low-risk pregnancy, the assessment shall be completed again at approximately the twenty-eighth week of pregnancy.

b. If the risk assessment reflects a high-risk pregnancy, referral shall be made for enhanced services. (See description of enhanced services at subrule 78.25(3).)

78.23(4) *Vaccines.* Vaccines available through the Vaccines for Children program under Section 1928 of the Social Security Act are not covered as clinic services. Clinics that wish to administer those vaccines to Medicaid members shall enroll in the Vaccines for Children program and obtain the vaccines from the department of public health. Clinics shall receive reimbursement for the administration of vaccines to Medicaid members.

This rule is intended to implement Iowa Code section 249A.4.

441—78.24(249A) Psychologists. Payment will be approved for services authorized by state law when they are provided by the psychologist in the psychologist's office, a hospital, nursing facility, or residential care facility.

78.24(1) Payment for covered services provided by the psychologist shall be made on a fee for service basis.

a. Payment shall be made only for time spent in face-to-face consultation with the client.

b. Time spent with clients shall be rounded to the quarter hour.

78.24(2) Payment will be approved for the following psychological procedures:

a. Individual outpatient psychotherapy or other psychological procedures not to exceed one hour per week or 40 hours in any 12-month period, or

b. Couple, marital, family, or group outpatient therapy not to exceed one and one-half hours per week or 60 hours in any 12-month period, or

c. A combination of individual and group therapy not to exceed the cost of 40 individual therapy hours in any 12-month period.

d. Psychological examinations and testing for purposes of evaluation, placement, psychotherapy, or assessment of therapeutic progress, not to exceed eight hours in any 12-month period.

e. Mileage at the same rate as in 78.1(8) when the following conditions are met:

(1) It is necessary for the psychologist to travel outside of the home community, and

(2) There is no qualified mental health professional more immediately available in the community, and

(3) The member has a medical condition which prohibits travel.

f. Covered procedures necessary to maintain continuity of psychological treatment during periods of hospitalization or convalescence for physical illness.

g. Procedures provided within a licensed hospital, residential treatment facility, day hospital, or nursing home as part of an approved treatment plan and a psychologist is not employed by the facility.

78.24(3) Payment will not be approved for the following services:

a. Psychological examinations performed without relationship to evaluations or psychotherapy for a specific condition, symptom, or complaint.

b. Psychological examinations covered under Part B of Medicare, except for the Part B Medicare deductible and coinsurance.

c. Psychological examinations employing unusual or experimental instrumentation.

d. Individual and group psychotherapy without specification of condition, symptom, or complaint.

e. Sensitivity training, marriage enrichment, assertiveness training, growth groups or marathons, or psychotherapy for nonspecific conditions of distress such as job dissatisfaction or general unhappiness.

78.24(4) Rescinded IAB 10/12/94, effective 12/1/94.

78.24(5) The following services shall require review by a consultant to the department.

a. Protracted therapy beyond 16 visits. These cases shall be reviewed following the sixteenth therapy session and periodically thereafter.

b. Any service which does not appear necessary or appears to fall outside the scope of what is professionally appropriate or necessary for a particular condition.

This rule is intended to implement Iowa Code sections 249A.4 and 249A.15.

441—78.25(249A) Maternal health centers. Payment will be made for prenatal and postpartum medical care, health education, and transportation to receive prenatal and postpartum services. Payment will be made for enhanced perinatal services for persons determined high risk. These services include additional health education services, nutrition counseling, social services, and one postpartum home visit. Maternal health centers shall provide trimester and postpartum reports to the referring physician. Risk assessment using Form 470-2942, Medicaid Prenatal Risk Assessment, shall be completed at the initial visit during a Medicaid member's pregnancy. If the risk assessment reflects a low-risk pregnancy, the assessment shall be completed again at approximately the twenty-eighth week of pregnancy. If the risk assessment reflects a high-risk pregnancy, referral shall be made for enhanced services. (See description of enhanced services at subrule 78.25(3).)

Vaccines available through the Vaccines for Children program under Section 1928 of the Social Security Act are not covered as maternal health center services. Maternal health centers that wish to administer those vaccines to Medicaid members shall enroll in the Vaccines for Children program and obtain the vaccines from the department of public health. Maternal health centers shall receive reimbursement for the administration of vaccines to Medicaid members.

78.25(1) *Provider qualifications.*

a. Prenatal and postpartum medical services shall be provided by a physician, a physician assistant, or a nurse practitioner employed by or on contract with the center. Medical services performed by maternal health centers shall be performed under the supervision of a physician. Nurse practitioners and physician assistants performing under the supervision of a physician must do so within the scope of practice of that profession, as defined by Iowa Code chapters 152 and 148C, respectively.

b. Rescinded IAB 12/3/08, effective 2/1/09.

c. Education services and postpartum home visits shall be provided by a registered nurse.

d. Nutrition services shall be provided by a licensed dietitian.

e. Psychosocial services shall be provided by a person with at least a bachelor's degree in social work, counseling, sociology, psychology, family and community services, health or human development, health education, or individual and family studies.

78.25(2) *Services covered for all pregnant women.* Services provided may include:

a. Prenatal and postpartum medical care.

b. Health education, which shall include:

(1) Importance of continued prenatal care.

(2) Normal changes of pregnancy including both maternal changes and fetal changes.

(3) Self-care during pregnancy.

(4) Comfort measures during pregnancy.

(5) Danger signs during pregnancy.

(6) Labor and delivery including the normal process of labor, signs of labor, coping skills, danger signs, and management of labor.

(7) Preparation for baby including feeding, equipment, and clothing.

(8) Education on the use of over-the-counter drugs.

(9) Education about HIV protection.

c. Home visit.

d. Transportation to receive prenatal and postpartum services that is not payable under rule 441—78.11(249A) or 441—78.13(249A).

e. Dental hygiene services within the scope of practice as defined by the dental board at 650—paragraph 10.5(3)*"b."*

78.25(3) *Enhanced services covered for women with high-risk pregnancies.* Enhanced perinatal services may be provided to a patient who has been determined to have a high-risk pregnancy as documented by Form 470-2942, Medicaid Prenatal Risk Assessment. An appropriately trained physician or advanced registered nurse practitioner must be involved in staffing the patients receiving enhanced services.

Enhanced services are as follows:

a. Rescinded IAB 12/3/08, effective 2/1/09.

b. Education, which shall include as appropriate education about the following:

(1) High-risk medical conditions.

(2) High-risk sexual behavior.

(3) Smoking cessation.

(4) Alcohol usage education.

(5) Drug usage education.

(6) Environmental and occupational hazards.

c. Nutrition assessment and counseling, which shall include:

(1) Initial assessment of nutritional risk based on height, current and prepregnancy weight status, laboratory data, clinical data, and self-reported dietary information.

(2) Ongoing nutritional assessment.

(3) Development of an individualized nutritional care plan.

(4) Referral to food assistance programs if indicated.

(5) Nutritional intervention.

d. Psychosocial assessment and counseling, which shall include:

(1) A psychosocial assessment including: needs assessment, profile of client demographic factors, mental and physical health history and concerns, adjustment to pregnancy and future parenting, and environmental needs.

(2) A profile of the client's family composition, patterns of functioning and support systems.

(3) An assessment-based plan of care, risk tracking, counseling and anticipatory guidance as appropriate, and referral and follow-up services.

e. A postpartum home visit within two weeks of the child's discharge from the hospital, which shall include:

(1) Assessment of mother's health status.

(2) Physical and emotional changes postpartum.

(3) Family planning.

(4) Parenting skills.

(5) Assessment of infant health.

(6) Infant care.

(7) Grief support for unhealthy outcome.

(8) Parenting of a preterm infant.

(9) Identification of and referral to community resources as needed.

This rule is intended to implement Iowa Code section 249A.4.

441—78.26(249A) Ambulatory surgical center services. Ambulatory surgical center services are those services furnished by an ambulatory surgical center in connection with a covered surgical procedure or a covered dental procedure. Covered procedures are listed in the fee schedule published on the department's Web site.

78.26(1) Covered surgical procedures shall be those medically necessary procedures that are eligible for payment as physicians' services, under the circumstances specified in rule 441—78.1(249A) and

performed on a Medicaid member, that can safely be performed in an outpatient setting as determined by the department upon advice from the Iowa Medicaid enterprise medical services unit.

78.26(2) Covered dental procedures are those medically necessary procedures that are eligible for payment as dentists' services, under the circumstances specified in rule 441—78.4(249A) and performed on a Medicaid member, that can safely be performed in an outpatient setting for Medicaid members whose mental, physical, or emotional condition necessitates deep sedation or general anesthesia.

78.26(3) The covered services provided by the ambulatory surgical center in connection with a Medicaid-covered surgical or dental procedure shall be those nonsurgical and nondental services that:

a. Are medically necessary in connection with a Medicaid-covered surgical or dental procedure;

b. Are eligible for payment as physicians' services under the circumstances specified in rule 441—78.1(249A) or as dentists' services under the circumstances specified in rule 441—78.4(249A); and

c. Can safely and economically be performed in an outpatient setting, as determined by the department upon advice from the Iowa Medicaid enterprise medical services unit.

78.26(4) Limits on covered services.

a. Abortion procedures are covered only when criteria in subrule 78.1(17) are met.

b. Sterilization procedures are covered only when criteria in subrule 78.1(16) are met.

c. Preprocedure review by the Iowa Foundation for Medical Care (IFMC) is required if ambulatory surgical centers are to be reimbursed for certain frequently performed surgical procedures as set forth under subrule 78.1(19). Criteria are available from IFMC, 1776 West Lakes Parkway, West Des Moines, Iowa 50266-8239, or in local hospital utilization review offices. (Cross-reference 78.28(6))

This rule is intended to implement Iowa Code section 249A.4.

[**ARC 8205B**, IAB 10/7/09, effective 11/11/09]

441—78.27(249A) Home- and community-based habilitation services.

78.27(1) *Definitions.*

"Adult" means a person who is 18 years of age or older.

"Assessment" means the review of the current functioning of the member using the service in regard to the member's situation, needs, strengths, abilities, desires, and goals.

"Case management" means case management services accredited under 441—Chapter 24 and provided according to 441—Chapter 90.

"Comprehensive service plan" means an individualized, goal-oriented plan of services written in language understandable by the member using the service and developed collaboratively by the member and the case manager.

"Department" means the Iowa department of human services.

"Emergency" means a situation for which no approved individual program plan exists that, if not addressed, may result in injury or harm to the member or to other persons or in significant amounts of property damage.

"HCBS" means home- and community-based services.

"Interdisciplinary team" means a group of persons with varied professional backgrounds who meet with the member to develop a comprehensive service plan to address the member's need for services.

"ISIS" means the department's individualized services information system.

"Member" means a person who has been determined to be eligible for Medicaid under 441—Chapter 75.

"Program" means a set of related resources and services directed to the accomplishment of a fixed set of goals for qualifying members.

78.27(2) *Member eligibility.* To be eligible to receive home- and community-based habilitation services, a member shall meet the following criteria:

a. *Risk factors.* The member has at least one of the following risk factors:

(1) The member has undergone or is currently undergoing psychiatric treatment more intensive than outpatient care (e.g., emergency services, alternative home care, partial hospitalization, or inpatient hospitalization) more than once in the member's life; or

(2) The member has a history of psychiatric illness resulting in at least one episode of continuous, professional supportive care other than hospitalization.

b. Need for assistance. The member has a need for assistance demonstrated by meeting at least two of the following criteria on a continuing or intermittent basis for at least two years:

(1) The member is unemployed, is employed in a sheltered setting, or has markedly limited skills and a poor work history.

(2) The member requires financial assistance for out-of-hospital maintenance and is unable to procure this assistance without help.

(3) The member shows severe inability to establish or maintain a personal social support system.

(4) The member requires help in basic living skills such as self-care, money management, housekeeping, cooking, and medication management.

(5) The member exhibits inappropriate social behavior that results in a demand for intervention.

c. Income. The countable income used in determining the member's Medicaid eligibility does not exceed 150 percent of the federal poverty level.

d. Needs assessment. The member's case manager has completed an assessment of the member's need for service, and, based on that assessment, the Iowa Medicaid enterprise medical services unit has determined that the member is in need of home- and community-based habilitation services. A member who is not eligible for Medicaid case management services under 441—Chapter 90 shall receive case management as a home- and community-based habilitation service. The designated case manager shall:

(1) Complete a needs-based evaluation that meets the standards for assessment established in 441—subrule 90.5(1) before services begin and annually thereafter.

(2) Use the evaluation results to develop a comprehensive service plan as specified in subrule 78.27(4).

e. Plan for service. The department has approved the member's plan for home- and community-based habilitation services. A service plan that has been validated through ISIS shall be considered approved by the department. Home- and community-based habilitation services provided before department approval of a member's eligibility for the program cannot be reimbursed.

(1) The member's comprehensive service plan shall be completed annually according to the requirements of subrule 78.27(4). A service plan may change at any time due to a significant change in the member's needs.

(2) The member's habilitation services shall not exceed the maximum number of units established for each service in 441—subrule 79.1(2).

(3) The cost of the habilitation services shall not exceed unit expense maximums established in 441—subrule 79.1(2).

78.27(3) *Application for services.* The case manager shall apply for services on behalf of a member by entering a program request for habilitation services in ISIS.

a. Assignment of payment slot. The number of persons who may be approved for home- and community-based habilitation services is subject to a yearly total to be served. The total is set by the department based on available funds and is contained in the Medicaid state plan approved by the federal Centers for Medicare and Medicaid Services. The limit is maintained through the awarding of payment slots to members applying for services.

(1) The case manager shall contact the Iowa Medicaid enterprise through ISIS to determine if a payment slot is available for each member applying for home- and community-based habilitation services.

(2) When a payment slot is assigned, the case manager shall give written notice to the member.

(3) The department shall hold the assigned payment slot for the member as long as reasonable efforts are being made to arrange services and the member has not been determined to be ineligible for the program. If services have not been initiated and reasonable efforts are no longer being made to arrange services, the slot shall revert for use by the next applicant on the waiting list, if applicable. The member must reapply for a new slot.

b. Waiting list for payment slots. When the number of applications exceeds the number of members specified in the state plan and there are no available payment slots to be assigned, the

member's application for habilitation services shall be denied. The department shall issue a notice of decision stating that the member's name will be maintained on a waiting list.

(1) The Iowa Medicaid enterprise shall enter the member on a waiting list based on the date and time when the member's request for habilitation services was entered into ISIS. In the event that more than one application is received at the same time, members shall be entered on the waiting list on the basis of the month of birth, January being month one and the lowest number.

(2) When a payment slot becomes available, the Iowa Medicaid enterprise shall notify the member's case manager, based on the member's order on the waiting list. The case manager shall give written notice to the member within five working days.

(3) The department shall hold the payment slot for 20 calendar days to allow the case manager to reapply for habilitation services by entering a program request through ISIS. If a request for habilitation services has not been entered within 20 calendar days, the slot shall revert for use by the next member on the waiting list, if applicable. The member assigned the slot must reapply for a new slot.

(4) The case manager shall notify the Iowa Medicaid enterprise within five working days of the withdrawal of an application.

c. Notice of decision. The department shall issue a notice of decision to the applicant when financial eligibility, determination of needs-based eligibility, and approval of the service plan have been completed.

78.27(4) *Comprehensive service plan.* Individualized, planned, and appropriate services shall be guided by a member-specific comprehensive service plan developed with the member in collaboration with an interdisciplinary team, as appropriate. Medically necessary services shall be planned for and provided at the locations where the member lives, learns, works, and socializes.

a. Development. A comprehensive service plan shall be developed for each member receiving home- and community-based habilitation services based on the member's current assessment and shall be reviewed on an annual basis.

(1) The case manager shall establish an interdisciplinary team for the member. The team shall include the case manager and the member and, if applicable, the member's legal representative, the member's family, the member's service providers, and others directly involved.

(2) With the interdisciplinary team, the case manager shall identify the member's services based on the member's needs, the availability of services, and the member's choice of services and providers.

(3) The comprehensive service plan development shall be completed at the member's home or at another location chosen by the member.

(4) The interdisciplinary team meeting shall be conducted before the current comprehensive service plan expires.

(5) The comprehensive service plan shall reflect desired individual outcomes.

(6) Services defined in the comprehensive service plan shall be appropriate to the severity of the member's problems and to the member's specific needs or disabilities.

(7) Activities identified in the comprehensive service plan shall encourage the ability and right of the member to make choices, to experience a sense of achievement, and to modify or continue participation in the treatment process.

(8) For members receiving home-based habilitation in a licensed residential care facility of 16 or fewer beds, the service plan shall address the member's opportunities for independence and community integration.

b. Service goals and activities. The comprehensive service plan shall:

(1) Identify observable or measurable individual goals.

(2) Identify interventions and supports needed to meet those goals with incremental action steps, as appropriate.

(3) Identify the staff persons, businesses, or organizations responsible for carrying out the interventions or supports.

(4) List all Medicaid and non-Medicaid services received by the member and identify:

1. The name of the provider responsible for delivering the service;
2. The funding source for the service; and

3. The number of units of service to be received by the member.

(5) Identify for a member receiving home-based habilitation:

1. The member's living environment at the time of enrollment;

2. The number of hours per day of on-site staff supervision needed by the member; and

3. The number of other members who will live with the member in the living unit.

(6) Include a separate, individualized, anticipated discharge plan that is specific to each service the member receives.

c. Rights restrictions. Any rights restrictions must be implemented in accordance with 441—subrule 77.25(4). The comprehensive service plan shall include documentation of:

(1) Any restrictions on the member's rights, including maintenance of personal funds and self-administration of medications;

(2) The need for the restriction; and

(3) Either a plan to restore those rights or written documentation that a plan is not necessary or appropriate.

d. Emergency plan. The comprehensive service plan shall include a plan for emergencies and identification of the supports available to the member in an emergency. Emergency plans shall be developed as follows:

(1) The member's interdisciplinary team shall identify in the comprehensive service plan any health and safety issues applicable to the individual member based on information gathered before the team meeting, including a risk assessment.

(2) The interdisciplinary team shall identify an emergency backup support and crisis response system to address problems or issues arising when support services are interrupted or delayed or the member's needs change.

(3) Providers of applicable services shall provide for emergency backup staff.

e. Plan approval. Services shall be entered into ISIS based on the comprehensive service plan. A service plan that has been validated and authorized through ISIS shall be considered approved by the department. Services must be authorized in ISIS as specified in paragraph 78.27(2)*"e."*

78.27(5) *Requirements for services.* Home- and community-based habilitation services shall be provided in accordance with the following requirements:

a. The services shall be based on the member's needs as identified in the member's comprehensive service plan.

b. The services shall be delivered in the least restrictive environment appropriate to the needs of the member.

c. The services shall include the applicable and necessary instruction, supervision, assistance, and support required by the member to achieve the member's life goals.

d. Service components that are the same or similar shall not be provided simultaneously.

e. Service costs are not reimbursable while the member is in a medical institution, including but not limited to a hospital or nursing facility.

f. Reimbursement is not available for room and board.

g. Services shall be billed in whole units.

h. Services shall be documented. Each unit billed must have corresponding financial and medical records as set forth in rule 441—79.3(249A).

78.27(6) *Case management.* Case management assists members in gaining access to needed medical, social, educational, housing, transportation, vocational, and other appropriate services in order to ensure the health, safety, and welfare of the member.

a. Scope. Case management services shall be provided as set forth in rules 441—90.5(249A) and 441—90.8(249A).

b. Exclusion. Payment shall not be made for case management provided to a member who is eligible for case management services under 441—Chapter 90.

78.27(7) *Home-based habilitation.* "Home-based habilitation" means individually tailored supports that assist with the acquisition, retention, or improvement of skills related to living in the community.

a. *Scope.* Home-based habilitation services are individualized supportive services provided in the member's home and community that assist the member to reside in the most integrated setting appropriate to the member's needs. Services are intended to provide for the daily living needs of the member and shall be available as needed during any 24-hour period. The specific support needs for each member shall be determined necessary by the interdisciplinary team and shall be identified in the member's comprehensive service plan. Covered supports include:

(1) Adaptive skill development;
(2) Assistance with activities of daily living;
(3) Community inclusion;
(4) Transportation;
(5) Adult educational supports;
(6) Social and leisure skill development;
(7) Personal care; and
(8) Protective oversight and supervision.

b. *Exclusions.* Home-based habilitation payment shall not be made for the following:

(1) Room and board and maintenance costs, including the cost of rent or mortgage, utilities, telephone, food, household supplies, and building maintenance, upkeep, or improvement.

(2) Service activities associated with vocational services, day care, medical services, or case management.

(3) Transportation to and from a day program.

(4) Services provided to a member who lives in a licensed residential care facility of more than 16 persons.

(5) Services provided to a member who lives in a facility that provides the same service as part of an inclusive or "bundled" service rate, such as a nursing facility or an intermediate care facility for persons with mental retardation.

(6) Personal care and protective oversight and supervision may be a component part of home-based habilitation services but may not comprise the entirety of the service.

78.27(8) *Day habilitation.* "Day habilitation" means assistance with acquisition, retention, or improvement of self-help, socialization, and adaptive skills.

a. *Scope.* Day habilitation activities and environments are designed to foster the acquisition of skills, appropriate behavior, greater independence, and personal choice. Services focus on enabling the member to attain or maintain the member's maximum functional level and shall be coordinated with any physical, occupational, or speech therapies in the comprehensive service plan. Services may serve to reinforce skills or lessons taught in other settings. Services must enhance or support the member's:

(1) Intellectual functioning;
(2) Physical and emotional health and development;
(3) Language and communication development;
(4) Cognitive functioning;
(5) Socialization and community integration;
(6) Functional skill development;
(7) Behavior management;
(8) Responsibility and self-direction;
(9) Daily living activities;
(10) Self-advocacy skills; or
(11) Mobility.

b. *Setting.* Day habilitation shall take place in a nonresidential setting separate from the member's residence. Services shall not be provided in the member's home. When the member lives in a residential care facility of more than 16 beds, day habilitation services provided in the facility are not considered to be provided in the member's home if the services are provided in an area apart from the member's sleeping accommodations.

c. *Duration.* Day habilitation services shall be furnished for four or more hours per day on a regularly scheduled basis for one or more days per week or as specified in the member's comprehensive

service plan. Meals provided as part of day habilitation shall not constitute a full nutritional regimen (three meals per day).

d. *Exclusions.* Day habilitation payment shall not be made for the following:

(1) Vocational or prevocational services.

(2) Services that duplicate or replace education or related services defined in Public Law 94-142, the Education of the Handicapped Act.

(3) Compensation to members for participating in day habilitation services.

78.27(9) *Prevocational habilitation.* "Prevocational habilitation" means services that prepare a member for paid or unpaid employment.

a. *Scope.* Prevocational habilitation services include teaching concepts such as compliance, attendance, task completion, problem solving, and safety. Services are not oriented to a specific job task, but instead are aimed at a generalized result. Services shall be reflected in the member's comprehensive service plan and shall be directed to habilitative objectives rather than to explicit employment objectives.

b. *Setting.* Prevocational habilitation services may be provided in a variety of community-based settings based on the individual need of the member. Meals provided as part of these services shall not constitute a full nutritional regimen (three meals per day).

c. *Exclusions.* Prevocational habilitation payment shall not be made for the following:

(1) Services that are available under a program funded under Section 110 of the Rehabilitation Act of 1973 or the Individuals with Disabilities Education Act (20 U.S.C. 1401 et seq.). Documentation that funding is not available for the service under these programs shall be maintained in the file of each member receiving prevocational habilitation services.

(2) Services that duplicate or replace education or related services defined in Public Law 94-142, the Education of the Handicapped Act.

(3) Compensation to members for participating in prevocational services.

78.27(10) *Supported employment habilitation.* "Supported employment habilitation" means services associated with maintaining competitive paid employment.

a. *Scope.* Supported employment habilitation services are intensive, ongoing supports that enable members to perform in a regular work setting. Services are provided to members who need support because of their disabilities and who are unlikely to obtain competitive employment at or above the minimum wage absent the provision of supports. Covered services include:

(1) Activities to obtain a job. Covered services directed to obtaining a job must be provided to or on behalf of a member for whom competitive employment is reasonably expected within less than one year. Services must be focused on job placement, not on teaching generalized employment skills or habilitative goals. Three conditions must be met before services are provided. First, the member and the interdisciplinary team described in subrule 78.27(4) must complete the form that Iowa vocational rehabilitation services uses to identify the supported employment services appropriate to meet a person's employment needs. Second, the member's interdisciplinary team must determine that the identified services are necessary. Third, the Iowa Medicaid enterprise medical services unit must approve the services. Available components of activities to obtain a job are as follows:

1. Job development services. Job development services are directed toward obtaining competitive employment. A unit of service is a job placement that the member holds for 30 consecutive calendar days or more. Payment is available once the service is authorized in the member's service plan. A member may receive two units of job development services during a 12-month period. The activities provided to the member may include job procurement training, including grooming and hygiene, application, résumé development, interviewing skills, follow-up letters, and job search activities; job retention training, including promptness, coworker relations, transportation skills, disability-related supports, job benefits, and an understanding of employee rights and self-advocacy; and customized job development services specific to the member.

2. Employer development services. The focus of employer development services is to support employers in hiring and retaining members in their workforce and to communicate expectations of the employers to the interdisciplinary team described in subrule 78.27(4). Employer development services

may be provided only to members who are reasonably expected to work for no more than 10 hours per week. A unit of service is one job placement that the member holds for 30 consecutive calendar days or more. Payment for this service may be made only after the member holds the job for 30 days. A member may receive two units of employer development services during a 12-month period if the member is competitively employed for 30 or more consecutive calendar days and the other conditions for service approval are met. The services provided may include: developing relationships with employers and providing leads for individual members when appropriate; job analysis for a specific job; development of a customized training plan identifying job-specific skill requirements, employer expectations, teaching strategies, time frames, and responsibilities; identifying and arranging reasonable accommodations with the employer; providing disability awareness and training to the employer when it is deemed necessary; and providing technical assistance to the employer regarding the training progress as identified on the member's customized training plan.

3. Enhanced job search activities. Enhanced job search activities are associated with obtaining initial employment after job development services have been provided to the member for a minimum of 30 days or with assisting the member in changing jobs due to layoff, termination, or personal choice. The interdisciplinary team must review and update the Iowa vocational rehabilitation services supported employment readiness analysis form to determine if this service remains appropriate for the member's employment goals. A unit of service is an hour. A maximum of 26 units may be provided in a 12-month period. The services provided may include: job opening identification with the member; assistance with applying for a job, including completion of applications or interviews; and work site assessment and job accommodation evaluation.

(2) Supports to maintain employment, including the following services provided to or on behalf of the member:

1. Individual work-related behavioral management.
2. Job coaching.
3. On-the-job or work-related crisis intervention.
4. Assistance in the use of skills related to sustaining competitive paid employment, including assistance with communication skills, problem solving, and safety.
5. Assistance with time management.
6. Assistance with appropriate grooming.
7. Employment-related supportive contacts.
8. On-site vocational assessment after employment.
9. Employer consultation.

b. *Setting.* Supported employment may be conducted in a variety of settings, particularly work sites where persons without disabilities are employed.

(1) The majority of coworkers at any employment site with more than two employees where members seek, obtain, or maintain employment must be persons without disabilities.

(2) In the performance of job duties at any site where members seek, obtain, or maintain employment, the member must have daily contact with other employees or members of the general public who do not have disabilities, unless the absence of daily contact with other employees or the general public is typical for the job as performed by persons without disabilities.

(3) When services for maintaining employment are provided to members in a teamwork or "enclave" setting, the team shall include no more than eight people with disabilities.

c. *Service requirements.* The following requirements shall apply to all supported employment services:

(1) All supported employment services shall provide individualized and ongoing support contacts at intervals necessary to promote successful job retention.

(2) The provider shall provide employment-related adaptations required to assist the member in the performance of the member's job functions as part of the service.

(3) Community transportation options (such as carpools, coworkers, self or public transportation, families, volunteers) shall be attempted before the service provider provides transportation. When no

other resources are available, employment-related transportation between work and home and to or from activities related to employment may be provided as part of the service.

(4) Members may access both services to maintain employment and services to obtain a job for the purpose of job advancement or job change. A member may receive a maximum of three job placements in a 12-month period and a maximum of 40 units per week of services to maintain employment.

d. *Exclusions.* Supported employment habilitation payment shall not be made for the following:

(1) Services that are available under a program funded under Section 110 of the Rehabilitation Act of 1973 or the Individuals with Disabilities Education Act (20 U.S.C. 1401 et seq.). Documentation that funding is not available under these programs shall be maintained in the file of each member receiving supported employment services.

(2) Incentive payments made to an employer to encourage or subsidize the employer's participation in a supported employment program.

(3) Subsidies or payments that are passed through to users of supported employment programs.

(4) Training that is not directly related to a member's supported employment program.

(5) Services involved in placing or maintaining members in day activity programs, work activity programs, or sheltered workshop programs.

(6) Supports for volunteer work or unpaid internships.

(7) Tuition for education or vocational training.

(8) Individual advocacy that is not member-specific.

78.27(11) *Adverse service actions.*

a. *Denial.* Services shall be denied when the department determines that:

(1) A payment slot is not available to the member pursuant to paragraph 78.27(3)*"a."*

(2) The member is not eligible for or in need of home- and community-based habilitation services.

(3) The service is not identified in the member's comprehensive service plan.

(4) Needed services are not available or received from qualifying providers, or no qualifying providers are available.

(5) The member's service needs exceed the unit or reimbursement maximums for a service as set forth in 441—subrule 79.1(2).

(6) Completion or receipt of required documents for the program has not occurred.

b. *Reduction.* A particular home- and community-based habilitation service may be reduced when the department determines that continued provision of service at its current level is not necessary.

c. *Termination.* A particular home- and community-based habilitation service may be terminated when the department determines that:

(1) The member's income exceeds the allowable limit, or the member no longer meets other eligibility criteria for the program established by the department.

(2) The service is not identified in the member's comprehensive service plan.

(3) Needed services are not available or received from qualifying providers, or no qualifying providers are available.

(4) The member's service needs are not being met by the services provided.

(5) The member has received care in a medical institution for 30 consecutive days in any one stay. When a member has been an inpatient in a medical institution for 30 consecutive days, the department will issue a notice of decision to inform the member of the service termination. If the member returns home before the effective date of the notice of decision and the member's condition has not substantially changed, the decision shall be rescinded, and eligibility for home- and community-based habilitation services shall continue.

(6) The member's service needs exceed the unit or reimbursement maximums for a service as established by the department.

(7) Duplication of services provided during the same period has occurred.

(8) The member or the member's legal representative, through the interdisciplinary process, requests termination of the service.

(9) Completion or receipt of required documents for the program has not occurred, or the member refuses to allow documentation of eligibility as to need and income.

d. *Appeal rights.* The department shall give notice of any adverse action and the right to appeal in accordance with 441—Chapter 7. The member is entitled to have a review of the determination of needs-based eligibility by the Iowa Medicaid enterprise medical services unit by sending a letter requesting a review to the medical services unit. If dissatisfied with that decision, the member may file an appeal with the department.

78.27(12) *County reimbursement.* The county board of supervisors of the member's county of legal settlement shall reimburse the department for all of the nonfederal share of the cost of home- and community-based habilitation services provided to an adult member with a chronic mental illness as defined in 441—Chapter 90. The department shall notify the county's central point of coordination administrator through ISIS of the approval of the member's service plan.

This rule is intended to implement Iowa Code section 249A.4.

[**ARC 7957B**, IAB 7/15/09, effective 7/1/09 (See Delay note at end of chapter)]

441—78.28(249A) List of medical services and equipment requiring prior approval, preprocedure review or preadmission review.

78.28(1) Services, procedures, and medications prescribed by a physician (M.D. or D.O.) which are subject to prior approval or preprocedure review are as follows or as specified in the preferred drug list published by the department pursuant to Iowa Code Supplement section 249A.20A:

a. Drugs require prior authorization as specified in the preferred drug list published by the department pursuant to Iowa Code section 249A.20A. For drugs requiring prior authorization, reimbursement will be made for a 72-hour supply dispensed in an emergency when a prior authorization request cannot be submitted.

b. Automated medication dispenser. (Cross-reference 78.10(2)*"b"*) Payment will be approved for an automated medication dispenser when prescribed for a member who meets all of the following conditions:

(1) The member has a diagnosis indicative of cognitive impairment or age-related factors that affect the member's ability to remember to take medications.

(2) The member is on two or more medications prescribed to be administered more than one time a day.

(3) The availability of a caregiver to administer the medications or perform setup is limited or nonexistent.

(4) Less costly alternatives, such as medisets or telephone reminders, have failed.

c. Enteral products and enteral delivery pumps and supplies require prior approval. Daily enteral nutrition therapy shall be approved as medically necessary only for a member who either has a metabolic or digestive disorder that prevents the member from obtaining the necessary nutritional value from usual foods in any form and cannot be managed by avoidance of certain food products or has a severe pathology of the body that does not allow ingestion or absorption of sufficient nutrients from regular food to maintain weight and strength commensurate with the member's general condition. (Cross-reference 78.10(3)*"c"*(2))

(1) A request for prior approval shall include a physician's, physician assistant's, or advanced registered nurse practitioner's written order or prescription and documentation to establish the medical necessity for enteral products and enteral delivery pumps and supplies pursuant to the above standards. The documentation shall include:

1. A statement of the member's total medical condition that includes a description of the member's metabolic or digestive disorder or pathology.

2. Documentation of the medical necessity for commercially prepared products. The information submitted must identify other methods attempted to support the member's nutritional status and indicate that the member's nutritional needs were not or could not be met by regular food in pureed form.

3. Documentation of the medical necessity for an enteral pump, if the request includes an enteral pump. The information submitted must identify the medical reasons for not using a gravity feeding set.

(2) Examples of conditions that will not justify approval of enteral nutrition therapy are: weight-loss diets, wired-shut jaws, diabetic diets, milk or food allergies (unless the member is under

five years of age and coverage through the Women, Infant and Children's program is not available), and the use of enteral products for convenience reasons when regular food in pureed form would meet the medical need of the member.

(3) Basis of payment for nutritional therapy supplies shall be the least expensive method of delivery that is reasonable and medically necessary based on the documentation submitted.

d. Rescinded IAB 5/11/05, effective 5/1/05.

e. Augmentative communication systems, which are provided to persons unable to communicate their basic needs through oral speech or manual sign language, require prior approval. Form 470-2145, Augmentative Communication System Selection, completed by a speech pathologist and a physician's prescription for a particular device shall be submitted to request prior approval. (Cross-reference 78.10(3)*"c"*(1))

(1) Information requested on the prior authorization form includes a medical history, diagnosis, and prognosis completed by a physician. In addition, a speech or language pathologist needs to describe current functional abilities in the following areas: communication skills, motor status, sensory status, cognitive status, social and emotional status, and language status.

(2) Also needed from the speech or language pathologist is information on educational ability and needs, vocational potential, anticipated duration of need, prognosis regarding oral communication skills, prognosis with a particular device, and recommendations.

(3) The department's consultants with an expertise in speech pathology will evaluate the prior approval requests and make recommendations to the department.

f. Preprocedure review by the Iowa Foundation for Medical Care (IFMC) will be required if payment under Medicaid is to be made for certain frequently performed surgical procedures which have a wide variation in the relative frequency the procedures are performed. Preprocedure surgical review applies to surgeries performed in hospitals (outpatient and inpatient) and ambulatory surgical centers. Approval by IFMC will be granted only if the procedures are determined to be necessary based on the condition of the patient and on the published criteria established by the department and the IFMC. If not so approved by the IFMC, payment will not be made under the program to the physician or to the facility in which the surgery is performed. The criteria are available from IFMC, 3737 Woodland Avenue, Suite 500, West Des Moines, Iowa 50265, or in local hospital utilization review offices.

The "Preprocedure Surgical Review List" shall be published by the department in the provider manuals for physicians, hospitals, and ambulatory surgical centers. (Cross-reference 78.1(19))

g. Prior authorization is required for enclosed beds. (Cross-reference 78.10(2)*"c"*) The department shall approve payment for an enclosed bed when prescribed for a patient who meets all of the following conditions:

(1) The patient has a diagnosis-related cognitive or communication impairment that results in risk to safety.

(2) The patient's mobility puts the patient at risk for injury.

(3) The patient has suffered injuries when getting out of bed.

(4) The patient has had a successful trial with an enclosed bed.

h. Prior authorization is required for external insulin infusion pumps and is granted according to Medicare coverage criteria. (Cross-reference 78.10(2)*"c"*)

i. Prior authorization is required for oral nutritional products. (Cross-reference 78.10(2)*"c"*) The department shall approve payment for oral nutritional products when the member is not able to ingest or absorb sufficient nutrients from regular food due to a metabolic, digestive, or psychological disorder or pathology to the extent that supplementation is necessary to provide 51 percent or more of the daily caloric intake, or when the use of oral nutritional products is otherwise determined medically necessary in accordance with evidence-based guidelines for treatment of the member's condition.

(1) A request for prior approval shall include a written order or prescription from a physician, physician assistant, or advanced registered nurse practitioner and documentation to establish the medical necessity for oral nutritional products pursuant to these standards. The documentation shall include:

1. A statement of the member's total medical condition that includes a description of the member's metabolic, digestive, or psychological disorder or pathology.

2. Documentation of the medical necessity for commercially prepared products. The information submitted must identify other methods attempted to support the member's nutritional status and indicate that the member's nutritional needs were not or could not be met by regular food in pureed form.

3. Documentation to support the fact that regular foods will not provide sufficient nutritional value to the member, if the request includes oral supplementation of a regular diet.

(2) Examples of conditions that will not justify approval of oral nutritional products are: weight-loss diets, wired-shut jaws, diabetic diets, and milk or food allergies (unless the member is under five years of age and coverage through the Special Supplemental Nutrition Program for Women, Infants, and Children is not available).

j. Prior authorization is required for vest airway clearance systems. (Cross-reference 78.10(2)*"c"*) The department shall approve payment for a vest airway clearance system when prescribed by a pulmonologist for a patient with a medical diagnosis related to a lung disorder if all of the following conditions are met:

(1) Pulmonary function tests for the 12 months before initiation of the vest demonstrate an overall significant decrease of lung function.

(2) The patient resides in an independent living situation or has a medical condition that precludes the caregiver from administering traditional chest physiotherapy.

(3) Treatment by flutter device failed or is contraindicated.

(4) Treatment by intrapulmonary percussive ventilation failed or is contraindicated.

(5) All other less costly alternatives have been tried.

k. Prior authorization is required for blood glucose monitors and diabetic test strips produced by a manufacturer that does not have a current agreement to provide a rebate to the department for monitors or test strips provided through the Medicaid program. The department shall approve payment when a blood glucose monitor or diabetic test strips produced by a manufacturer that does not have a current rebate agreement with the department are medically necessary.

78.28(2) Dental services. Dental services which require prior approval are as follows:

a. The following periodontal services:

(1) Payment for periodontal scaling and root planing will be approved when interproximal and subgingival calculus is evident in X-rays or when justified and documented that curettage, scaling or root planing is required in addition to routine prophylaxis. (Cross-reference 78.4(4)*"b"*)

(2) Payment for pedicle soft tissue graft and free soft tissue graft will be approved when the written narrative describes medical necessity. Payment for other periodontal surgical procedures will be approved after periodontal scaling and root planing has been provided, a reevaluation examination has been completed, and the patient has demonstrated reasonable oral hygiene, unless the patient is unable to demonstrate reasonable oral hygiene because of physical or mental disability or in cases which demonstrate gingival hyperplasia resulting from drug therapy. (Cross-reference 78.4(4)*"c"*)

(3) Payment for pedicle soft tissue graft and free soft tissue graft will be approved when the written narrative describes medical necessity. (Cross-reference 78.4(4)*"d"*)

(4) Payment for periodontal maintenance therapy may be approved after periodontal scaling and root planing or periodontal surgical procedures have been provided. Periodontal maintenance therapy may be approved once per three-month interval for moderate to advanced cases if the condition would deteriorate without treatment. (Cross-reference 78.4(4)*"e"*)

b. Surgical endodontic treatment which includes an apicoectomy, performed as a separate surgical procedure; an apicoectomy, performed in conjunction with endodontic procedure; an apical curettage; a root resection; or excision of hyperplastic tissue will be approved when nonsurgical treatment has been attempted and a reasonable time has elapsed after which failure has been demonstrated. Surgical endodontic procedures may be indicated when:

(1) Conventional root canal treatment cannot be successfully completed because canals cannot be negotiated, debrided or obturated due to calcifications, blockages, broken instruments, severe curvatures, and dilacerated roots.

(2) Correction of problems resulting from conventional treatment including gross underfilling, perforations, and canal blockages with restorative materials. (Cross-reference 78.4(5)*"c"*)

c. The following prosthetic services:

(1) A removable partial denture replacing posterior teeth will be approved when the member has fewer than eight posterior teeth in occlusion or the member has a full denture in one arch, and a partial denture replacing posterior teeth is required in the opposing arch to balance occlusion. When one removable partial denture brings eight posterior teeth in occlusion, no additional removable partial denture will be approved. A removable partial denture replacing posterior teeth is payable only once in a five-year period unless the removable partial denture is broken beyond repair, lost or stolen, or no longer fits due to growth or changes in jaw structure, and is required to prevent significant dental problems. Replacement of a removable partial denture replacing posterior teeth due to resorption in less than a five-year period is not payable. (Cross-reference 78.4(7)*"c"*)

(2) A fixed partial denture (including an acid etch fixed partial denture) replacing anterior teeth will be approved for members whose medical condition precludes the use of a removable partial denture. High noble or noble metals will be approved only when the member is allergic to all other restorative materials. A fixed partial denture replacing anterior teeth is payable only once in a five-year period unless the fixed partial denture is broken beyond repair. (Cross-reference 78.4(7)*"d"*)

(3) A fixed partial denture (including an acid etch fixed partial denture) replacing posterior teeth will be approved for members whose medical condition precludes the use of a removable partial denture and who have fewer than eight posterior teeth in occlusion or if the member has a full denture in one arch and a partial denture replacing posterior teeth is required in the opposing arch to balance occlusion. When one fixed partial denture brings eight posterior teeth in occlusion, no additional fixed partial denture will be approved. High noble or noble metals will be approved only when the member is allergic to all other restorative materials. A fixed partial denture replacing posterior teeth is payable only once in a five-year period unless the fixed partial denture is broken beyond repair. (Cross-reference 78.4(7)*"e"*)

(4) Dental implants and related services will be authorized when the member is missing significant oral structures due to cancer, traumatic injuries, or developmental defects such as cleft palate and cannot use a conventional denture.

d. Orthodontic services will be approved when it is determined that a patient has the most handicapping malocclusion. This determination is made in a manner consistent with the "Handicapping Malocclusion Assessment to Establish Treatment Priority," by J. A. Salzmann, D.D.S., American Journal of Orthodontics, October 1968.

(1) A handicapping malocclusion is a condition that constitutes a hazard to the maintenance of oral health and interferes with the well-being of the patient by causing impaired mastication, dysfunction of the temporomandibular articulation, susceptibility to periodontal disease, susceptibility to dental caries, and impaired speech due to malpositions of the teeth. Treatment of handicapping malocclusions will be approved only for the severe and the most handicapping. Assessment of the most handicapping malocclusion is determined by the magnitude of the following variables:

1. Degree of malalignment;
2. Missing teeth;
3. Angle classification;
4. Overjet and overbite;
5. Openbite; and
6. Crossbite.

(2) A request to perform an orthodontic procedure must be accompanied by an interpreted cephalometric radiograph and study models trimmed so that the models simulate centric occlusion of the patient. A written plan of treatment must accompany the diagnostic aids. Posttreatment records must be furnished upon request of the Iowa Medicaid enterprise medical services unit.

(3) Approval may be made for eight units of a three-month active treatment period. Additional units may be approved by the department's orthodontic consultant if the additional units are found to be medically necessary. (Cross-reference 78.4(8)*"a"*)

e. More than two laboratory-fabricated crowns will be approved in a 12-month period for anterior teeth that cannot be restored with a composite or amalgam restoration and for posterior teeth that

cannot be restored with a composite or amalgam restoration or stainless steel crown. (Cross-reference 78.4(3)*"d"*)

f. Endodontic retreatment of a tooth will be authorized when the conventional treatment has been completed, a reasonable time has elapsed, and failure has been demonstrated with a radiograph and narrative history.

78.28(3) Optometric services and ophthalmic materials which must be submitted for prior approval are as follows:

a. A second lens correction within a 24-month period for members eight years of age and older. Payment shall be made when the member's vision has at least a five-tenths diopter of change in sphere or cylinder or ten-degree change in axis in either eye.

b. Visual therapy may be authorized when warranted by case history or diagnosis for a period of time not greater than 90 days. Should continued therapy be warranted, the prior approval process should be reaccomplished, accompanied by a report showing satisfactory progress. Approved diagnoses are convergence insufficiency and amblyopia. Visual therapy is not covered when provided by opticians.

c. Subnormal visual aids where near visual acuity is better than 20/100 at 16 inches, 2M print. Prior authorization is not required if near visual acuity as described above is less than 20/100. Subnormal aids include, but are not limited to, hand magnifiers, loupes, telescopic spectacles or reverse Galilean telescope systems.

For all of the above, the optometrist shall furnish sufficient information to clearly establish that these procedures are necessary in terms of the visual condition of the patient. (Cross-references 78.6(4), 441—78.7(249A), and 78.1(18))

78.28(4) Hearing aids that must be submitted for prior approval are:

a. Replacement of a hearing aid less than four years old (except when the member is under 21 years of age). The department shall approve payment when the original hearing aid is lost or broken beyond repair or there is a significant change in the person's hearing that would require a different hearing aid. (Cross-reference 78.14(7)*"d"*(1))

b. A hearing aid costing more than $650. The department shall approve payment for either of the following purposes (Cross-reference 78.14(7)*"d"*(2)):

(1) Educational purposes when the member is participating in primary or secondary education or in a postsecondary academic program leading to a degree and an in-office comparison of an analog aid and a digital aid matched (+/- 5dB) for gain and output shows a significant improvement in either speech recognition in quiet or speech recognition in noise or an in-office comparison of two aids, one of which is single channel, shows significantly improved audibility.

(2) Vocational purposes when documentation submitted indicates the necessity, such as varying amounts of background noise in the work environment and a need to converse in order to do the job and an in-office comparison of an analog aid and a digital aid matched (+/- 5dB) for gain and output shows a significant improvement in either speech recognition in quiet or speech recognition in noise or an in-office comparison of two aids, one of which is single channel, shows significantly improved audibility.

78.28(5) Hospital services which must be subject to prior approval, preprocedure review or preadmission review are:

a. Any medical or surgical procedure requiring prior approval as set forth in Chapter 78 is subject to the conditions for payment set forth although a request form does not need to be submitted by the hospital as long as the approval is obtained by the physician. (Cross-reference 441—78.1(249A))

b. All inpatient hospital admissions are subject to preadmission review. Payment for inpatient hospital admissions is approved when it meets the criteria for inpatient hospital care as determined by the IFMC or its delegated hospitals. Criteria are available from IFMC, 6000 Westown Parkway, Suite 350E, West Des Moines, Iowa 50265-7771, or in local hospital utilization review offices. (Cross-reference 441—78.3(249A))

c. Preprocedure review by the IFMC is required if hospitals are to be reimbursed for the inpatient and outpatient surgical procedures set forth in subrule 78.1(19). Approval by the IFMC will be granted only if the procedures are determined to be necessary based on the condition of the patient and the criteria

established by the department and IFMC. The criteria are available from IFMC, 6000 Westown Parkway, Suite 350E, West Des Moines, Iowa 50265-7771, or in local hospital utilization review offices.

78.28(6) Ambulatory surgical centers are subject to prior approval and preprocedure review as follows:

a. Any medical or surgical procedure requiring prior approval as set forth in Chapter 78 is subject to the conditions for payment set forth although a request form does not need to be submitted by the ambulatory surgical center as long as the prior approval is obtained by the physician.

b. Preprocedure review by the IFMC is required if ambulatory surgical centers are to be reimbursed for surgical procedures as set forth in subrule 78.1(19). Approval by the IFMC will be granted only if the procedures are determined to be necessary based on the condition of the patient and criteria established by the IFMC and the department. The criteria are available from IFMC, 6000 Westown Parkway, Suite 350E, West Des Moines, Iowa 50265-7771, or in local hospital utilization review offices.

78.28(7) Rescinded IAB 6/4/08, effective 5/15/08.

78.28(8) Rescinded IAB 1/3/96, effective 3/1/96.

78.28(9) Private duty nursing or personal care services provided by a home health agency provider for persons aged 20 or under require prior approval and shall be approved if determined to be medically necessary. Payment shall be made on an hourly unit of service.

a. Definitions.

(1) Private duty nursing services are those services which are provided by a registered nurse or a licensed practical nurse under the direction of the member's physician to a member in the member's place of residence or outside the member's residence, when normal life activities take the member outside the place of residence. Place of residence does not include nursing facilities, intermediate care facilities for the mentally retarded, or hospitals.

Services shall be provided according to a written plan of care authorized by a licensed physician. The home health agency is encouraged to collaborate with the member, or in the case of a child with the child's caregiver, in the development and implementation of the plan of treatment. These services shall exceed intermittent guidelines as defined in subrule 78.9(3). Private duty nursing and personal care services shall be inclusive of all home health agency services personally provided to the member.

Private duty nursing services do not include:

1. Respite care, which is a temporary intermission or period of rest for the caregiver.
2. Nurse supervision services including chart review, case discussion or scheduling by a registered nurse.
3. Services provided to other persons in the member's household.
4. Services requiring prior authorization that are provided without regard to the prior authorization process.

(2) Personal care services are those services provided by a home health aide or certified nurse's aide and which are delegated and supervised by a registered nurse under the direction of the member's physician to a member in the member's place of residence or outside the member's residence, when normal life activities take the member outside the place of residence. Place of residence does not include nursing facilities, intermediate care facilities for the mentally retarded, or hospitals. Payment for personal care services for persons aged 20 and under that exceed intermittent guidelines may be approved if determined to be medically necessary as defined in subrule 78.9(7). These services shall be in accordance with the member's plan of care and authorized by a physician. The home health agency is encouraged to collaborate with the member, or in the case of a child with the child's caregiver, in the development and implementation of the plan of treatment.

Medical necessity means the service is reasonably calculated to prevent, diagnose, correct, cure, alleviate or prevent the worsening of conditions that endanger life, cause pain, result in illness or infirmity, threaten to cause or aggravate a disability or chronic illness, and no other equally effective course of treatment is available or suitable for the member requesting a service.

b. Requirements.

(1) Private duty nursing or personal care services shall be ordered in writing by a physician as evidenced by the physician's signature on the plan of care.

(2) Private duty nursing or personal care services shall be authorized by the department or the department's designated review agent prior to payment.

(3) Prior authorization shall be requested at the time of initial submission of the plan of care or at any time the plan of care is substantially amended and shall be renewed with the department or the department's designated review agent. Initial request for and request for renewal of prior authorization shall be submitted to the department's designated review agent. The provider of the service is responsible for requesting prior authorization and for obtaining renewal of prior authorization.

The request for prior authorization shall include a nursing assessment, the plan of care, and supporting documentation. The request for prior authorization shall include all items previously identified as required treatment plan information and shall further include: any planned surgical interventions and projected time frame; information regarding caregiver's desire to become involved in the member's care, to adhere to program objectives, to work toward treatment plan goals, and to work toward maximum independence; and identify the types and service delivery levels of all other services to the member whether or not the services are reimbursable by Medicaid. Providers shall indicate the expected number of private duty nursing RN hours, private duty nursing LPN hours, or home health aide hours per day, the number of days per week, and the number of weeks or months of service per discipline. If the member is currently hospitalized, the projected date of discharge shall be included.

Prior authorization approvals shall not be granted for treatment plans that exceed 16 hours of home health agency services per day. (Cross-reference 78.9(10))

78.28(10) Replacement of vibrotactile aids less than four years old shall be approved when the original aid is broken beyond repair or lost. (Cross-reference 78.10(3)*"b"*)

This rule is intended to implement Iowa Code section 249A.4.

[**ARC 7548B**, IAB 2/11/09, effective 4/1/09]

441—78.29(249A) Behavioral health services. Payment shall be made for medically necessary behavioral health services provided by a participating marital and family therapist, independent social worker, or master social worker within the practitioner's scope of practice pursuant to state law and subject to the limitations and exclusions set forth in this rule.

78.29(1) *Limitations.*

a. An assessment and a treatment plan are required.

b. Services provided by a licensed master social worker must be provided under the supervision of an independent social worker qualified to participate in the Medicaid program.

78.29(2) *Exclusions.* Payment will not be approved for the following services:

a. Services provided in a medical institution.

b. Services performed without relationship to a specific condition, risk factor, symptom, or complaint.

c. Services provided for nonspecific conditions of distress such as job dissatisfaction or general unhappiness.

d. Sensitivity training, marriage enrichment, assertiveness training, and growth groups or marathons.

78.29(3) *Payment.*

a. Payment shall be made only for time spent in face-to-face consultation with the member.

b. A unit of service is 15 minutes. Time spent with members shall be rounded to the quarter hour, where applicable.

This rule is intended to implement Iowa Code section 249A.4.

441—78.30(249A) Birth centers. Payment will be made for prenatal, delivery, and postnatal services.

78.30(1) *Risk assessment.* Risk assessment, using Form 470-2942, Medicaid Prenatal Risk Assessment, shall be completed at the initial visit during a Medicaid member's pregnancy.

a. If the risk assessment reflects a low-risk pregnancy, the assessment shall be completed again at approximately the twenty-eighth week of pregnancy.

b. If the risk assessment reflects a high-risk pregnancy, referral shall be made for enhanced services. (See description of enhanced services at subrule 78.25(3).)

78.30(2) *Vaccines.* Vaccines available through the Vaccines for Children program under Section 1928 of the Social Security Act are not covered as birth center services. Birth centers that wish to administer those vaccines to Medicaid members shall enroll in the Vaccines for Children program and obtain the vaccines from the department of public health. Birth centers shall receive reimbursement for the administration of vaccines to Medicaid members.

This rule is intended to implement Iowa Code section 249A.4.

441—78.31(249A) Hospital outpatient services.

78.31(1) *Covered hospital outpatient services.* Payment will be approved only for the following outpatient hospital services and medical services when provided on the licensed premises of the hospital or pursuant to subrule 78.31(5). Hospitals with alternate sites approved by the department of inspections and appeals are acceptable sites. All outpatient services listed in paragraphs *"g"* to *"m"* are subject to a random sample retrospective review for medical necessity by the Iowa Foundation for Medical Care. All services may also be subject to a more intensive retrospective review if abuse is suspected. Services in paragraphs *"a"* to *"f"* shall be provided in hospitals on an outpatient basis and are subject to no further limitations except medical necessity of the service.

Services listed in paragraphs *"g"* to *"m"* shall be provided by hospitals on an outpatient basis and must be certified by the department before payment may be made. Other limitations apply to these services.

a. Emergency service.

b. Outpatient surgery.

c. Laboratory, X-ray and other diagnostic services.

d. General or family medicine.

e. Follow-up or after-care specialty clinics.

f. Physical medicine and rehabilitation.

g. Alcoholism and substance abuse.

h. Eating disorders.

i. Cardiac rehabilitation.

j. Mental health.

k. Pain management.

l. Diabetic education.

m. Pulmonary rehabilitation.

n. Nutritional counseling for persons aged 20 and under.

78.31(2) *Requirements for all outpatient services.*

a. Need for service. It must be clearly established that the service meets a documented need in the area served by the hospital. There must be documentation of studies completed, consultations with other health care facilities and health care professionals in the area, community leaders, and organizations to determine the need for the service and to tailor the service to meet that particular need.

b. Professional direction. All outpatient services must be provided by or at the direction and under the supervision of a medical doctor or osteopathic physician except for mental health services which may be provided by or at the direction and under the supervision of a medical doctor, osteopathic physician, or certified health service provider in psychology.

c. Goals and objectives. The goals and objectives of the program must be clearly stated. Paragraphs *"d"* and *"f"* and the organization and administration of the program must clearly contribute to the fulfillment of the stated goals and objectives.

d. Treatment modalities used. The service must employ multiple treatment modalities and professional disciplines. The modalities and disciplines employed must be clearly related to the condition or disease being treated.

e. Criteria for selection and continuing treatment of patients. The condition or disease which is proposed to be treated must be clearly stated. Any indications for treatment or contraindications for treatment must be set forth together with criteria for determining the continued medical necessity of treatment.

f. Length of program. There must be established parameters that limit the program either in terms of its overall length or in terms of number of visits, etc.

g. Monitoring of services. The services provided by the program must be monitored and evaluated to determine the degree to which patients are receiving accurate assessments and effective treatment.

The monitoring of the services must be an ongoing plan and systematic process to identify problems in patient care or opportunities to improve patient care.

The monitoring and evaluation of the services are based on the use of clinical indicators that reflect those components of patient care important to quality.

h. Hospital outpatient programs that wish to administer vaccines which are available through the Vaccines for Children program to Medicaid members shall enroll in the Vaccines for Children program. In lieu of payment, vaccines available through the Vaccines for Children program shall be accessed from the department of public health for Medicaid members. Hospital outpatient programs receive payment via the APC reimbursement for the administration of vaccines to Medicaid members.

78.31(3) *Application for certification.* Hospital outpatient programs listed in subrule 78.31(1), paragraphs *"g"* to *"m,"* must submit an application to the Iowa Medicaid enterprise provider services unit for certification before payment will be made. The provider services unit will review the application against the requirements for the specific type of outpatient service and notify the provider whether certification has been approved.

Applications will consist of a narrative providing the following information:

a. Documented need for the program including studies, needs assessments, and consultations with other health care professionals.

b. Goals and objectives of the program.

c. Organization and staffing including how the program fits with the rest of the hospital, the number of staff, staff credentials, and the staff's relationship to the program, e.g., hospital employee, contractual consultant.

d. Policies and procedures including admission criteria, patient assessment, treatment plan, discharge plan and postdischarge services, and the scope of services provided, including treatment modalities.

e. Any accreditations or other types of approvals from national or state organizations.

f. The physical facility and any equipment to be utilized, and whether the facility is part of the hospital license.

78.31(4) *Requirements for specific types of service.*

a. Alcoholism and substance abuse.

(1) Approval by joint commission or substance abuse commission. In addition to certification by the department, alcoholism and substance abuse programs must also be approved by either the joint commission on the accreditation of hospitals or the Iowa substance abuse commission.

(2) General characteristics. The services must be designed to identify and respond to the biological, psychological and social antecedents, influences and consequences associated with the recipient's dependence.

These needed services must be provided either directly by the facility or through referral, consultation or contractual arrangements or agreements.

Special treatment needs of recipients by reason of age, gender, sexual orientation, or ethnic origin are evaluated and services for children and adolescents (as well as adults, if applicable) address the special needs of these age groups, including but not limited to, learning problems in education, family involvement, developmental status, nutrition, and recreational and leisure activities.

(3) Diagnostic and treatment staff. Each person who provides diagnostic or treatment services shall be determined to be competent to provide the services by reason of education, training, and experience.

Professional disciplines which must be represented on the diagnostic and treatment staff, either through employment by the facility (full-time or part-time), contract or referral, are a physician (M.D. or D.O.), a licensed psychologist and a substance abuse counselor certified by the Iowa board of substance abuse certification. Psychiatric consultation must be available and the number of staff should be appropriate to the patient load of the facility.

(4) Initial assessment. A comprehensive assessment of the biological, psychological, social, and spiritual orientation of the patient must be conducted which shall include:

A history of the use of alcohol and other drugs including age of onset, duration, patterns, and consequences of use; use of alcohol and drugs by family members and types of and responses to previous treatment.

A comprehensive medical history and physical examination including the history of physical problems associated with dependence.

Appropriate laboratory screening tests based on findings of the history and physical examination and tests for communicable diseases when indicated.

Any history of physical abuse.

A systematic mental status examination with special emphasis on immediate recall and recent and remote memory.

A determination of current and past psychiatric and psychological abnormality.

A determination of any degree of danger to self or others.

The family's history of alcoholism and other drug dependencies.

The patient's educational level, vocational status, and job performance history.

The patient's social support networks, including family and peer relationships.

The patient's perception of the patient's strengths, problem areas, and dependencies.

The patient's leisure, recreational, or vocational interests and hobbies.

The patient's ability to participate with peers and in programs and social activities.

Interview of family members and significant others as available with the patient's written or verbal permission.

Legal problems, if applicable.

(5) Admission criteria. Both of the first two criteria and one additional criterion from the following list must be present for a patient to be accepted for treatment.

Alcohol or drugs taken in greater amounts over a longer period than the person intended.

Two or more unsuccessful efforts to cut down or control use of alcohol or drugs.

Continued alcohol or drug use despite knowledge of having a persistent or recurrent family, social, occupational, psychological, or physical problem that is caused or exacerbated by the use of alcohol or drugs.

Marked tolerance: the need for markedly increased amounts of alcohol or drugs (i.e., at least a 50 percent increase) in order to achieve intoxication or desired effect or markedly diminished effect with continued use of same amount.

Characteristic withdrawal symptoms.

Alcohol or drugs taken often to relieve or avoid withdrawal symptoms.

(6) Plan of treatment. For each patient there is a written comprehensive and individualized description of treatment to be undertaken. The treatment plan is based on the problems and needs identified in the assessment and specifies the regular times at which the plan will be reassessed.

The patient's perception of needs and, when appropriate and available, the family's perception of the patient's needs shall be documented.

The patient's participation in the development of the treatment plan is sought and documented.

Each patient is reassessed to determine current clinical problems, needs, and responses to treatment. Changes in treatment are documented.

(7) Discharge plan. For each patient before discharge, a plan for discharge is designed to provide appropriate continuity of care which meets the following requirements:

The plan for continuing care must describe and facilitate the transfer of the patient and the responsibility for the patient's continuing care to another phase or modality of the program, other programs, agencies, persons or to the patient and the patient's personal support system.

The plan is in accordance with the patient's reassessed needs at the time of transfer.

The plan is developed in collaboration with the patient and, as appropriate and available, with the patient's written verbal permission with family members.

The plan is implemented in a manner acceptable to the patient and the need for confidentiality.

Implementation of the plan includes timely and direct communication with and transfer of information to the other programs, agencies, or persons who will be providing continuing care.

(8) Restrictions and limitations on payment. Medicaid will reimburse for a maximum of 28 treatment days. Payment beyond 28 days is made when documentation indicates that the patient has not reached an exit level.

If an individual has completed all or part of the basic 28-day program, a repeat of the program will be reimbursed with justification. The program will include an aftercare component meeting weekly for at least one year without charge.

b. Eating disorders.

(1) General characteristics. Eating disorders are characterized by gross disturbances in eating behavior. Eating disorders include anorexia nervosa, bulimia, or bulimarexia. Compulsive overeaters are not acceptable for this program.

(2) Diagnostic and treatment staff. Each person who provides diagnostic or treatment services shall be determined to be competent to provide the services by reason of education, training, and experience.

Professional disciplines which must be represented on the diagnostic and treatment staff, either through employment by a facility (full-time or part-time), contract or referral, are a physician (M.D. or D.O.), a licensed psychologist, a counselor with a master's or bachelor's degree and experience, a dietitian with a bachelor's degree and registered dietitian's certificate, and a licensed occupational therapist. The number of staff should be appropriate to the patient load of the facility.

(3) Initial assessment. A comprehensive assessment of the biological, psychological, social, and family orientation of the patient must be conducted. The assessment must include a weight history and a history of the patient's eating and dieting behavior, including binge eating, onset, patterns, and consequences. The assessment shall include the following:

A family history as well as self-assessment regarding chronic dieting, obesity, anorexia, bulimia, drug abuse, alcohol problems, depression, hospitalization for psychiatric reasons, and threatened or attempted suicide.

A history of purging behavior including frequency and history of vomiting, use of laxatives, history and frequency of use of diuretics, history and frequency of use of diet pills, ipecac, or any other weight control measures, and frequency of eating normal meals without vomiting.

A history of exercise behavior, including type, frequency, and duration.

A complete history of current alcohol and other drug use.

Any suicidal thoughts or attempts.

Sexual history, including sexual preference and activity. Sexual interest currently as compared to prior to the eating disorder is needed.

History of experiencing physical or sexual (incest or rape) abuse.

History of other counseling experiences.

Appropriate psychological assessment, including psychological orientation to the above questions.

A medical history, including a physical examination, covering the information listed in subparagraph (4) below.

Appropriate laboratory screening tests based on findings of the history and physical examination and tests for communicable diseases when indicated.

The patient's social support networks, including family and peer relationships.

The patient's educational level, vocational status, and job or school performance history, as appropriate.

The patient's leisure, recreational, or vocational interests and hobbies.

The patient's ability to participate with peers and programs and social activities.

Interview of family members and significant others as available with the patient's written or verbal permission as appropriate.

Legal problems, if applicable.

(4) Admission criteria. In order to be accepted for treatment, the patient shall meet the diagnostic criteria for anorexia nervosa or bulimia as established by the DSM III R (Diagnostic and Statistical Manual, Third Edition, Revised).

In addition to the diagnostic criteria, the need for treatment will be determined by a demonstrable loss of control of eating behaviors and the failure of the patient in recent attempts at voluntary self-control of the problem. Demonstrable impairment, dysfunction, disruption or harm of physical health, emotional health (e.g., significant depression withdrawal, isolation, suicidal ideas), vocational or educational functioning, or interpersonal functioning (e.g., loss of relationships, legal difficulties) shall have occurred.

The need for treatment may be further substantiated by substance abuse, out-of-control spending, incidence of stealing to support habit, or compulsive gambling.

The symptoms shall have been present for at least six months and three of the following criteria must be present:

Medical criteria including endocrine and metabolic factors (e.g., amenorrhea, menstrual irregularities, decreased reflexes, cold intolerance, hypercarotenemia, parotid gland enlargement, lower respiration rate, hair loss, abnormal cholesterol or triglyceride levels).

Other cardiovascular factors including hypotension, hypertension, arrhythmia, ipecac poisoning, fainting, or bradycardia.

Renal considerations including diuretic abuse, dehydration, elevated BUN, renal calculi, edema, or hypokalemia.

Gastrointestinal factors including sore throats, mallery-weiss tears, decreased gastric emptying, constipation, abnormal liver enzymes, rectal bleeding, laxative abuse, or esophagitis.

Hematologic considerations including anemia, leukopenia, or thrombocytopenia.

Ear, nose, and throat factors including headaches or dizziness.

Skin considerations including lanugo or dry skin.

Aspiration pneumonia, a pulmonary factor.

The presence of severe symptoms and complications as evaluated and documented by the medical director may require a period of hospitalization to establish physical or emotional stability.

(5) Plan of treatment. For each patient there is a written comprehensive and individualized description of treatment to be undertaken. The treatment plan is based on problems and needs identified in the assessment and specifies the regular times at which the plan will be reassessed.

The patient's perceptions of needs and, when appropriate and available, the family's perceptions of the patient's needs shall be documented.

The patient's participation in the development of the treatment plans is sought and documented.

Each patient is reassessed to determine current clinical problems, needs, and responses to treatment. Changes in treatment are documented.

(6) Discharge plan. Plans for discharge shall meet the requirements for discharge plans for alcohol and substance abuse patients in subrule 78.31(3), paragraph *"a,"* subparagraph (6).

(7) Restriction and limitations on payment. Medicaid will pay for a maximum of 30 days of a structured outpatient treatment program. Payment beyond 30 days is made when documentation indicates that the patient has not reached an exit level.

Eating disorder programs will include an aftercare component meeting weekly for at least one year without charge.

Family counseling groups held in conjunction with the eating disorders program will be part of the overall treatment charge.

c. Cardiac rehabilitation.

(1) General characteristics. Cardiac rehabilitation programs shall provide a supportive educational environment in which to facilitate behavior change with respect to the accepted cardiac risk factors,

initiate prescribed exercise as a mode of facilitating the return of the patient to everyday activities by improving cardiovascular functional capacity and work performance, and promote a long-term commitment to lifestyle changes that could positively affect the course of the cardiovascular disease process.

(2) Treatment staff. Professional disciplines who must be represented on the treatment staff, either by employment by the facility (full-time or part-time), contract or referral, are as follows:

At least one physician responsible for responding to emergencies must be physically present in the hospital when patients are receiving cardiac rehabilitation services. The physician must be trained and certified at least to the level of basic life support.

A medical consultant shall oversee the policies and procedures of the outpatient cardiac rehabilitation area. The director shall meet with the cardiac rehabilitation staff on a regular basis to review exercise prescriptions and any concerns of the team.

A cardiac rehabilitation nurse shall carry out the exercise prescription after assessment of the patient. The nurse shall be able to interpret cardiac disrhythmia and be able to initiate emergency action if necessary. The nurse shall assess and implement a plan of care for cardiac risk factor modification. The nurse shall have at least one year of experience in a coronary care unit.

A physical therapist shall offer expertise in unusual exercise prescriptions where a patient has an unusual exercise problem.

A dietitian shall assess the dietary needs of persons and appropriately instruct them on their prescribed diets.

A social worker shall provide counseling as appropriate and facilitate a spouse support group. A licensed occupational therapist shall be available as necessary.

(3) Admission criteria. Candidates for the program must be referred by the attending physician. The following conditions are eligible for the program:

Postmyocardial infarction (within three months postdischarge).

Postcardiac surgery (within three months postdischarge).

Poststreptokinase.

Postpercutaneous transluminal angioplasty (within three months postdischarge).

Patient with severe angina being treated medically because of client or doctor preference or inoperable cardiac disease.

(4) Physical environment and equipment. A cardiac rehabilitation unit must be an autonomous physical unit specifically equipped with the necessary telemetry monitoring equipment, exercise equipment, and appropriate equipment and supplies for cardiopulmonary resuscitation (CPR). The exercise equipment must have the capacity to measure the intensity, speed, and length of the exercises. The equipment must be periodically inspected and maintained in accordance with the hospital's preventive maintenance program.

(5) Medical records. Medical records for each cardiac rehabilitation patient shall consist of at least the following:

Referral form.

Physician's orders.

Laboratory reports.

Electrocardiogram reports.

History and physical examination.

Angiogram report, if applicable.

Operative report, if applicable.

Preadmission interview.

Exercise prescription.

Rehabilitation plan, including participant's goals.

Documentation for exercise sessions and progress notes.

Nurse's progress reports.

Discharge instructions.

(6) Discharge plan. The patient will be discharged from the program when the physician, staff, and patient agree that the work level is functional for them and little benefit could be derived from further continuation of the program, disrhythmia disturbances are resolved, and appropriate cardiovascular response to exercise is accomplished.

(7) Monitoring of services. The program should be monitored by the hospital on a periodic basis using measuring criteria for evaluating cardiac rehabilitation services provided.

(8) Restrictions and limitations. Payment will be made for a maximum of three visits per week for a period of 12 weeks. Payment beyond 12 weeks is made when documentation indicates that the patient has not reached an exit level.

d. Mental health.

(1) General characteristics. To be covered, mental health services must be prescribed by a physician or certified health service provider in psychology, provided under an individualized treatment plan and reasonable and necessary for the diagnosis or treatment of the patient's condition. This means the services must be for the purpose of diagnostic study or the services must reasonably be expected to improve the patient's condition.

(2) Individualized treatment plan. The individualized written plan of treatment shall be established by a physician or certified health service provider in psychology after any needed consultation with appropriate staff members. The plan must state the type, amount, frequency and duration of the services to be furnished and indicate the diagnoses and anticipated goals. (A plan is not required if only a few brief services will be furnished.)

(3) Supervision and evaluation. Services must be supervised and periodically evaluated by a physician, certified health service provider in psychology, or both within the scopes of their respective practices if clinically indicated to determine the extent to which treatment goals are being realized. The evaluation must be based on periodic consultation and conference with therapists and staff. The physician or certified health service provider in psychology must also provide supervision and direction to any therapist involved in the patient's treatment and see the patient periodically to evaluate the course of treatment and to determine the extent to which treatment goals are being realized and whether changes in direction or services are required.

(4) Reasonable expectation of improvement. Services must be for the purpose of diagnostic study or reasonably be expected to improve the patient's condition. The treatment must at a minimum be designed to reduce or control the patient's psychiatric or psychological symptoms so as to prevent relapse or hospitalization and improve or maintain the patient's level of functioning.

It is not necessary that a course of therapy have as its goal restoration of the patient to the level of functioning exhibited prior to the onset of the illness although this may be appropriate for some patients. For many other patients, particularly those with long-term chronic conditions, control of symptoms and maintenance of a functional level to avoid further deterioration or hospitalization is an acceptable expectation of improvement. "Improvement" in this context is measured by comparing the effect of continuing versus discontinuing treatment. Where there is a reasonable expectation that if treatment services were withdrawn, the patient's condition would deteriorate, relapse further, or require hospitalization, this criterion would be met.

(5) Diagnostic and treatment staff. Each person who provides diagnostic or treatment services shall be determined to be competent to provide the services by reason of education, training, and experience. The number of the above staff employed by the facility must be appropriate to the facility's patient load. The staff may be employees of the hospital, on contract, or the service may be provided through referral.

The diagnostic and treatment staff shall consist of a physician, a psychologist, social workers or counselors meeting the requirements for "mental health professionals" as set forth in rule 441—33.1(225C,230A).

(6) Initial assessment. A comprehensive assessment of the biological, psychological, social, and spiritual orientation of the patient must be conducted, which shall include:

A history of the mental health problem, including age of onset, duration, patterns of symptoms, consequences of symptoms, and responses to previous treatment.

A comprehensive clinical history, including the history of physical problems associated with the mental health problem. Appropriate referral for physical examination for determination of any communicable diseases.

Any history of physical abuse.

A systematic mental health examination, with special emphasis on any change in cognitive, social or emotional functioning.

A determination of current and past psychiatric and psychological abnormality.

A determination of any degree of danger to self or others.

The family's history of mental health problems.

The patient's educational level, vocational status, and job performance history.

The patient's social support network, including family and peer relationship.

The patient's perception of the patient's strengths, problem areas, and dependencies.

The patient's leisure, recreational or vocational interests and hobbies.

The patient's ability to participate with peers in programs and social activities.

Interview of family members and significant others, as available, with the patient's written or verbal permission.

Legal problems if applicable.

(7) Covered services. Services covered for the treatment of psychiatric conditions are:

1. Individual and group therapy with physicians, psychologists, social workers, counselors, or psychiatric nurses.

2. Occupational therapy services if the services require the skills of a qualified occupational therapist and must be performed by or under the supervision of a licensed occupational therapist or by an occupational therapy assistant.

3. Drugs and biologicals furnished to outpatients for therapeutic purposes only if they are of the type which cannot be self-administered and are not "covered Part D drugs" as defined by 42 U.S.C. Section 1395w-102(e)(1)-(2) for a "Part D eligible individual" as defined in 42 U.S.C. Section 1395w-101(a)(3)(A), including an individual who is not enrolled in a Part D plan.

4. Activity therapies which are individualized and essential for the treatment of the patient's condition. The treatment plan must clearly justify the need for each particular therapy utilized and explain how it fits into the patient's treatment.

5. Family counseling services are covered only if the primary purpose of the counseling is the treatment of the patient's condition.

6. Partial hospitalization and day treatment services to reduce or control a person's psychiatric or psychological symptoms so as to prevent relapse or hospitalization, improve or maintain the person's level of functioning and minimize regression. These services include all psychiatric services needed by the patient during the day.

Partial hospitalization services means an active treatment program that provides intensive and structured support that assists persons during periods of acute psychiatric or psychological distress or during transition periods, generally following acute inpatient hospitalization episodes.

Service components may include individual and group therapy, reality orientation, stress management and medication management.

Services are provided for a period for four to eight hours per day.

Day treatment services means structured, long-term services designed to assist in restoring, maintaining or increasing levels of functioning, minimizing regression and preventing hospitalization.

Service components include training in independent functioning skills necessary for self-care, emotional stability and psychosocial interactions, and training in medication management.

Services are structured with an emphasis on program variation according to individual need.

Services are provided for a period of three to five hours per day, three or four times per week.

7. Partial hospitalization and day treatment for persons aged 20 or under. Payment to a hospital will be approved for day treatment services for persons aged 20 or under if the hospital is certified by the department for hospital outpatient mental health services. All conditions for the day treatment program for persons aged 20 or under as outlined in subrule 78.16(7) for community mental health centers shall

apply to hospitals. All conditions of the day treatment program for persons aged 20 or under as outlined in subrule 78.16(7) for community mental health centers shall be applicable for the partial hospitalization program for persons aged 20 or under with the exception that the maximum hours shall be 25 hours per week.

(8) Restrictions and limitations on coverage. The following are generally not covered except as indicated:

Activity therapies, group activities, or other services and programs which are primarily recreational or diversional in nature. Outpatient psychiatric day treatment programs that consist entirely of activity therapies are not covered.

Geriatric day-care programs, which provide social and recreational activities to older persons who need some supervision during the day while other family members are away from home. These programs are not covered because they are not considered reasonable and necessary for a diagnosed psychiatric disorder.

Vocational training. While occupational therapy may include vocational and prevocational assessment of training, when the services are related solely to specific employment opportunities, work skills, or work setting, they are not covered.

(9) Frequency and duration of services. There are no specific limits on the length of time that services may be covered. There are many factors that affect the outcome of treatment. Among them are the nature of the illness, prior history, the goals of treatment, and the patient's response. As long as the evidence shows that the patient continues to show improvement in accordance with the individualized treatment plan and the frequency of services is within acceptable norms of medical practice, coverage will be continued.

(10) Documentation requirements. The provider shall develop and maintain sufficient written documentation to support each medical or remedial therapy, service, activity, or session for which billing is made. All outpatient mental health services shall include:

1. The specific services rendered.
2. The date and actual time the services were rendered.
3. Who rendered the services.
4. The setting in which the services were rendered.
5. The amount of time it took to deliver the services.
6. The relationship of the services to the treatment regimen described in the plan of care.
7. Updates describing the patient's progress.

For services that are not specifically included in the patient's treatment plan, a detailed explanation of how the services being billed relate to the treatment regimen and objectives contained in the patient's plan of care and the reason for the departure from the plan shall be given.

e. Pain management.

(1) Approval by commission on accreditation of rehabilitation facilities. In addition to certification by the department, pain management programs must also be approved by the commission on accreditation of rehabilitation facilities (CARF).

(2) General characteristics. A chronic pain management program shall provide coordinated, goal-oriented, interdisciplinary team services to reduce pain, improve quality of life, and decrease dependence on the health care system for persons with pain which interferes with physical, psychosocial, and vocational functioning.

(3) Treatment staff. Each person who provides treatment services shall be determined to be competent to provide the services by reason of education, training, and experience. Professional disciplines which must be represented on the treatment staff, either through employment by the facility (full-time or part-time), contract or referral, are a physician (M.D. or D.O.), a registered nurse, a licensed physical therapist and a licensed clinical psychologist or psychiatrist. The number of staff should be appropriate to the patient load of the facility.

(4) Admission criteria. Candidates for the program shall meet the following guidelines:

The person must have had adequate medical evaluation and treatment in the months preceding admission to the program including an orthopedic or neurological consultation if the problem is back pain or a neurological evaluation if the underlying problem is headaches.

The person must be free of any underlying psychosis or severe neurosis.

The person cannot be toxic on any addictive drugs.

The person must be capable of self-care; including being able to get to meals and to perform activities of daily living.

(5) Plan of treatment. For each patient there is a written comprehensive and individualized description of treatment to be undertaken. The treatment plan is based on the problems and needs identified in the assessment and specifies the times at which the plan will be reassessed.

The patient's perception of needs and, when appropriate and available, the family's perception of the patient's needs shall be documented.

The patient's participation in the development of the treatment plan is sought and documented.

Each patient is reassessed to determine current clinical problems, needs, and responses to treatment. Changes in treatment are documented.

(6) Discharge plan. For each patient before discharge, a plan for discharge is designed to provide appropriate continuity of care which meets the following requirements:

The plan for continuing care must describe and facilitate the transfer of the patient and the responsibility for the patient's continuing care to another phase or modality of the program, other programs, agencies, persons or to the patient and the patient's personal support system.

The plan is in accordance with the patient's reassessed needs at the time of transfer.

The plan is developed in collaboration with the patient and, as appropriate and available, with the patient's written verbal permission with the family members.

The plan is implemented in a manner acceptable to the patient and the need for confidentiality.

Implementation of the plan includes timely and direct communication with and transfer of information to the other programs, agencies, or persons who will be providing continuing care.

(7) Restrictions and limitations on payment. Medicaid will pay for a maximum of three weeks of a structured outpatient treatment program. When documentation indicates that the patient has not reached an exit level, coverage may be extended an extra week.

A repeat of the entire program for any patient will be covered only if a different disease process is causing the pain or a significant change in life situation can be demonstrated.

f. Diabetic education.

(1) Certification by department of public health. In addition to certification by the department for Medicaid, diabetic education programs must also be certified by the department of public health. (See department of public health rules 641—Chapter 9.)

(2) General characteristics. An outpatient diabetes self-management education program shall provide instruction which will enable people with diabetes and their families to understand the diabetes disease process and the daily management of diabetes. People with diabetes must learn to balance their special diet and exercise requirements with drug therapy (insulin or oral agents). They must learn self-care techniques such as monitoring their own blood glucose. And often, they must learn to self-treat insulin reactions, protect feet that are numb and have seriously compromised circulation, and accommodate their regimen to changes in blood glucose because of stress or infections.

(3) Program staff. Each person who provides services shall be determined to be competent to provide the services by reason of education, training and experience. Professional disciplines which must be represented on the staff, either through employment by the facility (full-time or part-time), contract or referral, are a physician (M.D. or D.O.), a registered nurse, a registered dietitian and a licensed pharmacist. The number of staff should be appropriate to the patient load of the facility.

(4) Admission criteria. Candidates for the program shall meet the following guidelines:

The person must have Type I or Type II diabetes.

The person must be referred by the attending physician.

The person shall demonstrate an ability to follow through with self-management.

(5) Health assessment. An individualized and documented assessment of needs shall be developed with the patient's participation. Follow-up assessments, planning and identification of problems shall be provided.

(6) Restrictions and limitations on payment. Medicaid will pay for a diabetic self-management education program. Diabetic education programs will include follow-up assessments at 3 and 12 months without charge. A complete diabetic education program is payable once in the lifetime of a recipient.

g. Pulmonary rehabilitation.

(1) General characteristics. Pulmonary rehabilitation is an individually tailored, multidisciplinary program through which accurate diagnosis, therapy, emotional support, and education stabilizes or reverses both the physio- and psychopathology of pulmonary diseases and attempts to return the patient to the highest possible functional capacity allowed by the pulmonary handicap and overall life situation.

(2) Diagnostic and treatment staff. Each person who provides diagnostic or treatment services shall be determined to be competent to provide the services by reason of education, training, and experience.

Professional disciplines which must be represented by the diagnostic and treatment staff, either through employment by the facility (full-time or part-time), contract, or referral, are a physician (doctor of medicine or osteopathy), a respiratory therapist, a licensed physical therapist, and a registered nurse.

(3) Initial assessment. A comprehensive assessment must occur initially, including:

A diagnostic workup which entails proper identification of the patient's specific respiratory ailment, appropriate pulmonary function studies, a chest radiograph, an electrocardiogram and, when indicated, arterial blood gas measurements at rest and during exercise, sputum analysis and blood theophylline measurements.

Behavioral considerations include emotional screening assessments and treatment or counseling when required, estimating the patient's learning skills and adjusting the program to the patient's ability, assessing family and social support, potential employment skills, employment opportunities, and community resources.

(4) Admission criteria. Criteria include a patient's being diagnosed and symptomatic of chronic obstructive pulmonary disease (COPD), having cardiac stability, social, family, and financial resources, ability to tolerate periods of sitting time; and being a nonsmoker for six months, or if a smoker, willingness to quit and a physician's order to participate anyway.

Factors which would make a person ineligible include acute or chronic illness that may interfere with rehabilitation, any illness or disease state that affects comprehension or retention of information, a strong history of medical noncompliance, unstable cardiac or cardiovascular problems, and orthopedic difficulties that would prohibit exercise.

(5) Plan of treatment. Individualized long- and short-term goals will be developed for each patient. The treatment goals will be based on the problems and needs identified in the assessment and specify the regular times at which the plan will be reassessed.

The patients and their families need to help determine and fully understand the goals, so that they realistically approach the treatment phase.

Patients are reassessed to determine current clinical problems, needs, and responses to treatment. Changes in treatment are documented.

Components of pulmonary rehabilitation to be included are physical therapy and relaxation techniques, exercise conditioning or physical conditioning for those with exercise limitations, respiratory therapy, education, an emphasis on the importance of smoking cessation, and nutritional information.

(6) Discharge plan. Ongoing care will generally be the responsibility of the primary care physician. Periodic reassessment will be conducted to evaluate progress and allow for educational reinforcement.

(7) Restrictions and limitations on payment. Medicaid will pay for a maximum of 25 treatment days. Payment beyond 25 days is made when documentation indicates that the patient has not reached an exit level.

h. Nutritional counseling. Payment will be made for persons aged 20 and under for nutritional counseling provided by a licensed dietitian employed by or under contract with a hospital for a nutritional problem or condition of a degree of severity that nutritional counseling beyond that normally expected

as part of the standard medical management is warranted. For persons eligible for the WIC program, a WIC referral is required. Medical necessity for nutritional counseling services exceeding those available through WIC shall be documented.

78.31(5) *Services rendered by advanced registered nurse practitioners certified in family, pediatric, or psychiatric mental health specialties and employed by a hospital.* Rescinded IAB 10/15/03, effective 12/1/03.

This rule is intended to implement Iowa Code section 249A.4.

441—78.32(249A) Area education agencies. Payment will be made for physical therapy, occupational therapy, psychological evaluations and counseling, psychotherapy, speech-language therapy, and audiological, nursing, and vision services provided by an area education agency (AEA). Services shall be provided directly by the AEA or through contractual arrangement with the AEA.

This rule is intended to implement Iowa Code section 249A.4.

441—78.33(249A) Case management services. Payment on a monthly payment per enrollee basis will be approved for the case management functions required in 441—Chapter 90.

78.33(1) Payment will be approved for MR/CMI/DD case management services pursuant to 441—Chapter 90 to:

a. Recipients 18 years of age or over with a primary diagnosis of mental retardation, developmental disabilities, or chronic mental illness as defined in rule 441—90.1(249A).

b. Rescinded IAB 1/8/03, effective 1/1/03.

c. Recipients under 18 years of age receiving HCBS MR waiver or HCBS children's mental health waiver services.

78.33(2) Payment for services pursuant to 441—Chapter 90 to recipients under age 18 who have a primary diagnosis of mental retardation or developmental disabilities as defined in rule 441—90.1(249A) and are residing in a child welfare decategorization county shall be made when the following conditions are met:

a. The child welfare decategorization county has entered into an agreement with the department certifying that the state match for case management is available within funds allocated for the purpose of decategorization.

b. The child welfare decategorization county has executed an agreement to remit the nonfederal share of the cost of case management services to the enhanced mental health, mental retardation and developmental disabilities services fund administered by the department.

c. The child welfare decategorization county has certified that the funds remitted for the nonfederal share of the cost of case management services are not federal funds.

78.33(3) Rescinded IAB 10/12/05, effective 10/1/05.

This rule is intended to implement Iowa Code section 249A.4.

441—78.34(249A) HCBS ill and handicapped waiver services. Payment will be approved for the following services to clients eligible for HCBS ill and handicapped waiver services as established in 441—Chapter 83. Services must be billed in whole units.

78.34(1) *Homemaker services.* Homemaker services are those services provided when the client lives alone or when the person who usually performs these functions for the client needs assistance with performing the functions. A unit of service is one hour. Components of the service are directly related to the care of the client and include:

a. Essential shopping: shopping for basic need items such as food, clothing or personal care items, or drugs.

b. Limited housecleaning: maintenance cleaning such as vacuuming, dusting, scrubbing floors, defrosting refrigerators, cleaning stoves, cleaning medical equipment, washing and mending clothes, washing personal items used by the client, and dishes.

c. Rescinded IAB 9/30/92, effective 12/1/92.

d. Meal preparation planning and preparing balanced meals.

78.34(2) *Home health services.* Home health services are personal or direct care services provided to the client which are not payable under Medicaid as set forth in rule 441—78.9(249A). A unit of service is a visit.

a. Components of the service include, but are not limited to:

(1) Observation and reporting of physical or emotional needs.

(2) Helping a client with bath, shampoo, or oral hygiene.

(3) Helping a client with toileting.

(4) Helping a client in and out of bed and with ambulation.

(5) Helping a client reestablish activities of daily living.

(6) Assisting with oral medications ordered by the physician which are ordinarily self-administered.

(7) Performing incidental household services which are essential to the client's health care at home and are necessary to prevent or postpone institutionalization in order to complete a full unit of service.

(8) Accompaniment to medical services or transport to and from school.

b. In some cases, a nurse may provide home health services if the health of the client is such that the agency is unable to place an aide in that situation due to limitations by state law or in the event that the agency's Medicare certification requirements prohibit the aide from providing the service. It is not permitted for the convenience of the provider.

c. Skilled nursing care is not covered.

78.34(3) *Adult day care services.* Adult day care services provide an organized program of supportive care in a group environment to persons who need a degree of supervision and assistance on a regular or intermittent basis in a day care center. A unit of service is a half day (1 to 4 hours), a full day (4 to 8 hours), or an extended day (8 to 12 hours). Components of the service are as set forth in rule 441—171.6(234) or the department of elder affairs rule 321—24.7(231).

78.34(4) *Nursing care services.* Nursing care services are services which are included in the plan of treatment approved by the physician and which are provided by licensed nurses to consumers in the home and community. The services shall be reasonable and necessary to the treatment of an illness or injury and include all nursing tasks recognized by the Iowa board of nursing. A unit of service is a visit.

78.34(5) *Respite care services.* Respite care services are services provided to the consumer that give temporary relief to the usual caregiver and provide all the necessary care that the usual caregiver would provide during that time period. The purpose of respite care is to enable the consumer to remain in the consumer's current living situation.

a. Services provided outside the consumer's home shall not be reimbursable if the living unit where respite is provided is reserved for another person on a temporary leave of absence.

b. Staff-to-consumer ratios shall be appropriate to the individual needs of the consumer as determined by the consumer's interdisciplinary team.

c. A unit of service is one hour.

d. Respite care is not to be provided to persons during the hours in which the usual caregiver is employed except when the consumer is attending a camp. Respite cannot be provided to a consumer whose usual caregiver is a consumer-directed attendant care provider for the consumer.

e. The interdisciplinary team shall determine if the consumer will receive basic individual respite, specialized respite, or group respite as defined in rule 441—83.1(249A).

f. A maximum of 14 consecutive days of 24-hour respite care may be reimbursed.

g. Respite services provided for a period exceeding 24 consecutive hours to three or more individuals who require nursing care because of a mental or physical condition must be provided by a health care facility licensed as described in Iowa Code chapter 135C.

78.34(6) *Counseling services.* Counseling services are face-to-face mental health services provided to the client and caregiver by a mental health professional as defined in rule 441—24.61(225C,230A) to facilitate home management of the client and prevent institutionalization. Counseling services are nonpsychiatric services necessary for the management of depression, assistance with the grief process, alleviation of psychosocial isolation and support in coping with a disability or illness, including terminal illness. Counseling services may be provided both for the purpose of training the client's family or other caregiver to provide care, and for the purpose of helping the client and those caring for the client to

adjust to the client's disability or terminal condition. Counseling services may be provided to the client's caregiver only when included in the case plan for the client.

Payment will be made for individual and group counseling. A unit of individual counseling for the waiver client or the waiver client and the client's caregiver is 15 minutes. A unit of group counseling is one hour. Payment for group counseling is based on the group rate divided by six, or, if the number of persons who comprise the group exceeds six, the actual number of persons who comprise the group.

78.34(7) *Consumer-directed attendant care service.* Consumer-directed attendant care services are service activities performed by a person to help a consumer with self-care tasks which the consumer would typically do independently if the consumer were otherwise able.

a. The service activities may include helping the consumer with any of the following nonskilled service activities:

(1) Dressing.

(2) Bath, shampoo, hygiene, and grooming.

(3) Access to and from bed or a wheelchair, transferring, ambulation, and mobility in general. It is recommended that the provider receive certification of training and return demonstration for transferring. Certification for this is available through the area community colleges.

(4) Toilet assistance, including bowel, bladder, and catheter assistance. It is recommended that the provider receive certification of training and return demonstration for catheter assistance. Certification for this is available through the area community colleges.

(5) Meal preparation, cooking, eating and feeding but not the cost of meals themselves.

(6) Housekeeping services which are essential to the consumer's health care at home.

(7) Medications ordinarily self-administered including those ordered by a physician or other qualified health care provider. It is recommended the provider successfully complete a medication aide course administered by an area community college.

(8) Wound care.

(9) Assistance needed to go to or return from a place of employment and assistance with job-related tasks while the consumer is on the job site. The cost of transportation for the consumer and assistance with understanding or performing the essential job functions are not included in consumer-directed attendant care services.

(10) Cognitive assistance with tasks such as handling money and scheduling.

(11) Fostering communication through interpreting and reading services as well as assistive devices for communication.

(12) Assisting or accompanying a consumer in using transportation essential to the health and welfare of the consumer. The cost of the transportation is not included.

b. The service activities may include helping the consumer with any of the following skilled services under the supervision of a licensed nurse or licensed therapist working under the direction of a physician. The licensed nurse or therapist shall retain accountability for actions that are delegated. The licensed nurse or therapist shall ensure appropriate assessment, planning, implementation, and evaluation. The licensed nurse or therapist shall make on-site supervisory visits every two weeks with the provider present. The cost of the supervision provided by the licensed nurse or therapist shall be paid from private insurance and other third-party payment sources, Medicare, the regular Medicaid program, or the early periodic screening diagnosis and treatment program before accessing the HCBS waiver.

(1) Tube feedings of consumers unable to eat solid foods.

(2) Intravenous therapy administered by a registered nurse.

(3) Parenteral injections required more than once a week.

(4) Catheterizations, continuing care of indwelling catheters with supervision of irrigations, and changing of Foley catheters when required.

(5) Respiratory care including inhalation therapy and tracheotomy care or tracheotomy care and ventilator.

(6) Care of decubiti and other ulcerated areas, noting and reporting to the nurse or therapist.

(7) Rehabilitation services including, but not limited to, bowel and bladder training, range of motion exercises, ambulation training, restorative nursing services, reteaching the activities of daily

living, respiratory care and breathing programs, reality orientation, reminiscing therapy, remotivation, and behavior modification.

(8) Colostomy care.

(9) Care of medical conditions out of control which includes brittle diabetes and comfort care of terminal conditions.

(10) Postsurgical nursing care.

(11) Monitoring medications requiring close supervision because of fluctuating physical or psychological conditions, e.g., antihypertensives, digitalis preparations, mood-altering or psychotropic drugs, or narcotics.

(12) Preparing and monitoring response to therapeutic diets.

(13) Recording and reporting of changes in vital signs to the nurse or therapist.

c. A unit of service is 1 hour, or one 8- to 24-hour day provided by an individual or an agency. Each service shall be billed in whole units.

d. The consumer, parent, guardian, or attorney in fact under a durable power of attorney for health care shall be responsible for selecting the person or agency who will provide the components of the attendant care services to be provided.

e. The consumer, parent, guardian, or attorney in fact under a durable power of attorney for health care shall determine the components of the attendant care services to be provided with the person who is providing the services to the consumer.

f. The service activities may not include parenting or child care for or on behalf of the consumer.

g. The consumer, parent, guardian, or attorney in fact under a durable power of attorney for health care and the provider shall complete and sign Form 470-3372, HCBS Consumer-Directed Attendant Care Agreement. A copy of the completed agreement shall be attached to the service plan, which is signed by the service worker prior to the initiation of services, and kept in the consumer's and department's records.

h. If the consumer has a guardian or attorney in fact under a durable power of attorney for health care, the care plan shall address how consumer-directed attendant care services will be monitored to ensure the consumer's needs are being adequately met. If the guardian or attorney in fact is the service provider, the service plan shall address how the service worker or case manager shall oversee service provision.

i. If the consumer has a guardian or attorney in fact under a durable power of attorney for health care, the guardian or attorney in fact shall sign the claim form in place of the consumer, indicating that the service has been provided as presented on the claim.

j. The frequency or intensity of services shall be indicated in the service plan.

k. Consumer-directed attendant care services may not be simultaneously reimbursed with any other HCBS waiver services.

l. Consumer-directed attendant care services may be provided to a recipient of in-home health-related care services, but not at the same time.

m. Services may be provided in the absence of a parent or guardian if the parent or guardian has given advanced direction for the service provision.

78.34(8) *Interim medical monitoring and treatment services.* Interim medical monitoring and treatment services are monitoring and treatment of a medical nature requiring specially trained caregivers beyond what is normally available in a day care setting. The services must be needed to allow the consumer's usual caregivers to be employed or, for a limited period of time, for academic or vocational training of a usual caregiver; due to the hospitalization, treatment for physical or mental illness, or death of a usual caregiver; or during a search for employment by a usual caregiver.

a. Service requirements. Interim medical monitoring and treatment services shall:

(1) Provide experiences for each consumer's social, emotional, intellectual, and physical development;

(2) Include comprehensive developmental care and any special services for a consumer with special needs; and

(3) Include medical assessment, medical monitoring, and medical intervention as needed on a regular or emergency basis.

b. Interim medical monitoring and treatment services may include supervision to and from school.

c. Limitations.

(1) A maximum of 12 one-hour units of service is available per day.

(2) Covered services do not include a complete nutritional regimen.

(3) Interim medical monitoring and treatment services may not duplicate any regular Medicaid or waiver services provided under the state plan.

(4) Interim medical monitoring and treatment services may be provided only in the consumer's home, in a registered group child care home, in a registered family child care home, in a licensed child care center, or during transportation to and from school.

(5) The staff-to-consumer ratio shall not be less than one to six.

d. A unit of service is one hour.

78.34(9) *Home and vehicle modifications.* Covered home and vehicle modifications are those physical modifications to the consumer's home or vehicle listed below that directly address the consumer's medical or remedial need. Covered modifications must be necessary to provide for the health, welfare, or safety of the consumer and enable the consumer to function with greater independence in the home or vehicle.

a. Modifications that are necessary or desirable without regard to the consumer's medical or remedial need and that would be expected to increase the fair market value of the home or vehicle, such as furnaces, fencing, roof repair, or adding square footage to the residence, are excluded except as specifically included below. Repairs are also excluded.

b. Only the following modifications are covered:

(1) Kitchen counters, sink space, cabinets, special adaptations to refrigerators, stoves, and ovens.

(2) Bathtubs and toilets to accommodate transfer, special handles and hoses for shower heads, water faucet controls, and accessible showers and sink areas.

(3) Grab bars and handrails.

(4) Turnaround space adaptations.

(5) Ramps, lifts, and door, hall and window widening.

(6) Fire safety alarm equipment specific for disability.

(7) Voice-activated, sound-activated, light-activated, motion-activated, and electronic devices directly related to the consumer's disability.

(8) Vehicle lifts, driver-specific adaptations, remote-start systems, including such modifications already installed in a vehicle.

(9) Keyless entry systems.

(10) Automatic opening device for home or vehicle door.

(11) Special door and window locks.

(12) Specialized doorknobs and handles.

(13) Plexiglas replacement for glass windows.

(14) Modification of existing stairs to widen, lower, raise or enclose open stairs.

(15) Motion detectors.

(16) Low-pile carpeting or slip-resistant flooring.

(17) Telecommunications device for the deaf.

(18) Exterior hard-surface pathways.

(19) New door opening.

(20) Pocket doors.

(21) Installation or relocation of controls, outlets, switches.

(22) Air conditioning and air filtering if medically necessary.

(23) Heightening of existing garage door opening to accommodate modified van.

(24) Bath chairs.

c. A unit of service is the completion of needed modifications or adaptations.

d. All modifications and adaptations shall be provided in accordance with applicable federal, state, and local building and vehicle codes.

e. Services shall be performed following department approval of a binding contract between the enrolled home and vehicle modification provider and the consumer.

f. The contract shall include, at a minimum, the work to be performed, cost, time frame for work completion, and assurance of liability and workers' compensation coverage.

g. Service payment shall be made to the enrolled home and vehicle modification provider. If applicable, payment will be forwarded to the subcontracting agency by the enrolled home and vehicle modification provider following completion of the approved modifications. Payment of up to $6,060 per year may be made to certified providers upon satisfactory completion of the service. The service worker shall encumber up to $505 per month within the monthly dollar cap allowed for the consumer until the amount of the modification is reached within the 12-month period.

h. Services shall be included in the consumer's service plan and shall exceed the Medicaid state plan services.

78.34(10) *Personal emergency response system.* A personal emergency response system is an electronic device that transmits a signal to a central monitoring station to summon assistance in the event of an emergency when the consumer is alone.

a. The required components of the system are:

(1) An in-home medical communications transmitter and receiver.

(2) A remote, portable activator.

(3) A central monitoring station with backup systems staffed by trained attendants at all times.

(4) Current data files at the central monitoring station containing response protocols and personal, medical, and emergency information for each consumer.

b. The service shall be identified in the consumer's service plan.

c. A unit of service is a one-time installation fee or one month of service.

d. Maximum units per state fiscal year shall be the initial installation and 12 months of service.

78.34(11) *Home-delivered meals.* Home-delivered meals means meals prepared elsewhere and delivered to a waiver recipient at the recipient's residence. Each meal shall ensure the recipient receives a minimum of one-third of the daily recommended dietary allowance as established by the Food and Nutrition Board of the National Research Council of the National Academy of Sciences. The meal may also be a liquid supplement that meets the minimum one-third standard. When a restaurant provides the home-delivered meal, the recipient is required to have a nutritional consultation. The nutritional consultation includes contact with the restaurant to explain the dietary needs of the client and what constitutes the minimum one-third daily dietary allowance.

A maximum of 14 meals is allowed per week. A unit of service is a meal.

78.34(12) *Nutritional counseling.* Nutritional counseling services may be provided for a nutritional problem or condition of such a degree of severity that nutritional counseling beyond that normally expected as part of the standard medical management is warranted. A unit of service is 15 minutes.

78.34(13) *Consumer choices option.* The consumer choices option provides a consumer with a flexible monthly individual budget that is based on the consumer's service needs. With the individual budget, the consumer shall have the authority to purchase goods and services and may choose to employ providers of services and supports. Components of this service are set forth below.

a. *Agreement.* As a condition of participating in the consumer choices option, a consumer shall sign Form 470-4289, HCBS Consumer Choices Informed Consent and Risk Agreement, to document that the consumer has been informed of the responsibilities and risks of electing the consumer choices option.

b. *Individual budget amount.* A monthly individual budget amount shall be set for each consumer. The consumer's department service worker or case manager shall determine the amount of each consumer's individual budget, based on the services and supports authorized in the consumer's service plan. The consumer shall be informed of the individual budget amount during the development of the service plan.

(1) Services that may be included in determining the individual budget amount for a consumer in the HCBS ill and handicapped waiver are:

1. Consumer-directed attendant care (unskilled).
2. Home and vehicle modification.
3. Home-delivered meals.
4. Homemaker service.
5. Basic individual respite care.

(2) The department shall determine an average unit cost for each service selected under subparagraph (1) based on actual unit costs from the previous fiscal year plus a cost-of-living adjustment.

(3) In aggregate, costs for individual budget services shall not exceed the current costs of waiver program services. In order to maintain cost neutrality, the department shall apply a utilization adjustment factor to the amount of service authorized in the consumer's service plan before calculating the value of that service to be included in the individual budget amount.

(4) The department shall compute the utilization adjustment factor for each service by dividing the net costs of all claims paid for the service by the total of the authorized costs for that service, using at least 12 consecutive months of aggregate service data. The utilization adjustment factor shall be no lower than 60 percent. The department shall analyze and adjust the utilization adjustment factor at least annually in order to maintain cost neutrality.

(5) Anticipated costs for home and vehicle modification are not subject to the average cost in subparagraph (2) or the utilization adjustment factor in subparagraph (3). Costs for home and vehicle modification may be released in a one-time payment.

(6) The individual budget amount may be changed only at the first of the month and shall remain fixed for the entire month.

c. Required service components. To participate in the consumer choices option, a consumer must hire an independent support broker and must work with a financial management service that is enrolled as a Medicaid HCBS ill and handicapped waiver services provider.

(1) Before hiring the individual support broker, the consumer shall receive the results of the background check conducted pursuant to 441—subrule 77.30(14).

(2) If the consumer chooses to hire a person who has a criminal record or founded abuse report, the consumer assumes the risk for this action and shall acknowledge this information on Form 470-4289, HCBS Consumer Choices Informed Consent and Risk Agreement.

d. Optional service components. A consumer who elects the consumer choices option may purchase the following services and supports, which shall be provided in the consumer's home or at an integrated community setting:

(1) Self-directed personal care services. Self-directed personal care services are services or goods that provide a range of assistance in activities of daily living and incidental activities of daily living that help the consumer remain in the home and community.

(2) Self-directed community supports and employment. Self-directed community supports and employment are services that support the consumer in developing and maintaining independence and community integration.

(3) Individual-directed goods and services. Individual-directed goods and services are services, equipment, or supplies not otherwise provided through the Medicaid program that address a need identified in the consumer's service plan. The item or service shall decrease the consumer's need for other Medicaid services, promote the consumer's inclusion in the community, or increase the consumer's safety in the community.

e. Development of the individual budget. The individual support broker shall assist the consumer in developing and implementing the consumer's individual budget. The individual budget shall include:

(1) The costs of the financial management service.

(2) The costs of the independent support broker. The independent support broker may be compensated for up to 6 hours of service for assisting with the implementation of the initial individual budget. After the initial implementation, the independent support broker shall not be paid for more than 20 hours of service during a 12-month period without prior approval by the department.

(3) The costs of any services and supports chosen by the consumer as described in paragraph *"d."*

f. *Budget authority.* The consumer shall have authority over the individual budget authorized by the department to perform the following tasks:

(1) Contract with entities to provide services and supports as described in this subrule.

(2) Determine the amount to be paid for services with the exception of the independent support broker and the financial management service. Reimbursement rates for the independent support broker and the financial management service are subject to the limits in 441—subrule 79.1(2).

(3) Schedule the provision of services.

(4) Authorize payment for waiver goods and services identified in the individual budget. Consumers shall not use the individual budget to purchase room and board, sheltered workshop services, child care, or personal entertainment items.

(5) Reallocate funds among services included in the budget.

g. *Delegation of budget authority.* The consumer may delegate responsibility for the individual budget to a representative in addition to the independent support broker.

(1) The representative must be at least 18 years old.

(2) The representative shall not be a current provider of service to the consumer.

(3) The consumer shall sign a consent form that designates who the consumer has chosen as a representative and what responsibilities the representative shall have.

(4) The representative shall not be paid for this service.

h. *Employer authority.* The consumer shall have the authority to be the common-law employer of employees providing services and support under the consumer choices option. A common-law employer has the right to direct and control the performance of the services. The consumer may perform the following functions:

(1) Recruit employees.

(2) Select employees from a worker registry.

(3) Verify employee qualifications.

(4) Specify additional employee qualifications.

(5) Determine employee duties.

(6) Determine employee wages and benefits.

(7) Schedule employees.

(8) Train and supervise employees.

i. *Employment agreement.* Any person employed by the consumer to provide services under the consumer choices option shall sign an employment agreement with the consumer that outlines the employee's and consumer's responsibilities.

j. *Responsibilities of the independent support broker.* The independent support broker shall perform the following services:

(1) Assist the consumer with developing the consumer's initial and subsequent individual budgets and with making any changes to the individual budget.

(2) Have monthly contact with the consumer for the first four months of implementation of the initial individual budget and have quarterly contact thereafter.

(3) Complete the required employment packet with the financial management service.

(4) Assist with interviewing potential employees and entities providing services and supports if requested by the consumer.

(5) Assist the consumer with determining whether a potential employee meets the qualifications necessary to perform the job.

(6) Assist the consumer with obtaining a signed consent from a potential employee to conduct background checks if requested by the consumer.

(7) Assist the consumer with negotiating with entities providing services and supports if requested by the consumer.

(8) Assist the consumer with contracts and payment methods for services and supports if requested by the consumer.

(9) Assist the consumer with developing an emergency backup plan. The emergency backup plan shall also address any health and safety concerns.

(10) Review expenditure reports from the financial management service to ensure that services and supports in the individual budget are being provided.

(11) Document in writing on the independent support broker timecard every contact the broker has with the consumer. Contact documentation shall include information on the extent to which the consumer's individual budget has addressed the consumer's needs and the satisfaction of the consumer.

k. Responsibilities of the financial management service. The financial management service shall perform all of the following services:

(1) Receive Medicaid funds in an electronic transfer.

(2) Process and pay invoices for approved goods and services included in the individual budget.

(3) Enter the individual budget into the Web-based tracking system chosen by the department and enter expenditures as they are paid.

(4) Provide real-time individual budget account balances for the consumer, the independent support broker, and the department, available at a minimum during normal business hours (9 a.m. to 5 p.m., Monday through Friday).

(5) Conduct criminal background checks on potential employees, if requested.

(6) Verify for the consumer an employee's citizenship or alien status.

(7) Assist the consumer with fiscal and payroll-related responsibilities. Key employer-related tasks include:

1. Verifying that hourly wages comply with federal and state labor rules.
2. Collecting and processing timecards.
3. Withholding, filing, and paying federal, state and local income taxes, Medicare and Social Security (FICA) taxes, and federal (FUTA) and state (SUTA) unemployment and disability insurance taxes, as applicable.
4. Computing and processing other withholdings, as applicable.
5. Processing all judgments, garnishments, tax levies, or other withholding on an employee's pay as may be required by federal, state, or local laws.
6. Preparing and issuing employee payroll checks.
7. Preparing and disbursing IRS Forms W-2 and W-3 annually.
8. Processing federal advance earned income tax credit for eligible employees.
9. Refunding over-collected FICA, when appropriate.
10. Refunding over-collected FUTA, when appropriate.

(8) Purchase from the individual budget workers' compensation or other forms of insurance, as applicable or if requested by the consumer.

(9) Assist the consumer in completing required federal, state, and local tax and insurance forms.

(10) Establish and manage documents and files for the consumer and the consumer's employees.

(11) Monitor timecards, receipts, and invoices to ensure that they are consistent with the individual budget. Keep records of all timecards and invoices for each consumer for a total of five years.

(12) Provide monthly and quarterly status reports for the department, the independent support broker, and the consumer that include a summary of expenditures paid and amount of budget unused.

(13) Establish an accessible customer service system and a method of communication for the consumer and the individual support broker that includes alternative communication formats.

(14) Establish a customer services complaint reporting system.

(15) Develop a policy and procedures manual that is current with state and federal regulations and update as necessary.

(16) Develop a business continuity plan in the case of emergencies and natural disasters.

(17) Provide to the department an annual independent audit of the financial management service.

(18) Assist in implementing the state's quality management strategy related to the financial management service.

This rule is intended to implement Iowa Code section 249A.4.

441—78.35(249A) Occupational therapist services. Payment will be approved for the same services provided by an occupational therapist that are payable under Title XVIII of the Social Security Act (Medicare).

This rule is intended to implement Iowa Code section 249A.4.

441—78.36(249A) Hospice services.

78.36(1) *General characteristics.* A hospice is a public agency or private organization or a subdivision of either that is primarily engaged in providing care to terminally ill individuals. A hospice provides palliative and supportive services to meet the physical, psychosocial, social and spiritual needs of a terminally ill individual and the individual's family or other persons caring for the individual regardless of where the individual resides. Hospice services are those services to control pain and provide support to individuals to continue life with as little disruption as possible.

a. Covered services. Covered services shall include, in accordance with Medicare guidelines, the following:

(1) Nursing care.

(2) Medical social services.

(3) Physician services.

(4) Counseling services provided to the terminally ill individual and the individual's family members or other persons caring for the individual at the individual's place of residence, including bereavement, dietary, and spiritual counseling.

(5) Short-term inpatient care provided in a participating hospice inpatient unit or a participating hospital or nursing facility that additionally meets the special hospice standards regarding staffing and patient areas for pain control, symptom management and respite purposes.

(6) Medical appliances and supplies, including drugs and biologicals, as needed for the palliation and management of the individual's terminal illness and related conditions, except for "covered Part D drugs" as defined by 42 U.S.C. Section 1395w-102(e)(1)-(2) for a "Part D eligible individual" as defined in 42 U.S.C. Section 1395w-101(a)(3)(A), including an individual who is not enrolled in a Part D plan.

(7) Homemaker and home health aide services.

(8) Physical therapy, occupational therapy and speech-language pathology unless this provision has been waived under the Medicare program for a specific provider.

(9) Other items or services specified in the resident's plan that would otherwise be paid under the Medicaid program.

Nursing care, medical social services, and counseling are core hospice services and must routinely be provided directly by hospice employees. The hospice may contract with other providers to provide the remaining services. Bereavement counseling, consisting of counseling services provided after the individual's death to the individual's family or other persons caring for the individual, is a required hospice service but is not reimbursable.

b. Noncovered services.

(1) Covered services not related to the terminal illness. In accordance with Medicare guidelines, all medical services related to the terminal illness are the responsibility of the hospice. Services unrelated to the terminal illness are to be billed separately by the respective provider.

(2) Administrative duties performed by the medical director, any hospice-employed physician, or any consulting physician are included in the normal hospice rates. Patient care provided by the medical director, hospice-employed physician, attending physician, or consulting physician is separately reimbursable. Payment to the attending or consulting physician includes other partners in practice.

(3) Hospice care provided by a hospice other than the hospice designated by the individual unless provided under arrangements made by the designated hospice.

(4) AZT (Retrovir) and other curative antiviral drugs targeted at the human immunodeficiency virus for the treatment of AIDS.

78.36(2) *Categories of care.* Hospice care entails the following four categories of daily care. Guidelines for core and other services must be adhered to for all categories of care.

a. Routine home care is care provided in the place of residence that is not continuous.

b. Continuous home care is provided only during a period of crisis when an individual requires continuous care which is primarily nursing care to achieve palliation or management of acute medical symptoms. Nursing care must be provided by either a registered nurse or a licensed practical nurse and a nurse must be providing care for more than half of the period of care. A minimum of eight hours of care per day must be provided during a 24-hour day to qualify as continuous care. Homemaker and aide services may also be provided to supplement the nursing care.

c. Inpatient respite care is provided to the individual only when necessary to relieve the family members or other persons caring for the individual at home. Respite care may be provided only on an occasional basis and may not be reimbursed for more than five consecutive days at a time. Respite care may not be provided when the individual is a resident of a nursing facility.

d. General inpatient care is provided in periods of acute medical crisis when the individual is hospitalized or in a participating hospice inpatient unit or nursing facility for pain control or acute or chronic symptom management.

78.36(3) *Residence in a nursing facility.* For purposes of the Medicaid hospice benefit, a nursing facility can be considered the residence of a beneficiary. When the person does reside in a nursing facility, the requirement that the care of a resident of a nursing facility must be provided under the immediate direction of either the facility or the resident's personal physician does not apply if all of the following conditions are met:

a. The resident is terminally ill.

b. The resident has elected to receive hospice services under the Medicaid program from a Medicaid-enrolled hospice program.

c. The nursing facility and the Medicaid-enrolled hospice program have entered into a written agreement under which the hospice program takes full responsibility for the professional management of the resident's hospice care and the facility agrees to provide room and board to the resident.

78.36(4) *Approval for hospice benefits.* Payment will be approved for hospice services to individuals who are certified as terminally ill, that is, the individuals have a medical prognosis that their life expectancy is six months or less if the illness runs its normal course, and who elect hospice care rather than active treatment for the illness.

a. Physician certification process. The hospice must obtain certification that an individual is terminally ill in accordance with the following procedures:

(1) The hospice may obtain verbal orders to initiate hospice service from the medical director of the hospice or the physician member of the hospice interdisciplinary group and by the individual's attending physician (if the individual has an attending physician). The verbal order shall be noted in the patient's record. The verbal order must be given within two days of the start of care and be followed up in writing no later than eight calendar days after hospice care is initiated. The certification must include the statement that the individual's medical prognosis is that the individual's life expectancy is six months or less if the illness runs its normal course.

(2) When verbal orders are not secured, the hospice must obtain, no later than two calendar days after hospice care is initiated, written certification signed by the medical director of the hospice or the physician member of the hospice interdisciplinary group and by the individual's attending physician (if the individual has an attending physician). The certification must include the statement that the individual's medical prognosis is that the individual's life expectancy is six months or less, if the illness runs its normal course.

(3) Hospice care benefit periods consist of up to two periods of 90 days each and an unlimited number of subsequent 60-day periods as elected by the individual. The medical director or a physician must recertify at the beginning of each benefit period that the individual is terminally ill.

b. Election procedures. Individuals who are dually eligible for Medicare and Medicaid must receive hospice coverage under Medicare.

(1) Election statement. An individual, or individual's representative, elects to receive the hospice benefit by filing an election statement, Form 470-2618, Election of Medicaid Hospice Benefit, with a particular hospice. The hospice may provide the individual with another election form to use provided the form includes the following information:

1. Identification of the hospice that will provide the care.
2. Acknowledgment that the recipient has been given a full understanding of hospice care.
3. Acknowledgment that the recipient waives the right to regular Medicaid benefits, except for payment to the regular physician and treatment for medical conditions unrelated to the terminal illness.
4. Acknowledgment that recipients are not responsible for copayment or other deductibles.
5. The recipient's Medicaid number.
6. The effective date of election.
7. The recipient's signature.

(2) Change of designation. An individual may change the designation of the particular hospice from which the individual elects to receive hospice care one time only.

(3) Effective date. An individual may designate an effective date for the hospice benefit that begins with the first day of the hospice care or any subsequent day of hospice care, but an individual may not designate an effective date that is earlier than the date that the election is made.

(4) Duration of election. The election to receive hospice care will be considered to continue until one of the following occurs:

1. The individual dies.
2. The individual or the individual's representative revokes the election.
3. The individual's situation changes so that the individual no longer qualifies for the hospice benefit.
4. The hospice elects to terminate the recipient's enrollment in accordance with the hospice's established discharge policy.

(5) Revocation. Form 470-2619, Revocation of Medicaid Hospice Benefit, is completed when an individual or the individual's representative revokes the hospice benefit allowed under Medicaid. When an individual revokes the election of Medicaid coverage of hospice care, the individual resumes Medicaid coverage of the benefits waived when hospice care was elected.

This rule is intended to implement Iowa Code section 249A.4.

441—78.37(249A) HCBS elderly waiver services. Payment will be approved for the following services to consumers eligible for the HCBS elderly waiver services as established in 441—Chapter 83. The consumer shall have a billable waiver service each calendar quarter. Services must be billed in whole units.

78.37(1) *Adult day care services.* Adult day care services provide an organized program of supportive care in a group environment to persons who need a degree of supervision and assistance on a regular or intermittent basis in a day care center. A unit of service is a half day (1 to 4 hours), a full day (4 to 8 hours), or an extended day (8 to 12 hours). Components of the service are set forth in rule 441—171.6(234) or as indicated in the Iowa department of elder affairs Annual Service and Fiscal Reporting Manual.

78.37(2) *Emergency response system.* The emergency response system allows a person experiencing a medical emergency at home to activate electronic components that transmit a coded signal via digital equipment over telephone lines to a central monitoring station. The necessary components of a system are:

a. An in-home medical communications transceiver.

b. A remote, portable activator.

c. A central monitoring station with backup systems staffed by trained attendants 24 hours per day, seven days per week.

d. Current data files at the central monitoring station containing preestablished response protocols and personal, medical, and emergency information for each client.

78.37(3) *Home health aide services.* Home health aide services are personal or direct care services provided to the client which are not payable under Medicaid as set forth in rule 441—78.9(249A). A unit of service is a visit. Components of the service include:

a. Observation and reporting of physical or emotional needs.

b. Helping a client with bath, shampoo, or oral hygiene.

c. Helping a client with toileting.

d. Helping a client in and out of bed and with ambulation.

e. Helping a client reestablish activities of daily living.

f. Assisting with oral medications ordinarily self-administered and ordered by a physician.

g. Performing incidental household services which are essential to the client's health care at home and are necessary to prevent or postpone institutionalization in order to complete a full unit of service.

78.37(4) *Homemaker services.* Homemaker services are those services provided when the client lives alone or when the person who usually performs these functions for the client is incapacitated or occupied providing direct care to the client. A unit of service is one hour. Components of the service include:

a. Essential shopping: shopping for basic need items such as food, clothing or personal care items, or drugs.

b. Limited housecleaning: maintenance cleaning such as vacuuming, dusting, scrubbing floors, defrosting refrigerators, cleaning stoves, and washing and mending clothes.

c. Accompaniment to medical or psychiatric services.

d. Meal preparation: planning and preparing balanced meals.

e. Bathing and dressing for self-directing recipients.

78.37(5) *Nursing care services.* Nursing care services are services provided by licensed agency nurses to clients in the home which are ordered by and included in the plan of treatment established by the physician. The services are reasonable and necessary to the treatment of an illness or injury and include: observation; evaluation; teaching; training; supervision; therapeutic exercise; bowel and bladder care; administration of medications; intravenous, hypodermoclysis, and enteral feedings; skin care; preparation of clinical and progress notes; coordination of services and informing the physician and other personnel of changes in the patient's condition and needs.

A unit of service is one visit. Nursing care service can pay for a maximum of eight nursing visits per month for intermediate level of care persons. There is no limit on the maximum visits for skilled level of care persons.

78.37(6) *Respite care services.* Respite care services are services provided to the consumer that give temporary relief to the usual caregiver and provide all the necessary care that the usual caregiver would provide during that time period. The purpose of respite care is to enable the consumer to remain in the consumer's current living situation.

a. Services provided outside the consumer's home shall not be reimbursable if the living unit where respite is provided is reserved for another person on a temporary leave of absence.

b. Staff-to-consumer ratios shall be appropriate to the individual needs of the consumer as determined by the consumer's interdisciplinary team.

c. A unit of service is one hour.

d. The interdisciplinary team shall determine if the consumer will receive basic individual respite, specialized respite or group respite as defined in rule 441—83.21(249A).

e. When respite care is provided, the provision of, or payment for, other duplicative services under the waiver is precluded.

f. A maximum of 14 consecutive days of 24-hour respite care may be reimbursed.

g. Respite services provided for a period exceeding 24 consecutive hours to three or more individuals who require nursing care because of a mental or physical condition must be provided by a health care facility licensed as described in Iowa Code chapter 135C.

h. Respite care is not to be provided to persons during the hours in which the usual caregiver is employed except when the consumer is attending a camp. Respite cannot be provided to a consumer whose usual caregiver is a consumer-directed attendant care provider for the consumer.

78.37(7) *Chore services.* Chore services include the following services: window and door maintenance, such as hanging screen windows and doors, replacing windowpanes, and washing windows; minor repairs to walls, floors, stairs, railings and handles; heavy cleaning which includes cleaning attics or basements to remove fire hazards, moving heavy furniture, extensive wall washing,

floor care or painting and trash removal; and yard work such as mowing lawns, raking leaves and shoveling walks. A unit of service is one-half hour.

78.37(8) *Home-delivered meals.* Home-delivered meals means meals prepared elsewhere and delivered to a waiver recipient at the recipient's residence. Each meal shall ensure the recipient receives a minimum of one-third of the daily recommended dietary allowance as established by the Food and Nutrition Board of the National Research Council of the National Academy of Sciences. The meal may also be a liquid supplement which meets the minimum one-third standard. When a restaurant provides the home-delivered meal, the recipient is required to have a nutritional consultation. The nutritional consultation includes contact with the restaurant to explain the dietary needs of the client and explain what constitutes the minimum one-third daily dietary allowance.

A maximum of 14 meals is allowed per week. A unit of service is a meal.

78.37(9) *Home and vehicle modification.* Covered home and vehicle modifications are those physical modifications to the consumer's home or vehicle listed below that directly address the consumer's medical or remedial need. Covered modifications must be necessary to provide for the health, welfare, or safety of the consumer and enable the consumer to function with greater independence in the home or vehicle.

a. Modifications that are necessary or desirable without regard to the consumer's medical or remedial need and that would be expected to increase the fair market value of the home or vehicle, such as furnaces, fencing, roof repair, or adding square footage to the residence, are excluded except as specifically included below. Repairs are also excluded.

b. Only the following modifications are covered:

(1) Kitchen counters, sink space, cabinets, special adaptations to refrigerators, stoves, and ovens.

(2) Bathtubs and toilets to accommodate transfer, special handles and hoses for shower heads, water faucet controls, and accessible showers and sink areas.

(3) Grab bars and handrails.

(4) Turnaround space adaptations.

(5) Ramps, lifts, and door, hall and window widening.

(6) Fire safety alarm equipment specific for disability.

(7) Voice-activated, sound-activated, light-activated, motion-activated, and electronic devices directly related to the consumer's disability.

(8) Vehicle lifts, driver-specific adaptations, remote-start systems, including such modifications already installed in a vehicle.

(9) Keyless entry systems.

(10) Automatic opening device for home or vehicle door.

(11) Special door and window locks.

(12) Specialized doorknobs and handles.

(13) Plexiglas replacement for glass windows.

(14) Modification of existing stairs to widen, lower, raise or enclose open stairs.

(15) Motion detectors.

(16) Low-pile carpeting or slip-resistant flooring.

(17) Telecommunications device for the deaf.

(18) Exterior hard-surface pathways.

(19) New door opening.

(20) Pocket doors.

(21) Installation or relocation of controls, outlets, switches.

(22) Air conditioning and air filtering if medically necessary.

(23) Heightening of existing garage door opening to accommodate modified van.

(24) Bath chairs.

c. A unit of service is the completion of needed modifications or adaptations.

d. All modifications and adaptations shall be provided in accordance with applicable federal, state, and local building and vehicle codes.

e. Services shall be performed following department approval of a binding contract between the enrolled home and vehicle modification provider and the consumer.

f. The contract shall include, at a minimum, the work to be performed, cost, time frame for work completion, and assurance of liability and workers' compensation coverage.

g. Service payment shall be made to the enrolled home and vehicle modification provider. If applicable, payment will be forwarded to the subcontracting agency by the enrolled home and vehicle modification provider following completion of the approved modifications.

h. Services shall be included in the consumer's service plan and shall exceed the Medicaid state plan services.

78.37(10) *Mental health outreach.* Mental health outreach services are services provided in a recipient's home to identify, evaluate, and provide treatment and psychosocial support. The services can only be provided on the basis of a referral from the consumer's interdisciplinary team established pursuant to 441—subrule 83.22(2). A unit of service is 15 minutes.

78.37(11) *Transportation.* Transportation services may be provided for recipients to conduct business errands, essential shopping, to receive medical services not reimbursed through medical transportation, and to reduce social isolation. A unit of service is per mile, per trip, or rate established by area agency on aging.

78.37(12) *Nutritional counseling.* Nutritional counseling services may be provided for a nutritional problem or condition of such a degree of severity that nutritional counseling beyond that normally expected as part of the standard medical management is warranted. A unit of service is 15 minutes.

78.37(13) *Assistive devices.* Assistive devices means practical equipment products to assist persons with activities of daily living and instrumental activities of daily living to allow the person more independence. They include, but are not limited to: long-reach brush, extra long shoehorn, nonslip grippers to pick up and reach items, dressing aids, shampoo rinse tray and inflatable shampoo tray, double-handled cup and sipper lid. A unit is an item.

78.37(14) *Senior companion.* Senior companion services are nonmedical care supervision, oversight, and respite. Companions may assist with such tasks as meal preparation, laundry, shopping and light housekeeping tasks. This service cannot provide hands-on nursing or medical care. A unit of service is one hour.

78.37(15) *Consumer-directed attendant care service.* Consumer-directed attendant care services are service activities performed by a person to help a consumer with self-care tasks which the consumer would typically do independently if the consumer were otherwise able.

a. The service activities may include helping the consumer with any of the following nonskilled service activities:

(1) Dressing.

(2) Bath, shampoo, hygiene, and grooming.

(3) Access to and from bed or a wheelchair, transferring, ambulation, and mobility in general. It is recommended that the provider receive certification of training and return demonstration for transferring. Certification for this is available through the area community colleges.

(4) Toilet assistance, including bowel, bladder, and catheter assistance. It is recommended that the provider receive certification of training and return demonstration for catheter assistance. Certification for this is available through the area community colleges.

(5) Meal preparation, cooking, eating and feeding but not the cost of meals themselves.

(6) Housekeeping services which are essential to the consumer's health care at home.

(7) Medications ordinarily self-administered including those ordered by a physician or other qualified health care provider. It is recommended the provider successfully complete a medication aide course administered by an area community college.

(8) Wound care.

(9) Assistance needed to go to or return from a place of employment and assistance with job-related tasks while the consumer is on the job site. The cost of transportation for the consumer and assistance with understanding or performing the essential job functions are not included in consumer-directed attendant care services.

(10) Cognitive assistance with tasks such as handling money and scheduling.

(11) Fostering communication through interpreting and reading services as well as assistive devices for communication.

(12) Assisting or accompanying a consumer in using transportation essential to the health and welfare of the consumer. The cost of the transportation is not included.

b. The service activities may include helping the consumer with any of the following skilled services under the supervision of a licensed nurse or licensed therapist working under the direction of a physician. The licensed nurse or therapist shall retain accountability for actions that are delegated. The licensed nurse or therapist shall ensure appropriate assessment, planning, implementation, and evaluation. The licensed nurse or therapist shall make on-site supervisory visits every two weeks with the provider present. The cost of the supervision provided by the licensed nurse or therapist shall be paid from private insurance and other third-party payment sources, Medicare, the regular Medicaid program, or the early periodic screening diagnosis and treatment program before accessing the HCBS waiver.

(1) Tube feedings of consumers unable to eat solid foods.

(2) Intravenous therapy administered by a registered nurse.

(3) Parenteral injections required more than once a week.

(4) Catheterizations, continuing care of indwelling catheters with supervision of irrigations, and changing of Foley catheters when required.

(5) Respiratory care including inhalation therapy and tracheotomy care or tracheotomy care and ventilator.

(6) Care of decubiti and other ulcerated areas, noting and reporting to the nurse or therapist.

(7) Rehabilitation services including, but not limited to, bowel and bladder training, range of motion exercises, ambulation training, restorative nursing services, reteaching the activities of daily living, respiratory care and breathing programs, reality orientation, reminiscing therapy, remotivation, and behavior modification.

(8) Colostomy care.

(9) Care of medical conditions out of control which includes brittle diabetes and comfort care of terminal conditions.

(10) Postsurgical nursing care.

(11) Monitoring medications requiring close supervision because of fluctuating physical or psychological conditions, e.g., antihypertensives, digitalis preparations, mood-altering or psychotropic drugs, or narcotics.

(12) Preparing and monitoring response to therapeutic diets.

(13) Recording and reporting of changes in vital signs to the nurse or therapist.

c. A unit of service provided by an individual or an agency, other than an assisted living program, is 1 hour, or one 8- to 24-hour day. When provided by an assisted living program, a unit of service is one calendar month. If services are provided by an assisted living program for less than one full calendar month, the monthly reimbursement rate shall be prorated based on the number of days service is provided. Except for services provided by an assisted living program, each service shall be billed in whole units.

d. The consumer, parent, guardian, or attorney in fact under a durable power of attorney for health care shall be responsible for selecting the person or agency who will provide the components of the attendant care services to be provided.

e. The consumer, parent, guardian, or attorney in fact under a durable power of attorney for health care shall determine the components of the attendant care services to be provided with the person who is providing the services to the consumer.

f. The service activities may not include parenting or child care for or on behalf of the consumer.

g. The consumer, parent, guardian, or attorney in fact under a durable power of attorney for health care and the provider shall complete and sign Form 470-3372, HCBS Consumer-Directed Attendant Care Agreement. A copy of the completed agreement shall be attached to the service plan, which is signed by the service worker prior to the initiation of services, and kept in the consumer's and department's records.

h. If the consumer has a guardian or attorney in fact under a durable power of attorney for health care, the care plan shall address how consumer-directed attendant care services will be monitored to ensure the consumer's needs are being adequately met. If the guardian or attorney in fact is the service provider, the service plan shall address how the service worker or case manager shall oversee service provision.

i. If the consumer has a guardian or attorney in fact under a durable power of attorney for health care, the guardian or attorney in fact shall sign the claim form in place of the consumer, indicating that the service has been provided as presented on the claim.

j. The frequency or intensity of services shall be indicated in the service plan.

k. Consumer-directed attendant care services may not be simultaneously reimbursed with any other HCBS waiver services.

l. Consumer-directed attendant care services may be provided to a recipient of in-home health-related care services, but not at the same time.

m. Services may be provided in the absence of a parent or guardian if the parent or guardian has given advanced direction for the service provision.

78.37(16) *Consumer choices option.* The consumer choices option provides a consumer with a flexible monthly individual budget that is based on the consumer's service needs. With the individual budget, the consumer shall have the authority to purchase goods and services and may choose to employ providers of services and supports. Components of this service are set forth below.

a. Agreement. As a condition of participating in the consumer choices option, a consumer shall sign Form 470-4289, HCBS Consumer Choices Informed Consent and Risk Agreement, to document that the consumer has been informed of the responsibilities and risks of electing the consumer choices option.

b. Individual budget amount. A monthly individual budget amount shall be set for each consumer. The consumer's department service worker or Medicaid targeted case manager shall determine the amount of each consumer's individual budget, based on the services and supports authorized in the consumer's service plan. The consumer shall be informed of the individual budget amount during the development of the service plan.

(1) Services that may be included in determining the individual budget amount for a consumer in the HCBS elderly waiver are:

1. Assistive devices.
2. Chore service.
3. Consumer-directed attendant care (unskilled).
4. Home and vehicle modification.
5. Home-delivered meals.
6. Homemaker service.
7. Basic individual respite care.
8. Senior companion.
9. Transportation.

(2) The department shall determine an average unit cost for each service listed in subparagraph (1) based on actual unit costs from the previous fiscal year plus a cost-of-living adjustment.

(3) In aggregate, costs for individual budget services shall not exceed the current costs of waiver program services. In order to maintain cost neutrality, the department shall apply a utilization adjustment factor to the amount of service authorized in the consumer's service plan before calculating the value of that service to be included in the individual budget amount.

(4) The department shall compute the utilization adjustment factor for each service by dividing the net costs of all claims paid for the service by the total of the authorized costs for that service, using at least 12 consecutive months of aggregate service data. The utilization adjustment factor shall be no lower than 60 percent. The department shall analyze and adjust the utilization adjustment factor at least annually in order to maintain cost neutrality.

(5) Anticipated costs for home and vehicle modification are not subject to the average cost in subparagraph (2) or the utilization adjustment factor in subparagraph (3). Costs for home and vehicle modification may be released in a one-time payment.

(6) The individual budget amount may be changed only at the first of the month and shall remain fixed for the entire month.

c. Required service components. To participate in the consumer choices option, a consumer must hire an independent support broker and must work with a financial management service that is enrolled as a Medicaid HCBS elderly waiver services provider.

(1) Before hiring the individual support broker, the consumer shall receive the results of the background check conducted pursuant to 441—subrule 77.30(14).

(2) If the consumer chooses to hire a person who has a criminal record or founded abuse report, the consumer assumes the risk for this action and shall acknowledge this information on Form 470-4289, HCBS Consumer Choices Informed Consent and Risk Agreement.

d. Optional service components. A consumer who elects the consumer choices option may purchase the following services and supports, which shall be provided in the consumer's home or at an integrated community setting:

(1) Self-directed personal care services. Self-directed personal care services are services or goods that provide a range of assistance in activities of daily living and incidental activities of daily living that help the consumer remain in the home and community.

(2) Self-directed community supports and employment. Self-directed community supports and employment are services that support the consumer in developing and maintaining independence and community integration.

(3) Individual-directed goods and services. Individual-directed goods and services are services, equipment, or supplies not otherwise provided through the Medicaid program that address a need identified in the consumer's service plan. The item or service shall decrease the consumer's need for other Medicaid services, promote the consumer's inclusion in the community, or increase the consumer's safety in the community.

e. Development of the individual budget. The individual support broker shall assist the consumer in developing and implementing the consumer's individual budget. The individual budget shall include:

(1) The costs of the financial management service.

(2) The costs of the independent support broker. The independent support broker may be compensated for up to 6 hours of service for assisting with the implementation of the initial individual budget. After the initial implementation, the independent support broker shall not be paid for more than 20 hours of service during a 12-month period without prior approval by the department.

(3) The costs of any services and supports chosen by the consumer as described in paragraph *"d."*

f. Budget authority. The consumer shall have authority over the individual budget authorized by the department to perform the following tasks:

(1) Contract with entities to provide services and supports as described in this subrule.

(2) Determine the amount to be paid for services with the exception of the independent support broker and the financial management service. Reimbursement rates for the independent support broker and the financial management service are subject to the limits in 441—subrule 79.1(2).

(3) Schedule the provision of services.

(4) Authorize payment for waiver goods and services identified in the individual budget. Consumers shall not use the individual budget to purchase room and board, sheltered workshop services, child care, or personal entertainment items.

(5) Reallocate funds among services included in the budget.

g. Delegation of budget authority. The consumer may delegate responsibility for the individual budget to a representative in addition to the independent support broker.

(1) The representative must be at least 18 years old.

(2) The representative shall not be a current provider of service to the consumer.

(3) The consumer shall sign a consent form that designates who the consumer has chosen as a representative and what responsibilities the representative shall have.

(4) The representative shall not be paid for this service.

h. *Employer authority.* The consumer shall have the authority to be the common-law employer of employees providing services and support under the consumer choices option. A common-law employer has the right to direct and control the performance of the services. The consumer may perform the following functions:

(1) Recruit employees.
(2) Select employees from a worker registry.
(3) Verify employee qualifications.
(4) Specify additional employee qualifications.
(5) Determine employee duties.
(6) Determine employee wages and benefits.
(7) Schedule employees.
(8) Train and supervise employees.

i. *Employment agreement.* Any person employed by the consumer to provide services under the consumer choices option shall sign an employment agreement with the consumer that outlines the employee's and consumer's responsibilities.

j. *Responsibilities of the independent support broker.* The independent support broker shall perform the services specified in 78.34(13)*"j."*

k. *Responsibilities of the financial management service.* The financial management service shall perform all of the services specified in 78.34(13)*"k."*

78.37(17) *Case management services.* Case management services are services that assist Medicaid members who reside in a community setting or are transitioning to a community setting in gaining access to needed medical, social, educational, housing, transportation, vocational, and other appropriate services in order to ensure the health, safety, and welfare of the member. Case management is provided at the direction of the member and the interdisciplinary team established pursuant to 441—subrule 83.22(2).

a. Case management services shall be provided as set forth in rules 441—90.5(249A) and 441—90.8(249A).

b. Case management shall not include the provision of direct services by the case managers.

c. Payment for case management shall not be made until the consumer is enrolled in the waiver. Payment shall be made only for case management services performed on behalf of the consumer during a month when the consumer is enrolled.

This rule is intended to implement Iowa Code section 249A.4.

[**ARC 7957B**, IAB 7/15/09, effective 7/1/09]

441—78.38(249A) HCBS AIDS/HIV waiver services. Payment will be approved for the following services to clients eligible for the HCBS AIDS/HIV waiver services as established in 441—Chapter 83. Services must be billed in whole units.

78.38(1) *Counseling services.* Counseling services are face-to-face mental health services provided to the client and caregiver by a mental health professional as defined in rule 441—24.61(225C,230A) to facilitate home management of the client and prevent institutionalization. Counseling services are nonpsychiatric services necessary for the management of depression, assistance with the grief process, alleviation of psychosocial isolation and support in coping with a disability or illness, including terminal illness. Counseling services may be provided both for the purpose of training the client's family or other caregiver to provide care, and for the purpose of helping the client and those caring for the client to adjust to the client's disability or terminal condition. Counseling services may be provided to the client's caregiver only when included in the case plan for the client.

Payment will be made for individual and group counseling. A unit of individual counseling for the waiver client or the waiver client and the client's caregiver is 15 minutes. A unit of group counseling is one hour. Payment for group counseling is based on the group rate divided by six, or, if the number of persons who comprise the group exceeds six, the actual number of persons who comprise the group.

78.38(2) *Home health aide services.* Home health aide services are personal or direct care services provided to the client which are not payable under Medicaid as set forth in rule 441—78.9(249A). A unit of service is a visit. Components of the service are:

a. Observation and reporting of physical or emotional needs.

b. Helping a client with bath, shampoo, or oral hygiene.

c. Helping a client with toileting.

d. Helping a client in and out of bed and with ambulation.

e. Helping a client reestablish activities of daily living.

f. Assisting with oral medications ordinarily self-administered and ordered by a physician.

g. Performing incidental household services which are essential to the client's health care at home and are necessary to prevent or postpone institutionalization in order to complete a full unit of service.

78.38(3) *Homemaker services.* Homemaker services are those services provided when the client lives alone or when the person who usually performs these functions for the client needs assistance with performing the functions. A unit of service is one hour. Components of the service are directly related to the care of the client and are:

a. Essential shopping: shopping for basic need items such as food, clothing or personal care items, or drugs.

b. Limited housecleaning: maintenance cleaning such as vacuuming, dusting, scrubbing floors, defrosting refrigerators, cleaning stoves, cleaning medical equipment, washing and mending clothes, washing personal items used by the client, and dishes.

c. Accompaniment to medical or psychiatric services or for children aged 18 and under to school.

d. Meal preparation: planning and preparing balanced meals.

78.38(4) *Nursing care services.* Nursing care services are services provided by licensed agency nurses to clients in the home which are ordered by and included in the plan of treatment established by the physician. The services shall be reasonable and necessary to the treatment of an illness or injury and include: observation; evaluation; teaching; training; supervision; therapeutic exercise; bowel and bladder care; administration of medications; intravenous and enteral feedings; skin care; preparation of clinical and progress notes; coordination of services; and informing the physician and other personnel of changes in the patient's conditions and needs. A unit of service is a visit.

78.38(5) *Respite care services.* Respite care services are services provided to the consumer that give temporary relief to the usual caregiver and provide all the necessary care that the usual caregiver would provide during that time period. The purpose of respite care is to enable the consumer to remain in the consumer's current living situation.

a. Services provided outside the consumer's home shall not be reimbursable if the living unit where respite is provided is otherwise reserved for another person on a temporary leave of absence.

b. Staff-to-consumer ratios shall be appropriate to the individual needs of the consumer as determined by the consumer's interdisciplinary team.

c. A unit of service is one hour.

d. The interdisciplinary team shall determine if the consumer will receive basic individual respite, specialized respite or group respite as defined in rule 441—83.41(249A).

e. When respite care is provided, the provision of, or payment for, other duplicative services under the waiver is precluded.

f. A maximum of 14 consecutive days of 24-hour respite care may be reimbursed.

g. Respite services provided for a period exceeding 24 consecutive hours to three or more individuals who require nursing care because of a mental or physical condition must be provided by a health care facility licensed as described in Iowa Code chapter 135C.

h. Respite care is not to be provided to persons during the hours in which the usual caregiver is employed except when the consumer is attending a camp. Respite cannot be provided to a consumer whose usual caregiver is a consumer-directed attendant care provider for the consumer.

78.38(6) *Home-delivered meals.* Home-delivered meals means meals prepared elsewhere and delivered to a waiver recipient at the recipient's residence. Each meal shall ensure the recipient receives a minimum of one-third of the daily recommended dietary allowance as established by the Food and

Nutrition Board of the National Research Council of the National Academy of Sciences. The meal may also be a liquid supplement which meets the minimum one-third standard. A maximum of 14 meals is allowed per week. A unit of service is a meal.

78.38(7) *Adult day care services.* Adult day care services provide an organized program of supportive care in a group environment to persons who need a degree of supervision and assistance on a regular or intermittent basis in a day care center. A unit of service is a half day (1 to 4 hours), a full day (4 to 8 hours), or an extended day (8 to 12 hours). Components of the service are as set forth in rule 441—171.6(234) or the department of elder affairs rule 321—24.7(231).

78.38(8) *Consumer-directed attendant care service.* Consumer-directed attendant care services are service activities performed by a person to help a consumer with self-care tasks which the consumer would typically do independently if the consumer were otherwise able.

a. The service activities may include helping the consumer with any of the following nonskilled service activities:

(1) Dressing.

(2) Bath, shampoo, hygiene, and grooming.

(3) Access to and from bed or a wheelchair, transferring, ambulation, and mobility in general. It is recommended that the provider receive certification of training and return demonstration for transferring. Certification for this is available through the area community colleges.

(4) Toilet assistance, including bowel, bladder, and catheter assistance. It is recommended that the provider receive certification of training and return demonstration for catheter assistance. Certification for this is available through the area community colleges.

(5) Meal preparation, cooking, eating and feeding but not the cost of meals themselves.

(6) Housekeeping services which are essential to the consumer's health care at home.

(7) Medications ordinarily self-administered including those ordered by a physician or other qualified health care provider. It is recommended the provider successfully complete a medication aide course administered by an area community college.

(8) Wound care.

(9) Assistance needed to go to or return from a place of employment and assistance with job-related tasks while the consumer is on the job site. The cost of transportation for the consumer and assistance with understanding or performing the essential job functions are not included in consumer-directed attendant care services.

(10) Cognitive assistance with tasks such as handling money and scheduling.

(11) Fostering communication through interpreting and reading services as well as assistive devices for communication.

(12) Assisting or accompanying a consumer in using transportation essential to the health and welfare of the consumer. The cost of the transportation is not included.

b. The service activities may include helping the consumer with any of the following skilled services under the supervision of a licensed nurse or licensed therapist working under the direction of a physician. The licensed nurse or therapist shall retain accountability for actions that are delegated. The licensed nurse or therapist shall ensure appropriate assessment, planning, implementation, and evaluation. The licensed nurse or therapist shall make on-site supervisory visits every two weeks with the provider present. The cost of the supervision provided by the licensed nurse or therapist shall be paid from private insurance and other third-party payment sources, Medicare, the regular Medicaid program, or the early periodic screening diagnosis and treatment program before accessing the HCBS waiver.

(1) Tube feedings of consumers unable to eat solid foods.

(2) Intravenous therapy administered by a registered nurse.

(3) Parenteral injections required more than once a week.

(4) Catheterizations, continuing care of indwelling catheters with supervision of irrigations, and changing of Foley catheters when required.

(5) Respiratory care including inhalation therapy and tracheotomy care or tracheotomy care and ventilator.

(6) Care of decubiti and other ulcerated areas, noting and reporting to the nurse or therapist.

(7) Rehabilitation services including, but not limited to, bowel and bladder training, range of motion exercises, ambulation training, restorative nursing services, reteaching the activities of daily living, respiratory care and breathing programs, reality orientation, reminiscing therapy, remotivation, and behavior modification.

(8) Colostomy care.

(9) Care of medical conditions out of control which includes brittle diabetes and comfort care of terminal conditions.

(10) Postsurgical nursing care.

(11) Monitoring medications requiring close supervision because of fluctuating physical or psychological conditions, e.g., antihypertensives, digitalis preparations, mood-altering or psychotropic drugs, or narcotics.

(12) Preparing and monitoring response to therapeutic diets.

(13) Recording and reporting of changes in vital signs to the nurse or therapist.

c. A unit of service is 1 hour, or one 8- to 24-hour day provided by an individual or an agency. Each service shall be billed in whole units.

d. The consumer, parent, guardian, or attorney in fact under a durable power of attorney for health care shall be responsible for selecting the person or agency who will provide the components of the attendant care services to be provided.

e. The consumer, parent, guardian, or attorney in fact under a durable power of attorney for health care shall determine the components of the attendant care services to be provided with the person who is providing the services to the consumer.

f. The service activities may not include parenting or child care for or on behalf of the consumer.

g. The consumer, parent, guardian, or attorney in fact under a durable power of attorney for health care and the provider shall complete and sign Form 470-3372, HCBS Consumer-Directed Attendant Care Agreement. A copy of the completed agreement shall be attached to the service plan, which is signed by the service worker prior to the initiation of services, and kept in the consumer's and department's records.

h. If the consumer has a guardian or attorney in fact under a durable power of attorney for health care, the care plan shall address how consumer-directed attendant care services will be monitored to ensure the consumer's needs are being adequately met. If the guardian or attorney in fact is the service provider, the service plan shall address how the service worker or case manager shall oversee service provision.

i. If the consumer has a guardian or attorney in fact under a durable power of attorney for health care, the guardian or attorney in fact shall sign the claim form in place of the consumer, indicating that the service has been provided as presented on the claim.

j. The frequency or intensity of services shall be indicated in the service plan.

k. Consumer-directed attendant care services may not be simultaneously reimbursed with any other HCBS waiver services.

l. Consumer-directed attendant care services may be provided to a recipient of in-home health-related care services, but not at the same time.

m. Services may be provided in the absence of a parent or guardian if the parent or guardian has given advanced direction for the service provision.

78.38(9) *Consumer choices option.* The consumer choices option provides a consumer with a flexible monthly individual budget that is based on the consumer's service needs. With the individual budget, the consumer shall have the authority to purchase goods and services and may choose to employ providers of services and supports. Components of this service are set forth below.

a. Agreement. As a condition of participating in the consumer choices option, a consumer shall sign Form 470-4289, HCBS Consumer Choices Informed Consent and Risk Agreement, to document that the consumer has been informed of the responsibilities and risks of electing the consumer choices option.

b. Individual budget amount. A monthly individual budget amount shall be set for each consumer. The consumer's department service worker or Medicaid targeted case manager shall determine the

amount of each consumer's individual budget, based on the services and supports authorized in the consumer's service plan. The consumer shall be informed of the individual budget amount during the development of the service plan.

(1) Services that may be included in determining the individual budget amount for a consumer in the HCBS AIDS/HIV waiver are:

1. Consumer-directed attendant care (unskilled).
2. Home-delivered meals.
3. Homemaker service.
4. Basic individual respite care.

(2) The department shall determine an average unit cost for each service listed in subparagraph (1) based on actual unit costs from the previous fiscal year plus a cost-of-living adjustment.

(3) In aggregate, costs for individual budget services shall not exceed the current costs of waiver program services. In order to maintain cost neutrality, the department shall apply a utilization adjustment factor to the amount of service authorized in the consumer's service plan before calculating the value of that service to be included in the individual budget amount.

(4) The department shall compute the utilization adjustment factor for each service by dividing the net costs of all claims paid for the service by the total of the authorized costs for that service, using at least 12 consecutive months of aggregate service data. The utilization adjustment factor shall be no lower than 60 percent. The department shall analyze and adjust the utilization adjustment factor at least annually in order to maintain cost neutrality.

(5) The individual budget amount may be changed only at the first of the month and shall remain fixed for the entire month.

c. Required service components. To participate in the consumer choices option, a consumer must hire an independent support broker and must work with a financial management service that is enrolled as a Medicaid HCBS AIDS/HIV waiver services provider.

(1) Before hiring the individual support broker, the consumer shall receive the results of the background check conducted pursuant to 441—subrule 77.30(14).

(2) If the consumer chooses to hire a person who has a criminal record or founded abuse report, the consumer assumes the risk for this action and shall acknowledge this information on Form 470-4289, HCBS Consumer Choices Informed Consent and Risk Agreement.

d. Optional service components. A consumer who elects the consumer choices option may purchase the following services and supports, which shall be provided in the consumer's home or at an integrated community setting:

(1) Self-directed personal care services. Self-directed personal care services are services or goods that provide a range of assistance in activities of daily living and incidental activities of daily living that help the consumer remain in the home and community.

(2) Self-directed community supports and employment. Self-directed community supports and employment are services that support the consumer in developing and maintaining independence and community integration.

(3) Individual-directed goods and services. Individual-directed goods and services are services, equipment, or supplies not otherwise provided through the Medicaid program that address a need identified in the consumer's service plan. The item or service shall decrease the consumer's need for other Medicaid services, promote the consumer's inclusion in the community, or increase the consumer's safety in the community.

e. Development of the individual budget. The individual support broker shall assist the consumer in developing and implementing the consumer's individual budget. The individual budget shall include:

(1) The costs of the financial management service.

(2) The costs of the independent support broker. The independent support broker may be compensated for up to 6 hours of service for assisting with the implementation of the initial individual budget. After the initial implementation, the independent support broker shall not be paid for more than 20 hours of service during a 12-month period without prior approval by the department.

(3) The costs of any services and supports chosen by the consumer as described in paragraph *"d."*

f. *Budget authority.* The consumer shall have authority over the individual budget authorized by the department to perform the following tasks:

(1) Contract with entities to provide services and supports as described in this subrule.

(2) Determine the amount to be paid for services with the exception of the independent support broker and the financial management service. Reimbursement rates for the independent support broker and the financial management service are subject to the limits in 441—subrule 79.1(2).

(3) Schedule the provision of services.

(4) Authorize payment for waiver goods and services identified in the individual budget. Consumers shall not use the individual budget to purchase room and board, sheltered workshop services, child care, or personal entertainment items.

(5) Reallocate funds among services included in the budget.

g. *Delegation of budget authority.* The consumer may delegate responsibility for the individual budget to a representative in addition to the independent support broker.

(1) The representative must be at least 18 years old.

(2) The representative shall not be a current provider of service to the consumer.

(3) The consumer shall sign a consent form that designates who the consumer has chosen as a representative and what responsibilities the representative shall have.

(4) The representative shall not be paid for this service.

h. *Employer authority.* The consumer shall have the authority to be the common-law employer of employees providing services and support under the consumer choices option. A common-law employer has the right to direct and control the performance of the services. The consumer may perform the following functions:

(1) Recruit employees.

(2) Select employees from a worker registry.

(3) Verify employee qualifications.

(4) Specify additional employee qualifications.

(5) Determine employee duties.

(6) Determine employee wages and benefits.

(7) Schedule employees.

(8) Train and supervise employees.

i. *Employment agreement.* Any person employed by the consumer to provide services under the consumer choices option shall sign an employment agreement with the consumer that outlines the employee's and consumer's responsibilities.

j. *Responsibilities of the independent support broker.* The independent support broker shall perform the services specified in 78.34(13)*"j."*

k. *Responsibilities of the financial management service.* The financial management service shall perform all of the services specified in 78.34(13)*"k."*

This rule is intended to implement Iowa Code section 249A.4.

441—78.39(249A) Federally qualified health centers. Payment shall be made for services as defined in Section 1905(a)(2)(C) of the Social Security Act.

78.39(1) *Utilization review.* Utilization review shall be conducted of Medicaid members who access more than 24 outpatient visits in any 12-month period from physicians, advanced registered nurse practitioners, federally qualified health centers, other clinics, and emergency rooms. Refer to rule 441—76.9(249A) for further information concerning the member lock-in program.

78.39(2) *Risk assessment.* Risk assessment, using Form 470-2942, Medicaid Prenatal Risk Assessment, shall be completed at the initial visit during a Medicaid member's pregnancy.

a. If the risk assessment reflects a low-risk pregnancy, the assessment shall be completed again at approximately the twenty-eighth week of pregnancy.

b. If the risk assessment reflects a high-risk pregnancy, referral shall be made for enhanced services. (See description of enhanced services at subrule 78.25(3).)

78.39(3) *Vaccines.* Vaccines available through the Vaccines for Children program under Section 1928 of the Social Security Act are not covered services. Federally qualified health centers that wish to administer those vaccines to Medicaid members shall enroll in the Vaccines for Children program and obtain the vaccines from the department of public health. However, vaccine administration is a covered service.

This rule is intended to implement Iowa Code section 249A.4.

441—78.40(249A) Advanced registered nurse practitioners. Payment shall be approved for services provided by advanced registered nurse practitioners within their scope of practice and the limitations of state law, with the exception of services not payable to physicians under rule 441—78.1(249A) or otherwise not payable under any other applicable rule.

78.40(1) *Direct payment.* Payment shall be made to advanced registered nurse practitioners directly, without regard to whether the advanced registered nurse practitioner is employed by or associated with a physician, hospital, birth center, clinic or other health care provider recognized under state law. An established protocol between a physician and the advanced registered nurse practitioner shall not cause an advanced registered nurse practitioner to be considered auxiliary personnel of a physician, or an employee of a hospital, birth center, or clinic.

78.40(2) *Location of service.* Payment shall be approved for services rendered in any location in which the advanced registered nurse practitioner is legally authorized to provide services under state law. The nurse practitioner shall have promptly available the necessary equipment and personnel to handle emergencies.

78.40(3) *Utilization review.* Utilization review shall be conducted of Medicaid members who access more than 24 outpatient visits in any 12-month period from physicians, advanced registered nurse practitioners, other clinics, and emergency rooms. Refer to rule 441—76.9(249A) for further information concerning the member lock-in program.

78.40(4) *Vaccine administration.* Vaccines available through the Vaccines for Children program under Section 1928 of the Social Security Act are not covered services. Advanced registered nurse practitioners who wish to administer those vaccines to Medicaid members shall enroll in the Vaccines for Children program and obtain the vaccines from the department of public health. Advanced registered nurse practitioners shall receive reimbursement for the administration of vaccines to Medicaid members.

78.40(5) *Prenatal risk assessment.* Risk assessment, using Form 470-2942, Medicaid Prenatal Risk Assessment, shall be completed at the initial visit during a Medicaid member's pregnancy.

a. If the risk assessment reflects a low-risk pregnancy, the assessment shall be completed again at approximately the twenty-eighth week of pregnancy.

b. If the risk assessment reflects a high-risk pregnancy, referral shall be made for enhanced services. (See description of enhanced services at subrule 78.25(3).)

This rule is intended to implement Iowa Code section 249A.4.

441—78.41(249A) HCBS MR waiver services. Payment will be approved for the following services to consumers eligible for the HCBS MR waiver services as established in 441—Chapter 83 and as identified in the consumer's service plan. All services include the applicable and necessary instruction, supervision, assistance and support as required by the consumer in achieving the consumer's life goals. The services, amount and supports provided under the HCBS MR waiver shall be delivered in the least restrictive environment and in conformity with the consumer's service plan.

Reimbursement shall not be available under the waiver for any services that the consumer can obtain through the Medicaid state plan.

All services shall be billed in whole units.

78.41(1) *Supported community living services.* Supported community living services are provided by the provider within the consumer's home and community, according to the individualized consumer need as identified in the service plan pursuant to rule 441—83.67(249A).

a. Available components of the service are personal and home skills training services, individual advocacy services, community skills training services, personal environment support services, transportation, and treatment services.

(1) Personal and home skills training services are those activities which assist a consumer to develop or maintain skills for self-care, self-directedness, and care of the immediate environment.

(2) "Individual advocacy services" means the act or process of representing the individual's rights and interests in order to realize the rights to which the individual is entitled and to remove barriers to meeting the individual's needs.

(3) "Community skills training services" means activities which assist a person to develop or maintain skills allowing better participation in the community. Services shall focus on the following areas as they are applicable to individuals being served:

1. Personal management skills training services are activities which assist a person to maintain or develop skills necessary to sustain oneself in the physical environment and are essential to the management of one's personal business and property. This includes self-advocacy skills. Examples of personal management skills are the ability to maintain a household budget; plan and prepare nutritional meals; ability to use community resources such as public transportation, libraries, etc., and ability to select foods at the grocery store.

2. Socialization skills training services are those activities which assist a consumer to develop or maintain skills which include self-awareness and self-control, social responsiveness, community participation, social amenities, and interpersonal skills.

3. Communication skills training services are activities which assist a person to develop or maintain skills including expressive and receptive skills in verbal and nonverbal language and the functional application of acquired reading and writing skills.

(4) "Personal and environmental support services" means activities and expenditures provided to or on behalf of a person in the areas of personal needs in order to allow the person to function in the least restrictive environment.

(5) "Transportation services" means activities and expenditures designed to assist the person to travel from one place to another to obtain services or carry out life's activities. The service excludes transportation to and from work.

(6) "Treatment services" means activities designed to assist the person to maintain or improve physiological, emotional and behavioral functioning and to prevent conditions that would present barriers to a person's functioning. Treatment services include physical or physiological treatment and psychotherapeutic treatment.

1. Physiological treatment means activities including medication regimens designed to prevent, halt, control, relieve, or reverse symptoms or conditions which interfere with the normal functioning of the human body. The activities shall be provided by or under the supervision of a health care professional certified or licensed to provide the treatment activity specified.

2. Psychotherapeutic treatment means activities provided to assist a person in the identification or modification of beliefs, emotions, attitudes, or behaviors in order to maintain or improve the person's functioning in response to the physical, emotional, and social environment.

b. The supported community living services are intended to provide for the daily living needs of the consumer and shall be available as needed during any 24-hour period. Activities do not include those associated with vocational services, academics, day care, medical services, Medicaid case management or other case management. Services are individualized supportive services provided in a variety of community-based, integrated settings.

(1) Supported community living services shall be available at a daily rate to consumers living outside the home of their family, legal representative, or foster family and for whom a provider has primary responsibility for supervision or structure during the month. This service will provide supervision or structure in identified time periods when another resource is not available.

(2) Supported community living services shall be available at an hourly rate to consumers for whom a daily rate is not established.

c. Services may be provided to a child or an adult. A maximum of three consumers receiving community-supported alternative living arrangements or HCBS MR services may reside in a living unit except providers meeting requirements set forth in 441—paragraph 77.37(14)*"e."*

(1) Consumers may live within the home of their family or legal representative or within other types of typical community living arrangements.

(2) Consumers of services living with families or legal representatives are not subject to the maximum of three consumers in a living unit.

(3) Consumers may not live in licensed medical or health care facilities or in settings required to be licensed as medical or health care facilities.

(4) Consumers aged 17 or under living within the home of their family, legal representative, or foster families shall receive services based on development of adaptive, behavior, or health skills. Duration of services shall be based on age appropriateness and individual attention span.

d. Rescinded IAB 2/5/03, effective 2/1/03.

e. Transportation to and from a day program is not a reimbursable service. Maintenance and room and board costs are not reimbursable.

f. Provider budgets shall reflect all staff-to-consumer ratios and shall reflect costs associated with consumers' specific support needs for travel and transportation, consulting, instruction, and environmental modifications and repairs, as determined necessary by the interdisciplinary team for each consumer. The specific support needs must be identified in the Medicaid case manager's service plan, the total costs shall not exceed $1570 per consumer per year, and the provider must maintain records to support the expenditures. A unit of service is:

(1) One full calendar day when a consumer residing in the living unit receives on-site staff supervision for 14 or more hours per day as an average over a 7-day week and the consumer's individual comprehensive plan or case plan identifies and reflects the need for this amount of supervision.

(2) One hour when subparagraph (1) does not apply.

g. The maximum number of units available per consumer is as follows:

(1) 365 daily units per state fiscal year except a leap year when 366 daily units are available.

(2) 5,110 hourly units are available per state fiscal year except a leap year when 5,124 hourly units are available.

h. The service shall be identified in the consumer's individual comprehensive plan.

i. Services shall not be simultaneously reimbursed with other residential services, HCBS MR respite, Medicaid or HCBS MR nursing, or Medicaid or HCBS MR home health aide services.

78.41(2) *Respite services.* Respite care services are services provided to the consumer that give temporary relief to the usual caregiver and provide all the necessary care that the usual caregiver would provide during that time period. The purpose of respite care is to enable the consumer to remain in the consumer's current living situation.

a. Services provided outside the consumer's home shall not be reimbursable if the living unit where the respite is provided is reserved for another person on a temporary leave of absence.

b. Staff-to-consumer ratios shall be appropriate to the individual needs of the consumer as determined by the consumer's interdisciplinary team.

c. A unit of service is one hour.

d. Payment for respite services shall not exceed $7,050 per the consumer's waiver year.

e. The service shall be identified in the consumer's individual comprehensive plan.

f. Respite services shall not be simultaneously reimbursed with other residential or respite services, HCBS MR waiver supported community living services, Medicaid or HCBS MR nursing, or Medicaid or HCBS MR home health aide services.

g. Respite care is not to be provided to persons during the hours in which the usual caregiver is employed except when the consumer is attending a camp. Respite cannot be provided to a consumer whose usual caregiver is a consumer-directed attendant care provider for the consumer.

h. The interdisciplinary team shall determine if the consumer will receive basic individual respite, specialized respite or group respite as defined in rule 441—83.60(249A).

i. A maximum of 14 consecutive days of 24-hour respite care may be reimbursed.

j. Respite services provided for a period exceeding 24 consecutive hours to three or more individuals who require nursing care because of a mental or physical condition must be provided by a health care facility licensed as described in Iowa Code chapter 135C.

78.41(3) *Personal emergency response system.* The personal emergency response system is an electronic component that transmits a coded signal via digital equipment to a central monitoring station. The electronic device allows a person to access assistance in the event of an emergency when alone.

a. The necessary components of the system are:

(1) An in-home medical communications transceiver.

(2) A remote, portable activator.

(3) A central monitoring station with backup systems staffed by trained attendants 24 hours per day, seven days per week.

(4) Current data files at the central monitoring station containing response protocols and personal, medical and emergency information for each consumer.

b. The service shall be identified in the consumer's individual comprehensive plan.

c. A unit is a one-time installation fee or one month of service.

d. Maximum units per state fiscal year are the initial installation and 12 months of service.

78.41(4) *Home and vehicle modifications.* Covered home and vehicle modifications are those physical modifications to the consumer's home or vehicle listed below that directly address the consumer's medical or remedial need. Covered modifications must be necessary to provide for the health, welfare, or safety of the consumer and enable the consumer to function with greater independence in the home or vehicle.

a. Modifications that are necessary or desirable without regard to the consumer's medical or remedial need and that would be expected to increase the fair market value of the home or vehicle, such as furnaces, fencing, roof repair, or adding square footage to the residence, are excluded except as specifically included below. Repairs are also excluded.

b. Only the following modifications are covered:

(1) Kitchen counters, sink space, cabinets, special adaptations to refrigerators, stoves, and ovens.

(2) Bathtubs and toilets to accommodate transfer, special handles and hoses for shower heads, water faucet controls, and accessible showers and sink areas.

(3) Grab bars and handrails.

(4) Turnaround space adaptations.

(5) Ramps, lifts, and door, hall and window widening.

(6) Fire safety alarm equipment specific for disability.

(7) Voice-activated, sound-activated, light-activated, motion-activated, and electronic devices directly related to the consumer's disability.

(8) Vehicle lifts, driver-specific adaptations, remote-start systems, including such modifications already installed in a vehicle.

(9) Keyless entry systems.

(10) Automatic opening device for home or vehicle door.

(11) Special door and window locks.

(12) Specialized doorknobs and handles.

(13) Plexiglas replacement for glass windows.

(14) Modification of existing stairs to widen, lower, raise or enclose open stairs.

(15) Motion detectors.

(16) Low-pile carpeting or slip-resistant flooring.

(17) Telecommunications device for the deaf.

(18) Exterior hard-surface pathways.

(19) New door opening.

(20) Pocket doors.

(21) Installation or relocation of controls, outlets, switches.

(22) Air conditioning and air filtering if medically necessary.

(23) Heightening of existing garage door opening to accommodate modified van.

(24) Bath chairs.

c. A unit of service is the completion of needed modifications or adaptations.

d. All modifications and adaptations shall be provided in accordance with applicable federal, state, and local building and vehicle codes.

e. Services shall be performed following department approval of a binding contract between the enrolled home and vehicle modification provider and the consumer.

f. The contract shall include, at a minimum, the work to be performed, cost, time frame for work completion, and assurance of liability and workers' compensation coverage.

g. Service payment shall be made to the enrolled home and vehicle modification provider. If applicable, payment will be forwarded to the subcontracting agency by the enrolled home and vehicle modification provider following completion of the approved modifications.

h. Services shall be included in the consumer's service plan and shall exceed the Medicaid state plan services.

78.41(5) *Nursing services.* Nursing services are individualized in-home medical services provided by licensed nurses. Services shall exceed the Medicaid state plan services and be included in the consumer's individual comprehensive plan.

a. A unit of service is one hour.

b. A maximum of ten units are available per week.

78.41(6) *Home health aide services.* Home health aide services are personal or direct care services provided to the consumer which are not payable under Medicaid as set forth in rule 441—78.9(249A). Services shall include unskilled medical services and shall exceed those services provided under HCBS MR supported community living. Instruction, supervision, support or assistance in personal hygiene, bathing, and daily living shall be provided under supported community living.

a. Services shall be included in the consumer's individual comprehensive plan.

b. A unit is one hour.

c. A maximum of 14 units are available per week.

78.41(7) *Supported employment services.* Supported employment services are individualized services associated with obtaining and maintaining competitive paid employment in the least restrictive environment possible, provided to individuals for whom competitive employment at or above minimum wage is unlikely and who, because of their disability, need intense and ongoing support to perform in a work setting. Individual placements are the preferred service model. Covered services are those listed in paragraphs *"a"* and *"b"* that address the disability-related challenges to securing and keeping a job.

a. *Activities to obtain a job.* Covered services directed to obtaining a job must be provided to or on behalf of a consumer for whom competitive employment is reasonably expected within less than one year. Services must be focused on job placement, not on teaching generalized employment skills or habilitative goals. Three conditions must be met before services are provided. First, the consumer and the interdisciplinary team described in 441—subrule 83.67(1) must complete the form that Iowa vocational rehabilitation services uses to identify the supported employment services appropriate to meet a person's employment needs. Second, the consumer's interdisciplinary team must determine that the identified services are necessary. Third, the consumer's case manager must approve the services. Available components of activities to obtain a job are as follows:

(1) Job development services. Job development services are directed toward obtaining competitive employment. A unit of service is a job placement that the consumer holds for 30 consecutive calendar days or more. Payment is available once the service is authorized in the member's service plan. A consumer may receive two units of job development services during a 12-month period. The activities provided to the consumer may include:

1. Job procurement training, including grooming and hygiene, application, résumé development, interviewing skills, follow-up letters, and job search activities.

2. Job retention training, including promptness, coworker relations, transportation skills, disability-related supports, job benefits, and an understanding of employee rights and self-advocacy.

3. Customized job development services specific to the consumer.

(2) Employer development services. The focus of employer development services is to support employers in hiring and retaining consumers in their workforce and to communicate expectations of the employers to the interdisciplinary team described in 441—subrule 83.67(1). Employer development services may be provided only to consumers who are reasonably expected to work for no more than 10 hours per week. A unit of service is one job placement that the consumer holds for 30 consecutive calendar days or more. Payment for this service may be made only after the consumer holds the job for 30 days. A consumer may receive two units of employer development services during a 12-month period if the consumer is competitively employed for 30 or more consecutive calendar days and the other conditions for service approval are met. The services provided may include:

1. Developing relationships with employers and providing leads for individual consumers when appropriate.
2. Job analysis for a specific job.
3. Development of a customized training plan identifying job-specific skill requirements, employer expectations, teaching strategies, time frames, and responsibilities.
4. Identifying and arranging reasonable accommodations with the employer.
5. Providing disability awareness and training to the employer when it is deemed necessary.
6. Providing technical assistance to the employer regarding the training progress as identified on the consumer's customized training plan.

(3) Enhanced job search activities. Enhanced job search activities are associated with obtaining initial employment after job development services have been provided for a minimum of 30 days or with assisting the consumer in changing jobs due to layoff, termination, or personal choice. The interdisciplinary team must review and update the Iowa vocational rehabilitation services supported employment readiness analysis form to determine if this service remains appropriate for the consumer's employment goals. A unit of service is an hour. A maximum of 26 units may be provided in a 12-month period. The services provided may include:

1. Job opening identification with the consumer.
2. Assistance with applying for a job, including completion of applications or interviews.
3. Work site assessment and job accommodation evaluation.

b. Supports to maintain employment.

(1) Covered services provided to or on behalf of the consumer associated with maintaining competitive paid employment are the following:

1. Individual work-related behavioral management.
2. Job coaching.
3. On-the-job or work-related crisis intervention.
4. Assisting the consumer to use skills related to sustaining competitive paid employment, including assistance with communication skills, problem solving, and safety.
5. Consumer-directed attendant care services as defined in subrule 78.41(8).
6. Assistance with time management.
7. Assistance with appropriate grooming.
8. Employment-related supportive contacts.
9. Employment-related transportation between work and home and to or from activities related to employment and disability. Other forms of community transportation (including car pools, coworkers, self or public transportation, families, and volunteers) must be attempted before transportation is provided as a supported employment service.
10. On-site vocational assessment after employment.
11. Employer consultation.

(2) Services for maintaining employment may include services associated with sustaining consumers in a team of no more than eight individuals with disabilities in a teamwork or "enclave" setting.

(3) A unit of service is one hour.

(4) A maximum of 40 units may be received per week.

c. The following requirements apply to all supported employment services:

(1) Employment-related adaptations required to assist the consumer within the performance of the consumer's job functions shall be provided by the provider as part of the services.

(2) Employment-related transportation between work and home and to or from activities related to employment and disability shall be provided by the provider as part of the services. Other forms of community transportation (car pools, coworkers, self or public transportation, families, volunteers) must be attempted before the service provider provides transportation.

(3) The majority of coworkers at any employment site with more than two employees where consumers seek, obtain, or maintain employment must be persons without disabilities. In the performance of job duties at any site where consumers seek, obtain, or maintain employment, the consumer must have daily contact with other employees or members of the general public who do not have disabilities, unless the absence of daily contact with other employees or the general public is typical for the job as performed by persons without disabilities.

(4) All supported employment services shall provide individualized and ongoing support contacts at intervals necessary to promote successful job retention. Each provider contact shall be documented.

(5) Documentation that services provided are not currently available under a program funded under the Rehabilitation Act of 1973 or Public Law 94-142 shall be maintained in the provider file of each consumer.

(6) All services shall be identified in the consumer's service plan maintained pursuant to rule 441—83.67(249A).

(7) The following services are not covered:

1. Services involved in placing or maintaining consumers in day activity programs, work activity programs or sheltered workshop programs;
2. Supports for volunteer work or unpaid internships;
3. Tuition for education or vocational training; or
4. Individual advocacy that is not consumer specific.

(8) Services to maintain employment shall not be provided simultaneously with day activity programs, work activity programs, sheltered workshop programs, other HCBS services, or other Medicaid services. However, services to obtain a job and services to maintain employment may be provided simultaneously for the purpose of job advancement or job change.

78.41(8) *Consumer-directed attendant care service.* Consumer-directed attendant care services are service activities performed by a person to help a consumer with self-care tasks which the consumer would typically do independently if the consumer were otherwise able.

a. The service activities may include helping the consumer with any of the following nonskilled service activities:

(1) Dressing.

(2) Bath, shampoo, hygiene, and grooming.

(3) Access to and from bed or a wheelchair, transferring, ambulation, and mobility in general. It is recommended that the provider receive certification of training and return demonstration for transferring. Certification for this is available through the area community colleges.

(4) Toilet assistance, including bowel, bladder, and catheter assistance. It is recommended that the provider receive certification of training and return demonstration for catheter assistance. Certification for this is available through the area community colleges.

(5) Meal preparation, cooking, eating and feeding but not the cost of meals themselves.

(6) Housekeeping services which are essential to the consumer's health care at home.

(7) Medications ordinarily self-administered including those ordered by a physician or other qualified health care provider. It is recommended the provider successfully complete a medication aide course administered by an area community college.

(8) Wound care.

(9) Assistance needed to go to or return from a place of employment and assistance with job-related tasks while the consumer is on the job site. The cost of transportation for the consumer and assistance with understanding or performing the essential job functions are not included in consumer-directed attendant care services.

(10) Cognitive assistance with tasks such as handling money and scheduling.

(11) Fostering communication through interpreting and reading services as well as assistive devices for communication.

(12) Assisting or accompanying a consumer in using transportation essential to the health and welfare of the consumer. The cost of the transportation is not included.

b. The service activities may include helping the consumer with any of the following skilled services under the supervision of a licensed nurse or licensed therapist working under the direction of a physician. The licensed nurse or therapist shall retain accountability for actions that are delegated. The licensed nurse or therapist shall ensure appropriate assessment, planning, implementation, and evaluation. The licensed nurse or therapist shall make on-site supervisory visits every two weeks with the provider present. The cost of the supervision provided by the licensed nurse or therapist shall be paid from private insurance and other third-party payment sources, Medicare, the regular Medicaid program, or the early periodic screening diagnosis and treatment program before accessing the HCBS waiver.

(1) Tube feedings of consumers unable to eat solid foods.

(2) Intravenous therapy administered by a registered nurse.

(3) Parenteral injections required more than once a week.

(4) Catheterizations, continuing care of indwelling catheters with supervision of irrigations, and changing of Foley catheters when required.

(5) Respiratory care including inhalation therapy and tracheotomy care or tracheotomy care and ventilator.

(6) Care of decubiti and other ulcerated areas, noting and reporting to the nurse or therapist.

(7) Rehabilitation services including, but not limited to, bowel and bladder training, range of motion exercises, ambulation training, restorative nursing services, reteaching the activities of daily living, respiratory care and breathing programs, reality orientation, reminiscing therapy, remotivation, and behavior modification.

(8) Colostomy care.

(9) Care of medical conditions out of control which includes brittle diabetes and comfort care of terminal conditions.

(10) Postsurgical nursing care.

(11) Monitoring medications requiring close supervision because of fluctuating physical or psychological conditions, e.g., antihypertensives, digitalis preparations, mood-altering or psychotropic drugs, or narcotics.

(12) Preparing and monitoring response to therapeutic diets.

(13) Recording and reporting of changes in vital signs to the nurse or therapist.

c. A unit of service is 1 hour, or one 8- to 24-hour day provided by an individual or an agency. Each service shall be billed in whole units.

d. The consumer, parent, guardian, or attorney in fact under a durable power of attorney for health care shall be responsible for selecting the person or agency who will provide the components of the attendant care services to be provided.

e. The consumer, parent, guardian, or attorney in fact under a durable power of attorney for health care shall determine the components of the attendant care services to be provided with the person who is providing the services to the consumer.

f. The service activities may not include parenting or child care for or on behalf of the consumer.

g. The consumer, parent, guardian, or attorney in fact under a durable power of attorney for health care and the provider shall complete and sign Form 470-3372, HCBS Consumer-Directed Attendant Care Agreement. A copy of the completed agreement shall be attached to the service plan, which is signed by the service worker or case manager prior to the initiation of services, and kept in the consumer's and department's records.

h. If the consumer has a guardian or attorney in fact under a durable power of attorney for health care, the care plan shall address how consumer-directed attendant care services will be monitored to ensure the consumer's needs are being adequately met. If the guardian or attorney in fact is the service

provider, the service plan shall address how the service worker or case manager shall oversee service provision.

i. If the consumer has a guardian or attorney in fact under a durable power of attorney for health care, the guardian or attorney in fact shall sign the claim form in place of the consumer, indicating that the service has been provided as presented on the claim.

j. The frequency or intensity of services shall be indicated in the service plan.

k. Consumer-directed attendant care services may not be simultaneously reimbursed with any other HCBS waiver services.

l. Consumer-directed attendant care services may be provided to a recipient of in-home health-related care services, but not at the same time.

m. Services may be provided in the absence of a parent or guardian if the parent or guardian has given advanced direction for the service provision.

78.41(9) *Interim medical monitoring and treatment services.* Interim medical monitoring and treatment services are monitoring and treatment of a medical nature requiring specially trained caregivers beyond what is normally available in a day care setting. The services must be needed to allow the consumer's usual caregivers to be employed or, for a limited period of time, for academic or vocational training of a usual caregiver; due to the hospitalization, treatment for physical or mental illness, or death of a usual caregiver; or during a search for employment by a usual caregiver.

a. Service requirements. Interim medical monitoring and treatment services shall:

(1) Provide experiences for each consumer's social, emotional, intellectual, and physical development;

(2) Include comprehensive developmental care and any special services for a consumer with special needs; and

(3) Include medical assessment, medical monitoring, and medical intervention as needed on a regular or emergency basis.

b. Interim medical monitoring and treatment services may include supervision to and from school.

c. Limitations.

(1) A maximum of 12 one-hour units of service is available per day.

(2) Covered services do not include a complete nutritional regimen.

(3) Interim medical monitoring and treatment services may not duplicate any regular Medicaid or waiver services provided under the state plan.

(4) Interim medical monitoring and treatment services may be provided only in the consumer's home, in a registered group child care home, in a registered family child care home, in a licensed child care center, or during transportation to and from school.

(5) The staff-to-consumer ratio shall not be less than one to six.

d. A unit of service is one hour.

78.41(10) *Residential-based supported community living services.* Residential-based supported community living services are medical or remedial services provided to children under the age of 18 while living outside their home in a residential-based living environment furnished by the residential-based supported community living service provider. The services eliminate barriers to family reunification or develop self-help skills for maximum independence.

a. Allowable service components are the following:

(1) Daily living skills development. These are services to develop the child's ability to function independently in the community on a daily basis, including training in food preparation, maintenance of living environment, time and money management, personal hygiene, and self-care.

(2) Social skills development. These are services to develop a child's communication and socialization skills, including interventions to develop a child's ability to solve problems, resolve conflicts, develop appropriate relationships with others, and develop techniques for controlling behavior.

(3) Family support development. These are services necessary to allow a child to return to the child's family or another less restrictive service environment. These services must include counseling and therapy sessions that involve both the child and the child's family at least 50 percent of the time and

that focus on techniques for dealing with the special care needs of the child and interventions needed to alleviate behaviors that are disruptive to the family or other group living unit.

(4) Counseling and behavior intervention services. These are services to halt, control, or reverse stress and social, emotional, or behavioral problems that threaten or have negatively affected the child's stability. Activities under this service include counseling and behavior intervention with the child, including interventions to ameliorate problem behaviors.

b. Residential-based supported community living services must also address the ordinary daily-living needs of the child, excluding room and board, such as needs for safety and security, social functioning, and other medical care.

c. Residential-based supported community living services do not include services associated with vocational needs, academics, day care, Medicaid case management, other case management, or any other services that the child can otherwise obtain through Medicaid.

d. Room and board costs are not reimbursable as residential-based supported community living services.

e. The scope of service shall be identified in the child's service plan pursuant to 441—paragraph 77.37(23)*"d."*

f. Residential-based supported community living services shall not be simultaneously reimbursed with other residential services provided under an HCBS waiver or otherwise provided under the Medicaid program.

g. A unit of service is a day.

h. The maximum number of units of residential-based supported community living services available per child is 365 daily units per state fiscal year, except in a leap year when 366 daily units are available.

78.41(11) *Transportation.* Transportation services may be provided for consumers to conduct business errands and essential shopping, to receive medical services when not reimbursed through medical transportation, to travel to and from work or day programs, and to reduce social isolation. A unit of service is either per mile, per trip, or the unit established by an area agency on aging. Transportation may not be reimbursed simultaneously with HCBS MR waiver supported community living service.

78.41(12) *Adult day care services.* Adult day care services provide an organized program of supportive care in a group environment to persons who need a degree of supervision and assistance on a regular or intermittent basis. A unit of service is a full day (4 to 8 hours) or a half-day (1 to 4 hours) or an extended day (8 to 12 hours).

78.41(13) *Prevocational services.* Prevocational services are services that are aimed at preparing a consumer eligible for the HCBS MR waiver for paid or unpaid employment, but are not job-task oriented. These services include teaching the consumer concepts necessary as job readiness skills, such as following directions, attending to tasks, task completion, problem solving, and safety and mobility training.

a. Prevocational services are intended to have a more generalized result as opposed to vocational training for a specific job or supported employment. Services include activities that are not primarily directed at teaching specific job skills but at more generalized habilitative goals, and are reflected in a habilitative plan that focuses on general habilitative rather than specific employment objectives.

b. Prevocational services do not include:

(1) Services defined in Section 4(a)(4) of the 1975 amendments to the Education of the Handicapped Act (20 U.S.C. 1404(16) and (17)) that are otherwise available to the consumer through a state or local education agency.

(2) Vocational rehabilitation services that are otherwise available to the consumer through a program funded under Section 110 of the Rehabilitation Act of 1973 (29 U.S.C. 730).

78.41(14) *Day habilitation services.*

a. *Scope.* Day habilitation services are services that assist or support the consumer in developing or maintaining life skills and community integration. Services must enable or enhance the consumer's intellectual functioning, physical and emotional health and development, language and communication development, cognitive functioning, socialization and community integration,

functional skill development, behavior management, responsibility and self-direction, daily living activities, self-advocacy skills, or mobility.

b. Family training option. Day habilitation services may include training families in treatment and support methodologies or in the care and use of equipment. Family training may be provided in the consumer's home. The unit of service is an hour. The units of services payable are limited to a maximum of 10 hours per month.

c. Unit of service. Except as provided in paragraph *"b,"* the unit of service may be an hour, a half-day (1 to 4 hours), or a full day (4 to 8 hours).

d. Exclusions.

(1) Services shall not be provided in the consumer's home, except as provided in paragraph *"b."* For this purpose, services provided in a residential care facility where the consumer lives are not considered to be provided in the consumer's home.

(2) Services shall not include vocational or prevocational services and shall not involve paid work.

(3) Services shall not duplicate or replace education or related services defined in Public Law 94-142, the Education of the Handicapped Act.

(4) Services shall not be provided simultaneously with other Medicaid-funded services.

78.41(15) *Consumer choices option.* The consumer choices option provides a consumer with a flexible monthly individual budget that is based on the consumer's service needs. With the individual budget, the consumer shall have the authority to purchase goods and services and may choose to employ providers of services and supports. Components of this service are set forth below.

a. Agreement. As a condition of participating in the consumer choices option, a consumer shall sign Form 470-4289, HCBS Consumer Choices Informed Consent and Risk Agreement, to document that the consumer has been informed of the responsibilities and risks of electing the consumer choices option.

b. Individual budget amount. A monthly individual budget amount shall be set for each consumer. The consumer's department service worker or Medicaid targeted case manager shall determine the amount of each consumer's individual budget, based on the services and supports authorized in the consumer's service plan. The consumer shall be informed of the individual budget amount during the development of the service plan.

(1) Services that may be included in determining the individual budget amount for a consumer in the HCBS mental retardation waiver are:

1. Consumer-directed attendant care (unskilled).
2. Day habilitation.
3. Home and vehicle modification.
4. Prevocational services.
5. Basic individual respite care.
6. Supported community living.
7. Supported employment.
8. Transportation.

(2) The department shall determine an average unit cost for each service listed in subparagraph (1) based on actual unit costs from the previous fiscal year plus a cost-of-living adjustment.

(3) In aggregate, costs for individual budget services shall not exceed the current costs of waiver program services. In order to maintain cost neutrality, the department shall apply a utilization adjustment factor to the amount of service authorized in the consumer's service plan before calculating the value of that service to be included in the individual budget amount.

(4) The department shall compute the utilization adjustment factor for each service by dividing the net costs of all claims paid for the service by the total of the authorized costs for that service, using at least 12 consecutive months of aggregate service data. The utilization adjustment factor shall be no lower than 60 percent. The department shall analyze and adjust the utilization adjustment factor at least annually in order to maintain cost neutrality.

(5) Anticipated costs for home and vehicle modification are not subject to the average cost in subparagraph (2) or the utilization adjustment factor in subparagraph (3). Costs for home and vehicle modification may be released in a one-time payment.

(6) The individual budget amount may be changed only at the first of the month and shall remain fixed for the entire month.

c. Required service components. To participate in the consumer choices option, a consumer must hire an independent support broker and must work with a financial management service that is enrolled as a Medicaid HCBS mental retardation waiver services provider.

(1) Before hiring the individual support broker, the consumer shall receive the results of the background check conducted pursuant to 441—subrule 77.30(14).

(2) If the consumer chooses to hire a person who has a criminal record or founded abuse report, the consumer assumes the risk for this action and shall acknowledge this information on Form 470-4289, HCBS Consumer Choices Informed Consent and Risk Agreement.

d. Optional service components. A consumer who elects the consumer choices option may purchase the following services and supports, which shall be provided in the consumer's home or at an integrated community setting:

(1) Self-directed personal care services. Self-directed personal care services are services or goods that provide a range of assistance in activities of daily living and incidental activities of daily living that help the consumer remain in the home and community.

(2) Self-directed community supports and employment. Self-directed community supports and employment are services that support the consumer in developing and maintaining independence and community integration.

(3) Individual-directed goods and services. Individual-directed goods and services are services, equipment, or supplies not otherwise provided through the Medicaid program that address a need identified in the consumer's service plan. The item or service shall decrease the consumer's need for other Medicaid services, promote the consumer's inclusion in the community, or increase the consumer's safety in the community.

e. Development of the individual budget. The individual support broker shall assist the consumer in developing and implementing the consumer's individual budget. The individual budget shall include:

(1) The costs of the financial management service.

(2) The costs of the independent support broker. The independent support broker may be compensated for up to 6 hours of service for assisting with the implementation of the initial individual budget. After the initial implementation, the independent support broker shall not be paid for more than 20 hours of service during a 12-month period without prior approval by the department.

(3) The costs of any services and supports chosen by the consumer as described in paragraph *"d."*

f. Budget authority. The consumer shall have authority over the individual budget authorized by the department to perform the following tasks:

(1) Contract with entities to provide services and supports as described in this subrule.

(2) Determine the amount to be paid for services with the exception of the independent support broker and the financial management service. Reimbursement rates for the independent support broker and the financial management service are subject to the limits in 441—subrule 79.1(2).

(3) Schedule the provision of services.

(4) Authorize payment for waiver goods and services identified in the individual budget. Consumers shall not use the individual budget to purchase room and board, sheltered workshop services, child care, or personal entertainment items.

(5) Reallocate funds among services included in the budget.

g. Delegation of budget authority. The consumer may delegate responsibility for the individual budget to a representative in addition to the independent support broker.

(1) The representative must be at least 18 years old.

(2) The representative shall not be a current provider of service to the consumer.

(3) The consumer shall sign a consent form that designates who the consumer has chosen as a representative and what responsibilities the representative shall have.

(4) The representative shall not be paid for this service.

h. *Employer authority.* The consumer shall have the authority to be the common-law employer of employees providing services and support under the consumer choices option. A common-law employer has the right to direct and control the performance of the services. The consumer may perform the following functions:

(1) Recruit employees.
(2) Select employees from a worker registry.
(3) Verify employee qualifications.
(4) Specify additional employee qualifications.
(5) Determine employee duties.
(6) Determine employee wages and benefits.
(7) Schedule employees.
(8) Train and supervise employees.

i. *Employment agreement.* Any person employed by the consumer to provide services under the consumer choices option shall sign an employment agreement with the consumer that outlines the employee's and consumer's responsibilities.

j. *Responsibilities of the independent support broker.* The independent support broker shall perform the services specified in 78.34(13)*"j."*

k. *Responsibilities of the financial management service.* The financial management service shall perform all of the services specified in 78.34(13)*"k."*

This rule is intended to implement Iowa Code section 249A.4.

441—78.42(249A) Rehabilitative treatment services. Rescinded IAB 8/1/07, effective 9/5/07.

441—78.43(249A) HCBS brain injury waiver services. Payment shall be approved for the following services to consumers eligible for the HCBS brain injury services as established in 441—Chapter 83 and as identified in the consumer's service plan. All services shall include the applicable and necessary instructions, supervision, assistance and support as required by the consumer in achieving the goals written specifically in the service plan. The services, amount and supports provided under the HCBS brain injury waiver shall be delivered in the least restrictive environment and in conformity with the consumer's service plan.

Reimbursement shall not be available under the waiver for any services that the consumer can obtain through regular Medicaid.

All services shall be billed in whole units.

78.43(1) *Case management services.* Individual case management services means services that assist members who reside in a community setting or are transitioning to a community setting in gaining access to needed medical, social, educational, housing, transportation, vocational, and other appropriate services in order to ensure the health, safety, and welfare of the member.

a. Case management services shall be provided as set forth in rules 441—90.5(249A) and 441—90.8(249A).

b. The service shall be delivered in such a way as to enhance the capabilities of consumers and their families to exercise their rights and responsibilities as citizens in the community. The goal is to enhance the ability of the consumer to exercise choice, make decisions, take risks that are a typical part of life, and fully participate as members of the community.

c. The case manager must develop a relationship with the consumer so that the abilities, needs and desires of the consumer can be clearly identified and communicated and the case manager can help to ensure that the system and specific services are responsive to the needs of the individual consumers.

d. Members who are at the ICF/MR level of care whose county has voluntarily chosen to participate in the HCBS brain injury waiver are eligible for targeted case management and, therefore, are not eligible for case management as a waiver service.

78.43(2) *Supported community living services.* Supported community living services are provided by the provider within the consumer's home and community, according to the individualized consumer

need as identified in the individual comprehensive plan (ICP) or department case plan. Intermittent service shall be provided as defined in rule 441—83.81(249A).

a. The basic components of the service may include, but are not limited to, personal and home skills training services, individual advocacy services, community skills training services, personal environment support services, transportation, and treatment services.

(1) Personal and home skills training services are those activities which assist a consumer to develop or maintain skills for self-care, self-directedness, and care of the immediate environment.

(2) Individual advocacy is the act or process of representing the individual's rights and interests in order to realize the rights to which the individual is entitled and to remove barriers to meeting the individual's needs.

(3) Community skills training services are those activities which assist a person to develop or maintain skills allowing better participation in the community. Services shall focus on the following areas as they are applicable to individuals being served:

1. Personal management skills training services are activities which assist a person to maintain or develop skills necessary to sustain oneself in the physical environment and are essential to the management of one's personal business and property. This includes self-advocacy skills. Examples of personal management skills are the ability to maintain a household budget, plan and prepare nutritional meals, use community resources such as public transportation and libraries, and select foods at the grocery store.

2. Socialization skills training services are those activities which assist a consumer to develop or maintain skills which include self-awareness and self-control, social responsiveness, community participation, social amenities, and interpersonal skills.

3. Communication skills training services are activities which assist a person to develop or maintain skills including expressive and receptive skills in verbal and nonverbal language and the functional application of acquired reading and writing skills.

(4) Personal and environmental support services are those activities and expenditures provided to or on behalf of a person in the areas of personal needs in order to allow the person to function in the least restrictive environment.

(5) Transportation services are those activities and expenditures designed to assist the consumer to travel from one place to another to obtain services or carry out life's activities. The service excludes transportation to and from work or day programs.

(6) Treatment services are those activities designed to assist the person to maintain or improve physiological, emotional and behavioral functioning and to prevent conditions that would present barriers to a person's functioning. Treatment services include physical or physiological treatment and psychotherapeutic treatment.

Physiological treatment means activities including medication regimens designed to prevent, halt, control, relieve, or reverse symptoms or conditions which interfere with the normal functioning of the human body. The activities shall be provided by or under the supervision of a health care professional certified or licensed to provide the treatment activity specified.

Psychotherapeutic treatment means activities provided to assist a person in the identification or modification of beliefs, emotions, attitudes, or behaviors in order to maintain or improve the person's functioning in response to the physical, emotional, and social environment.

b. The supported community living services are intended to provide for the daily living needs of the consumer and shall be available as needed during any 24-hour period. Activities do not include those associated with vocational services, academics, day care, medical services, Medicaid case management or other case management. Services are individualized supportive services provided in a variety of community-based, integrated settings.

(1) Supported community living services shall be available at a daily rate to consumers living outside the home of their family, legal representative, or foster family and for whom a provider has primary responsibility for supervision or structure during the month. This service shall provide supervision or structure in identified time periods when another resource is not available.

(2) Supported community living services shall be available at an hourly rate to consumers for whom a daily rate is not established.

(3) Intermittent service shall be provided as defined in rule 441—83.81(249A).

c. Services may be provided to a child or an adult. Children must first access all other services for which they are eligible and which are appropriate to meet their needs before accessing the HCBS brain injury waiver services. A maximum of three consumers may reside in a living unit, except when the provider meets the requirements set forth in 441—paragraph 77.39(13)*"e."*

(1) Consumers may live in the home of their family or legal representative or in other types of typical community living arrangements.

(2) Consumers of services living with families or legal representatives are not subject to the maximum of three consumers in a living unit.

(3) Consumers may not live in licensed medical or health care facilities or in settings required to be licensed as medical or health care facilities.

(4) Consumers aged 17 or under living in the home of their family, legal representative, or foster families shall receive services based on development of adaptive, behavior, or health skills. Duration of services shall be based on age appropriateness and individual attention span.

d. Rescinded IAB 2/5/03, effective 2/1/03.

e. Provider budgets shall reflect all staff-to-consumer ratios and shall reflect costs associated with consumers' specific support needs for travel and transportation, consulting, instruction, and environmental modifications and repairs, as determined necessary by the interdisciplinary team for each consumer. The specific support needs must be identified in the Medicaid case manager's service plan, the total costs shall not exceed $1570 per consumer per year, and the provider must maintain records to support the expenditures. A unit of service is:

(1) One full calendar day when a consumer residing in the living unit receives on-site staff supervision for 19 or more hours during a 24-hour calendar day and the consumer's individual comprehensive plan identifies and reflects the need for this amount of supervision.

(2) One hour when subparagraph (1) does not apply.

f. The maximum numbers of units available per consumer are as follows:

(1) 365 daily units per state fiscal year except a leap year, when 366 daily units are available.

(2) 8,395 hourly units are available per state fiscal year except a leap year, when 8,418 hourly units are available.

g. The service shall be identified in the consumer's individual comprehensive plan.

h. Services shall not be simultaneously reimbursed with other residential services, HCBS brain injury waiver respite, transportation or personal assistance services, Medicaid nursing, or Medicaid home health aide services.

78.43(3) *Respite services.* Respite care services are services provided to the consumer that give temporary relief to the usual caregiver and provide all the necessary care that the usual caregiver would provide during that time period. The purpose of respite care is to enable the consumer to remain in the consumer's current living situation.

a. Services provided outside the consumer's home shall not be reimbursable if the living unit where respite is provided is reserved for another person on a temporary leave of absence.

b. Staff-to-consumer ratios shall be appropriate to the individual needs of the consumer as determined by the consumer's interdisciplinary team.

c. A unit of service is one hour.

d. Respite care is not to be provided to persons during the hours in which the usual caregiver is employed except when the consumer is attending a camp. Respite cannot be provided to a consumer whose usual caregiver is a consumer-directed attendant care provider for the consumer.

e. Respite services shall not be simultaneously reimbursed with other residential or respite services, HCBS brain injury waiver supported community living services, Medicaid nursing, or Medicaid home health aide services.

f. The interdisciplinary team shall determine if the consumer will receive basic individual respite, specialized respite or group respite as defined in rule 441—83.81(249A).

g. A maximum of 14 consecutive days of 24-hour respite care may be reimbursed.

h. Respite services provided for a period exceeding 24 consecutive hours to three or more individuals who require nursing care because of a mental or physical condition must be provided by a health care facility licensed as described in Iowa Code chapter 135C.

78.43(4) *Supported employment services.* Supported employment services are individualized services associated with obtaining and maintaining competitive paid employment in the least restrictive environment possible, provided to individuals for whom competitive employment at or above minimum wage is unlikely and who, because of their disability, need intense and ongoing support to perform in a work setting. Individual placements are the preferred service model. Covered services are those listed in paragraphs *"a"* and *"b"* that address the disability-related challenges to securing and keeping a job.

a. Activities to obtain a job. Covered services directed to obtaining a job must be provided to or on behalf of a consumer for whom competitive employment is reasonably expected within less than one year. Services must be focused on job placement, not on teaching generalized employment skills or habilitative goals. Three conditions must be met before services are provided. First, the consumer and the interdisciplinary team described in rule 441—83.87(249A) must complete the form that Iowa vocational rehabilitation services uses to identify the supported employment services appropriate to meet the consumer's employment needs. Second, the consumer's interdisciplinary team must determine that the identified services are necessary. Third, the consumer's case manager must approve the services. Available components of activities to obtain a job are as follows:

(1) Job development services. Job development services are directed toward obtaining competitive employment. A unit of service is a job placement that the consumer holds for 30 consecutive calendar days or more. Payment is available once the service is authorized in the member's service plan. A consumer may receive two units of job development services during a 12-month period. The activities provided to the consumer may include:

1. Job procurement training, including grooming and hygiene, application, résumé development, interviewing skills, follow-up letters, and job search activities.

2. Job retention training, including promptness, coworker relations, transportation skills, disability-related supports, job benefits, and an understanding of employee rights and self-advocacy.

3. Customized job development services specific to the consumer.

(2) Employer development services. The focus of employer development services is to support employers in hiring and retaining consumers in their workforce and to communicate expectations of the employers to the interdisciplinary team described in rule 441—83.87(249A). Employer development services may be provided only to consumers who are reasonably expected to work for no more than 10 hours per week. A unit of service is one job placement that the consumer holds for 30 consecutive calendar days or more. Payment for this service may be made only after the consumer holds the job for 30 days. A consumer may receive two units of employer development services during a 12-month period if the consumer is competitively employed for 30 or more consecutive calendar days and the other conditions for service approval are met. The services provided may include:

1. Developing relationships with employers and providing leads for individual consumers when appropriate.

2. Job analysis for a specific job.

3. Development of a customized training plan identifying job-specific skill requirements, employer expectations, teaching strategies, time frames, and responsibilities.

4. Identifying and arranging reasonable accommodations with the employer.

5. Providing disability awareness and training to the employer when it is deemed necessary.

6. Providing technical assistance to the employer regarding the training progress as identified on the consumer's customized training plan.

(3) Enhanced job search activities. Enhanced job search activities are associated with obtaining initial employment after job development services have been provided to the consumer for a minimum of 30 days or with assisting the consumer in changing jobs due to layoff, termination, or personal choice. The interdisciplinary team must review and update the Iowa vocational rehabilitation services supported employment readiness analysis form to determine if this service remains appropriate for the consumer's

employment goals. A unit of service is an hour. A maximum of 26 units may be provided in a 12-month period. The services provided may include:

1. Job opening identification with the consumer.
2. Assistance with applying for a job, including completion of applications or interviews.
3. Work site assessment and job accommodation evaluation.

b. Supports to maintain employment.

(1) Covered services provided to or on behalf of the consumer associated with maintaining competitive paid employment are the following:

1. Individual work-related behavioral management.
2. Job coaching.
3. On-the-job or work-related crisis intervention.
4. Assisting the consumer to use skills related to sustaining competitive paid employment, including assistance with communication skills, problem solving, and safety.
5. Consumer-directed attendant care services as defined in subrule 78.43(13).
6. Assistance with time management.
7. Assistance with appropriate grooming.
8. Employment-related supportive contacts.
9. Employment-related transportation between work and home and to or from activities related to employment and disability. Other forms of community transportation (including car pools, coworkers, self or public transportation, families, and volunteers) must be attempted before transportation is provided as a supported employment service.
10. On-site vocational assessment after employment.
11. Employer consultation.

(2) Services for maintaining employment may include services associated with sustaining consumers in a team of no more than eight individuals with disabilities in a teamwork or "enclave" setting.

(3) A unit of service is one hour.

(4) A maximum of 40 units may be received per week.

c. The following requirements apply to all supported employment services:

(1) Employment-related adaptations required to assist the consumer within the performance of the consumer's job functions shall be provided by the provider as part of the services.

(2) Employment-related transportation between work and home and to or from activities related to employment and disability shall be provided by the provider as part of the services. Other forms of community transportation (car pools, coworkers, self or public transportation, families, volunteers) must be attempted before the service provider provides transportation.

(3) The majority of coworkers at any employment site with more than two employees where consumers seek, obtain, or maintain employment must be persons without disabilities. In the performance of job duties at any site where consumers seek, obtain, or maintain employment, the consumer must have daily contact with other employees or members of the general public who do not have disabilities, unless the absence of daily contact with other employees or the general public is typical for the job as performed by persons without disabilities.

(4) All supported employment services shall provide individualized and ongoing support contacts at intervals necessary to promote successful job retention. Each provider contact shall be documented.

(5) Documentation that services provided are not currently available under a program funded under the Rehabilitation Act of 1973 or Public Law 94-142 shall be maintained in the provider file of each consumer.

(6) All services shall be identified in the consumer's service plan maintained pursuant to rule 441—83.67(249A).

(7) The following services are not covered:

1. Services involved in placing or maintaining consumers in day activity programs, work activity programs or sheltered workshop programs;
2. Supports for volunteer work or unpaid internships;

3. Tuition for education or vocational training; or

4. Individual advocacy that is not consumer specific.

(8) Services to maintain employment shall not be provided simultaneously with day activity programs, work activity programs, sheltered workshop programs, other HCBS services, or other Medicaid services. However, services to obtain a job and services to maintain employment may be provided simultaneously for the purpose of job advancement or job change.

78.43(5) *Home and vehicle modifications.* Covered home and vehicle modifications are those physical modifications to the consumer's home or vehicle listed below that directly address the consumer's medical or remedial need. Covered modifications must be necessary to provide for the health, welfare, or safety of the consumer and enable the consumer to function with greater independence in the home or vehicle.

a. Modifications that are necessary or desirable without regard to the consumer's medical or remedial need and that would be expected to increase the fair market value of the home or vehicle, such as furnaces, fencing, roof repair, or adding square footage to the residence, are excluded except as specifically included below. Repairs are also excluded.

b. Only the following modifications are covered:

(1) Kitchen counters, sink space, cabinets, special adaptations to refrigerators, stoves, and ovens.

(2) Bathtubs and toilets to accommodate transfer, special handles and hoses for shower heads, water faucet controls, and accessible showers and sink areas.

(3) Grab bars and handrails.

(4) Turnaround space adaptations.

(5) Ramps, lifts, and door, hall and window widening.

(6) Fire safety alarm equipment specific for disability.

(7) Voice-activated, sound-activated, light-activated, motion-activated, and electronic devices directly related to the consumer's disability.

(8) Vehicle lifts, driver-specific adaptations, remote-start systems, including such modifications already installed in a vehicle.

(9) Keyless entry systems.

(10) Automatic opening device for home or vehicle door.

(11) Special door and window locks.

(12) Specialized doorknobs and handles.

(13) Plexiglas replacement for glass windows.

(14) Modification of existing stairs to widen, lower, raise or enclose open stairs.

(15) Motion detectors.

(16) Low-pile carpeting or slip-resistant flooring.

(17) Telecommunications device for the deaf.

(18) Exterior hard-surface pathways.

(19) New door opening.

(20) Pocket doors.

(21) Installation or relocation of controls, outlets, switches.

(22) Air conditioning and air filtering if medically necessary.

(23) Heightening of existing garage door opening to accommodate modified van.

(24) Bath chairs.

c. A unit of service is the completion of needed modifications or adaptations.

d. All modifications and adaptations shall be provided in accordance with applicable federal, state, and local building and vehicle codes.

e. Services shall be performed following department approval of a binding contract between the enrolled home and vehicle modification provider and the consumer.

f. The contract shall include, at a minimum, the work to be performed, cost, time frame for work completion, and assurance of liability and workers' compensation coverage.

g. Service payment shall be made to the enrolled home and vehicle modification provider. If applicable, payment will be forwarded to the subcontracting agency by the enrolled home and vehicle

modification provider following completion of the approved modifications. Payment of up to $6,060 per year may be made to certified providers upon satisfactory completion of the service. The service worker shall encumber up to $505 per month within the monthly dollar cap allowed for the consumer until the amount of the modification is reached within the 12-month period.

h. Services shall be included in the consumer's service plan and shall exceed the Medicaid state plan services.

78.43(6) *Personal emergency response system.* The personal emergency response system allows a consumer experiencing a medical emergency at home to activate electronic components that transmit a coded signal via digital equipment over telephone lines to a central monitoring station. The necessary components of a system are:

a. An in-home medical communications transceiver.

b. A remote, portable activator.

c. A central monitoring station with backup systems staffed by trained attendants 24 hours per day, seven days per week.

d. Current data files at the central monitoring station containing response protocols and personal, medical and emergency information for each consumer.

e. The service shall be identified in the consumer's individual and comprehensive plan.

f. A unit is a one-time installation fee or one month of service.

g. Maximum units per state fiscal year are the initial installation and 12 months of service.

78.43(7) *Transportation.* Transportation services may be provided for consumers to conduct business errands and essential shopping, to receive medical services when not reimbursed through medical transportation, to travel to and from work or day programs, and to reduce social isolation. A unit of service is either per mile, per trip, or the unit established by an area agency on aging. Transportation may not be reimbursed simultaneously with HCBS brain injury waiver supported community living service.

78.43(8) *Specialized medical equipment.* Specialized medical equipment shall include medically necessary items for personal use by consumers with a brain injury which provide for health and safety of the consumer which are not ordinarily covered by Medicaid, and are not funded by educational or vocational rehabilitation programs, and are not provided by voluntary means. This includes, but is not limited to: electronic aids and organizers, medicine dispensing devices, communication devices, bath aids, and noncovered environmental control units. This includes repair and maintenance of items purchased through the waiver in addition to the initial purchase cost.

a. Consumers may receive specialized medical equipment once per month until a maximum yearly usage of $6,060 has been reached.

b. The need for specialized medical equipment shall be documented by a health care professional as necessary for the consumer's health and safety and identified in the consumer's individual comprehensive plan.

78.43(9) *Adult day care services.* Adult day care services provide an organized program of supportive care in a group environment to persons who need a degree of supervision and assistance on a regular or intermittent basis in a day care center. A unit of service is a full day (4 to 8 hours) or a half day (1 to 4 hours) or an extended day (8 to 12 hours). Components of the service are set forth in rule 441—171.6(234).

78.43(10) *Family counseling and training services.* Family counseling and training services are face-to-face mental health services provided to the consumer and the family with whom the consumer lives, or who routinely provide care to the consumer to increase the consumer's or family members' capabilities to maintain and care for the consumer in the community. Counseling may include helping the consumer or the consumer's family members with crisis, coping strategies, stress reduction, management of depression, alleviation of psychosocial isolation and support in coping with the effects of a brain injury. It may include the use of treatment regimes as specified in the ITP. Periodic training updates may be necessary to safely maintain the consumer in the community.

Family may include spouse, children, friends, or in-laws of the consumer. Family does not include individuals who are employed to care for the consumer.

78.43(11) *Prevocational services.* Prevocational services are services aimed at preparing a consumer eligible for the HCBS brain injury waiver for paid or unpaid employment, but which are not job task oriented. These services include teaching the consumer concepts necessary as job readiness skills, such as following directions, attending to tasks, task completion, problem solving, and safety and mobility training. Prevocational services are intended to have a more generalized result as opposed to vocational training for a specific job or supported employment. Services include activities which are not primarily directed at teaching specific job skills but more generalized habilitative goals and are reflected in a habilitative plan which focuses on general habilitative rather than specific employment objectives.

Prevocational services do not include services defined in Section 4(a)(4) of the 1975 amendments to the Education of the Handicapped Act (20 U.S.C. 1404(16) and (17)) which are otherwise available to the individual through a state or local education agency or vocational rehabilitation services which are otherwise available to the individual through a program funded under Section 110 of the Rehabilitation Act of 1973 (29 U.S.C. 730).

78.43(12) *Behavioral programming.* Behavioral programming consists of individually designed strategies to increase the consumer's appropriate behaviors and decrease the consumer's maladaptive behaviors which have interfered with the consumer's ability to remain in the community. Behavioral programming includes:

a. A complete assessment of both appropriate and maladaptive behaviors.

b. Development of a structured behavioral intervention plan which should be identified in the ITP.

c. Implementation of the behavioral intervention plan.

d. Ongoing training and supervision to caregivers and behavioral aides.

e. Periodic reassessment of the plan.

Types of appropriate behavioral programming include, but are not limited to, clinical redirection, token economies, reinforcement, extinction, modeling, and over-learning.

78.43(13) *Consumer-directed attendant care service.* Consumer-directed attendant care services are service activities performed by a person to help a consumer with self-care tasks which the consumer would typically do independently if the consumer were otherwise able.

a. The service activities may include helping the consumer with any of the following nonskilled service activities:

(1) Dressing.

(2) Bath, shampoo, hygiene, and grooming.

(3) Access to and from bed or a wheelchair, transferring, ambulation, and mobility in general. It is recommended that the provider receive certification of training and return demonstration for transferring. Certification for this is available through the area community colleges.

(4) Toilet assistance, including bowel, bladder, and catheter assistance. It is recommended that the provider receive certification of training and return demonstration for catheter assistance. Certification for this is available through the area community colleges.

(5) Meal preparation, cooking, eating and feeding but not the cost of meals themselves.

(6) Housekeeping services which are essential to the consumer's health care at home.

(7) Medications ordinarily self-administered including those ordered by a physician or other qualified health care provider. It is recommended the provider successfully complete a medication aide course administered by an area community college.

(8) Wound care.

(9) Assistance needed to go to or return from a place of employment and assistance with job-related tasks while the consumer is on the job site. The cost of transportation for the consumer and assistance with understanding of performing the essential job functions are not included in consumer-directed attendant care services.

(10) Cognitive assistance with tasks such as handling money and scheduling.

(11) Fostering communication through interpreting and reading services as well as assistive devices for communication.

(12) Assisting or accompanying a consumer in using transportation essential to the health and welfare of the consumer. The cost of the transportation is not included.

b. The service activities may include helping the consumer with any of the following skilled services under the supervision of a licensed nurse or licensed therapist working under the direction of a physician. The licensed nurse or therapist shall retain accountability for actions that are delegated. The licensed nurse or therapist shall ensure appropriate assessment, planning, implementation, and evaluation. The licensed nurse or therapist shall make on-site supervisory visits every two weeks with the provider present. The cost of the supervision provided by the licensed nurse or therapist shall be paid from private insurance and other third-party payment sources, Medicare, the regular Medicaid program, or the early periodic screening diagnosis and treatment program before accessing the HCBS waiver.

(1) Tube feedings of consumers unable to eat solid foods.

(2) Intravenous therapy administered by a registered nurse.

(3) Parenteral injections required more than once a week.

(4) Catheterizations, continuing care of indwelling catheters with supervision of irrigations, and changing of Foley catheters when required.

(5) Respiratory care including inhalation therapy and tracheotomy care or tracheotomy care and ventilator.

(6) Care of decubiti and other ulcerated areas, noting and reporting to the nurse or therapist.

(7) Rehabilitation services including, but not limited to, bowel and bladder training, range of motion exercises, ambulation training, restorative nursing services, reteaching the activities of daily living, respiratory care and breathing programs, reality orientation, reminiscing therapy, remotivation, and behavior modification.

(8) Colostomy.

(9) Care of medical conditions out of control which includes brittle diabetes and comfort care of terminal conditions.

(10) Postsurgical nursing care.

(11) Monitoring medications requiring close supervision because of fluctuating physical or psychological conditions, e.g., antihypertensives, digitalis preparations, mood-altering or psychotropic drugs, or narcotics.

(12) Preparing and monitoring response to therapeutic diets.

(13) Recording and reporting of changes in vital signs to the nurse or therapist.

c. A unit of service is 1 hour, or one 8- to 24-hour day provided by an individual or an agency. Each service shall be billed in whole units.

d. The consumer, parent, guardian, or attorney in fact under a durable power of attorney for health care shall be responsible for selecting the person or agency who will provide the components of the attendant care services to be provided.

e. The consumer, parent, guardian, or attorney in fact under a durable power of attorney for health care shall determine the components of the attendant care services to be provided with the person who is providing the services to the consumer.

f. The service activities may not include parenting or child care for or on behalf of the consumer.

g. The consumer, parent, guardian, or attorney in fact under a durable power of attorney for health care and the provider shall complete and sign Form 470-3372, HCBS Consumer-Directed Attendant Care Agreement. A copy of the completed agreement shall be attached to the service plan, which is signed by the service worker or case manager prior to the initiation of services, and kept in the consumer's and department's records.

h. If the consumer has a guardian or attorney in fact under a durable power of attorney for health care, the care plan shall address how consumer-directed attendant care services will be monitored to ensure the consumer's needs are being adequately met. If the guardian or attorney in fact is the service provider, the service plan shall address how the service worker or case manager shall oversee service provision.

i. If the consumer has a guardian or attorney in fact under a durable power of attorney for health care, the guardian or attorney in fact shall sign the claim form in place of the consumer, indicating that the service has been provided as presented on the claim.

j. The frequency or intensity of services shall be indicated in the service plan.

k. Consumer-directed attendant care services may not be simultaneously reimbursed with any other HCBS waiver services.

l. Consumer-directed attendant care services may be provided to a recipient of in-home health-related care services, but not at the same time.

m. Services may be provided in the absence of a parent or guardian if the parent or guardian has given advanced direction for the service provision.

78.43(14) *Interim medical monitoring and treatment services.* Interim medical monitoring and treatment services are monitoring and treatment of a medical nature requiring specially trained caregivers beyond what is normally available in a day care setting. The services must be needed to allow the consumer's usual caregivers to be employed or, for a limited period of time, for academic or vocational training of a usual caregiver; due to the hospitalization, treatment for physical or mental illness, or death of a usual caregiver; or during a search for employment by a usual caregiver.

a. Service requirements. Interim medical monitoring and treatment services shall:

(1) Provide experiences for each consumer's social, emotional, intellectual, and physical development;

(2) Include comprehensive developmental care and any special services for a consumer with special needs; and

(3) Include medical assessment, medical monitoring, and medical intervention as needed on a regular or emergency basis.

b. Interim medical monitoring and treatment services may include supervision to and from school.

c. Limitations.

(1) A maximum of 12 one-hour units of service is available per day.

(2) Covered services do not include a complete nutritional regimen.

(3) Interim medical monitoring and treatment services may not duplicate any regular Medicaid or waiver services provided under the state plan.

(4) Interim medical monitoring and treatment services may be provided only in the consumer's home, in a registered group child care home, in a registered family child care home, in a licensed child care center, or during transportation to and from school.

(5) The staff-to-consumer ratio shall not be less than one to six.

d. A unit of service is one hour.

78.43(15) *Consumer choices option.* The consumer choices option provides a consumer with a flexible monthly individual budget that is based on the consumer's service needs. With the individual budget, the consumer shall have the authority to purchase goods and services and may choose to employ providers of services and supports. Components of this service are set forth below.

a. *Agreement.* As a condition of participating in the consumer choices option, a consumer shall sign Form 470-4289, HCBS Consumer Choices Informed Consent and Risk Agreement, to document that the consumer has been informed of the responsibilities and risks of electing the consumer choices option.

b. *Individual budget amount.* A monthly individual budget amount shall be set for each consumer. The consumer's department service worker or Medicaid targeted case manager shall determine the amount of each consumer's individual budget, based on the services and supports authorized in the consumer's service plan. The consumer shall be informed of the individual budget amount during the development of the service plan.

(1) Services that may be included in determining the individual budget amount for a consumer in the HCBS brain injury waiver are:

1. Consumer-directed attendant care (unskilled).
2. Day habilitation.
3. Home and vehicle modification.
4. Prevocational services.
5. Basic individual respite care.
6. Specialized medical equipment.
7. Supported community living.

8. Supported employment.

9. Transportation.

(2) The department shall determine an average unit cost for each service listed in subparagraph (1) based on actual unit costs from the previous fiscal year plus a cost-of-living adjustment.

(3) In aggregate, costs for individual budget services shall not exceed the current costs of waiver program services. In order to maintain cost neutrality, the department shall apply a utilization adjustment factor to the amount of service authorized in the consumer's service plan before calculating the value of that service to be included in the individual budget amount.

(4) The department shall compute the utilization adjustment factor for each service by dividing the net costs of all claims paid for the service by the total of the authorized costs for that service, using at least 12 consecutive months of aggregate service data. The utilization adjustment factor shall be no lower than 60 percent. The department shall analyze and adjust the utilization adjustment factor at least annually in order to maintain cost neutrality.

(5) Anticipated costs for home and vehicle modification are not subject to the average cost in subparagraph (2) or the utilization adjustment factor in subparagraph (3). Costs for home and vehicle modification may be released in a one-time payment.

(6) The individual budget amount may be changed only at the first of the month and shall remain fixed for the entire month.

c. Required service components. To participate in the consumer choices option, a consumer must hire an independent support broker and must work with a financial management service that is enrolled as a Medicaid HCBS brain injury waiver services provider.

(1) Before hiring the individual support broker, the consumer shall receive the results of the background check conducted pursuant to 441—subrule 77.30(14).

(2) If the consumer chooses to hire a person who has a criminal record or founded abuse report, the consumer assumes the risk for this action and shall acknowledge this information on Form 470-4289, HCBS Consumer Choices Informed Consent and Risk Agreement.

d. Optional service components. A consumer who elects the consumer choices option may purchase the following services and supports, which shall be provided in the consumer's home or at an integrated community setting:

(1) Self-directed personal care services. Self-directed personal care services are services or goods that provide a range of assistance in activities of daily living and incidental activities of daily living that help the consumer remain in the home and community.

(2) Self-directed community supports and employment. Self-directed community supports and employment are services that support the consumer in developing and maintaining independence and community integration.

(3) Individual-directed goods and services. Individual-directed goods and services are services, equipment, or supplies not otherwise provided through the Medicaid program that address a need identified in the consumer's service plan. The item or service shall decrease the consumer's need for other Medicaid services, promote the consumer's inclusion in the community, or increase the consumer's safety in the community.

e. Development of the individual budget. The individual support broker shall assist the consumer in developing and implementing the consumer's individual budget. The individual budget shall include:

(1) The costs of the financial management service.

(2) The costs of the independent support broker. The independent support broker may be compensated for up to 6 hours of service for assisting with the implementation of the initial individual budget. After the initial implementation, the independent support broker shall not be paid for more than 20 hours of service during a 12-month period without prior approval by the department.

(3) The costs of any services and supports chosen by the consumer as described in paragraph *"d."*

f. Budget authority. The consumer shall have authority over the individual budget authorized by the department to perform the following tasks:

(1) Contract with entities to provide services and supports as described in this subrule.

(2) Determine the amount to be paid for services with the exception of the independent support broker and the financial management service. Reimbursement rates for the independent support broker and the financial management service are subject to the limits in 441—subrule 79.1(2).

(3) Schedule the provision of services.

(4) Authorize payment for waiver goods and services identified in the individual budget. Consumers shall not use the individual budget to purchase room and board, sheltered workshop services, child care, or personal entertainment items.

(5) Reallocate funds among services included in the budget.

g. *Delegation of budget authority.* The consumer may delegate responsibility for the individual budget to a representative in addition to the independent support broker.

(1) The representative must be at least 18 years old.

(2) The representative shall not be a current provider of service to the consumer.

(3) The consumer shall sign a consent form that designates who the consumer has chosen as a representative and what responsibilities the representative shall have.

(4) The representative shall not be paid for this service.

h. *Employer authority.* The consumer shall have the authority to be the common-law employer of employees providing services and support under the consumer choices option. A common-law employer has the right to direct and control the performance of the services. The consumer may perform the following functions:

(1) Recruit employees.

(2) Select employees from a worker registry.

(3) Verify employee qualifications.

(4) Specify additional employee qualifications.

(5) Determine employee duties.

(6) Determine employee wages and benefits.

(7) Schedule employees.

(8) Train and supervise employees.

i. *Employment agreement.* Any person employed by the consumer to provide services under the consumer choices option shall sign an employment agreement with the consumer that outlines the employee's and consumer's responsibilities.

j. *Responsibilities of the independent support broker.* The independent support broker shall perform the services specified in 78.34(13)*"j."*

k. *Responsibilities of the financial management service.* The financial management service shall perform all of the services specified in 78.34(13)*"k."*

This rule is intended to implement Iowa Code section 249A.4.

[**ARC 7957B**, IAB 7/15/09, effective 7/1/09]

441—78.44(249A) Lead inspection services. Payment shall be approved for lead inspection services. This service shall be provided for children who have had two venous blood lead levels of 15 to 19 micrograms per deciliter or one venous level greater than or equal to 20 micrograms per deciliter. This service includes, but is not limited to, X-ray fluorescence analyzer (XRF) readings, visual examination of paint, preventive education of the resident and homeowner, health education about lead poisoning, and a written report to the family, homeowner, medical provider, and local childhood lead poisoning prevention program.

This rule is intended to implement Iowa Code section 249A.4.

441—78.45(249A) Teleconsultive services. Rescinded IAB 9/6/00, effective 11/1/00.

441—78.46(249A) Physical disability waiver service. Payment shall be approved for the following services to consumers eligible for the HCBS physical disability waiver established in 441—Chapter 83 when identified in the consumer's service plan. All services shall include the applicable and necessary instructions, supervision, assistance and support as required by the consumer in achieving

the goals written specifically in the service plan and those delineated in Form 470-3372, HCBS Consumer-Directed Attendant Care Agreement. The service shall be delivered in the least restrictive environment consistent with the consumer's needs and in conformity with the consumer's service plan.

Reimbursement shall not be available under the waiver for any services that the consumer can obtain through regular Medicaid or from any other funding source.

All services shall be billed in whole units as specified in the following subrules.

78.46(1) *Consumer-directed attendant care service.* Consumer-directed attendant care services are service activities listed below performed by a person to help a consumer with self-care tasks which the consumer would typically do independently if the consumer were otherwise able. The services must be cost-effective and necessary to prevent institutionalization.

Providers must demonstrate proficiency in delivery of the services in the consumer's plan of care. Proficiency must be demonstrated through documentation of prior training or experience or a certificate of formal training. All training or experience will be detailed on Form 470-3372, HCBS Consumer-Directed Attendant Care Agreement, which must be reviewed and approved by the service worker for appropriateness of training or experience prior to the provision of services. Form 470-3372 becomes an attachment to and part of the case plan. Consumers shall give direction and training for activities which are not medical in nature to maintain independence. Licensed registered nurses and therapists must provide on-the-job training and supervision to the provider for skilled activities listed below and described on Form 470-3372. The training and experience must be sufficient to protect the health, welfare and safety of the consumer.

a. Nonskilled service activities covered are:

(1) Help with dressing.

(2) Help with bath, shampoo, hygiene, and grooming.

(3) Help with access to and from bed or a wheelchair, transferring, ambulation, and mobility in general. Certification for this is available through the area community colleges.

(4) Toilet assistance, including bowel, bladder, and catheter assistance which includes emptying the catheter bag, collecting a specimen and cleaning the external area around the catheter. Certification of training which includes demonstration of competence for catheter assistance is available through the area community colleges.

(5) Meal preparation, cooking, eating and feeding assistance but not the cost of meals themselves.

(6) Housekeeping services which are essential to the consumer's health care at home.

(7) Help with medications ordinarily self-administered including those ordered by a physician or other qualified health care provider. Certification of training in a medication aide course is available through the area community colleges.

(8) Minor wound care which does not require skilled nursing care.

(9) Assistance needed to go to or return from a place of employment and assistance with job-related tasks while the consumer is on the job site. The cost of transportation for the consumer and assistance with understanding or performing the essential job functions are not included in consumer-directed attendant care services.

(10) Cognitive assistance with tasks such as handling money and scheduling.

(11) Fostering communication through interpreting and reading services as well as assistance in use of assistive devices for communication.

(12) Assisting and accompanying a consumer in using transportation essential to the health and welfare of the consumer, but not the cost of the transportation.

b. Skilled service activities covered are the following performed under the supervision of a licensed nurse or licensed therapist working under the direction of a licensed physician. The licensed nurse or therapist shall retain accountability for actions that are delegated. The licensed nurse or therapist shall ensure appropriate assessment, planning, implementation, and evaluation. The licensed nurse or therapist shall make on-site supervisory visits every two weeks with the provider present. The cost of the supervision provided by the licensed nurse or therapist shall not be included in the reimbursement for consumer-directed attendant care services.

(1) Tube feedings of consumers unable to eat solid foods.

(2) Assistance with intravenous therapy which is administered by a registered nurse.

(3) Parenteral injections required more than once a week.

(4) Catheterizations, continuing care of indwelling catheters with supervision of irrigations, and changing of Foley catheters when required.

(5) Respiratory care including inhalation therapy and tracheotomy care or tracheotomy care and ventilator.

(6) Care of decubiti and other ulcerated areas, noting and reporting to the nurse or therapist.

(7) Rehabilitation services including bowel and bladder training, range of motion exercises, ambulation training, restorative nursing services, reteaching the activities of daily living, respiratory care and breathing programs, reality orientation, reminiscing therapy, remotivation, and behavior modification.

(8) Colostomy care.

(9) Care of medical conditions such as brittle diabetes and comfort care of terminal conditions.

(10) Postsurgical nurse-delegated activities under the supervision of the registered nurse.

(11) Monitoring medication reactions requiring close supervision because of fluctuating physical or psychological conditions, e.g., antihypertensives, digitalis preparations, mood altering or psychotropic drugs or narcotics.

(12) Preparing and monitoring response to therapeutic diets.

(13) Recording and reporting of changes in vital signs to the nurse or therapist.

c. A unit of service is 1 hour for up to 7 hours per day or one 8- to 24-hour day provided by an individual or an agency. Each service shall be billed in whole units.

d. The consumer, parent, guardian, or attorney in fact under a durable power of attorney for health care shall be responsible for selecting the person or agency who will provide the components of the attendant care services to be provided.

e. The consumer, parent, guardian, or attorney in fact under a durable power of attorney for health care shall determine the components of the attendant care services to be provided with the person who is providing the services to the consumer.

f. The service activities may not include parenting or child care on behalf of the consumer.

g. The consumer, parent, guardian, or attorney in fact under a durable power of attorney for health care and the provider shall complete and sign Form 470-3372, HCBS Consumer-Directed Attendant Care Agreement. A copy of the completed agreement shall be attached to the service plan, which is signed by the service worker prior to the initiation of services, and kept in the consumer's and department's records.

h. If the consumer has a guardian or attorney in fact under a durable power of attorney for health care, the care plan shall address how consumer-directed attendant care services will be monitored to ensure the consumer's needs are being adequately met. If the guardian or attorney in fact is the service provider, the service plan shall address how the service worker or case manager shall oversee service provision.

i. If the consumer has a guardian or attorney in fact under a durable power of attorney for health care, the guardian or attorney in fact shall sign the claim form in place of the consumer, indicating that the service has been provided as presented on the claim.

j. The frequency or intensity of services shall be indicated in the service plan.

k. Consumer-directed attendant care services may not be simultaneously reimbursed with any other HCBS waiver services.

l. Consumer-directed attendant care services may be provided to a recipient of in-home health-related care services, but not at the same time.

m. Services may be provided in the absence of a parent or guardian if the parent or guardian has given advanced direction for the service provision.

78.46(2) *Home and vehicle modifications.* Covered home and vehicle modifications are those physical modifications to the consumer's home or vehicle listed below that directly address the consumer's medical or remedial need. Covered modifications must be necessary to provide for

the health, welfare, or safety of the consumer and enable the consumer to function with greater independence in the home or vehicle.

a. Modifications that are necessary or desirable without regard to the consumer's medical or remedial need and that would be expected to increase the fair market value of the home or vehicle, such as furnaces, fencing, roof repair, or adding square footage to the residence, are excluded except as specifically included below. Repairs are also excluded.

b. Only the following modifications are covered:

(1) Kitchen counters, sink space, cabinets, special adaptations to refrigerators, stoves, and ovens.

(2) Bathtubs and toilets to accommodate transfer, special handles and hoses for shower heads, water faucet controls, and accessible showers and sink areas.

(3) Grab bars and handrails.

(4) Turnaround space adaptations.

(5) Ramps, lifts, and door, hall and window widening.

(6) Fire safety alarm equipment specific for disability.

(7) Voice-activated, sound-activated, light-activated, motion-activated, and electronic devices directly related to the consumer's disability.

(8) Vehicle lifts, driver-specific adaptations, remote-start systems, including such modifications already installed in a vehicle.

(9) Keyless entry systems.

(10) Automatic opening device for home or vehicle door.

(11) Special door and window locks.

(12) Specialized doorknobs and handles.

(13) Plexiglas replacement for glass windows.

(14) Modification of existing stairs to widen, lower, raise or enclose open stairs.

(15) Motion detectors.

(16) Low-pile carpeting or slip-resistant flooring.

(17) Telecommunications device for the deaf.

(18) Exterior hard-surface pathways.

(19) New door opening.

(20) Pocket doors.

(21) Installation or relocation of controls, outlets, switches.

(22) Air conditioning and air filtering if medically necessary.

(23) Heightening of existing garage door opening to accommodate modified van.

(24) Bath chairs.

c. A unit of service is the completion of needed modifications or adaptations.

d. All modifications and adaptations shall be provided in accordance with applicable federal, state, and local building and vehicle codes.

e. Services shall be performed following department approval of a binding contract between the enrolled home and vehicle modification provider and the consumer.

f. The contract shall include, at a minimum, the work to be performed, cost, time frame for work completion, and assurance of liability and workers' compensation coverage.

g. Service payment shall be made to the enrolled home and vehicle modification provider. If applicable, payment will be forwarded to the subcontracting agency by the enrolled home and vehicle modification provider following completion of the approved modifications. Payment of up to $6,060 per year may be made to certified providers upon satisfactory completion of the service. The service worker shall encumber up to $505 per month within the monthly dollar cap allowed for the consumer until the amount of the modification is reached within the 12-month period.

h. Services shall be included in the consumer's service plan and shall exceed the Medicaid state plan services.

78.46(3) *Personal emergency response system.* The personal emergency response system allows a consumer experiencing a medical emergency at home to activate electronic components that transmit a coded signal via digital equipment over telephone lines to a central monitoring station. The service shall

be identified in the consumer's service plan. A unit is a one-time installation fee or one month of service. Maximum units per state fiscal year are the initial installation and 12 months of service. The necessary components of a system are:

a. An in-home medical communications transceiver.

b. A remote, portable activator.

c. A central monitoring station with backup systems staffed by trained attendants 24 hours per day, seven days a week.

d. Current data files at the central monitoring station containing response protocols and personal, medical, and emergency information for each consumer.

78.46(4) *Specialized medical equipment.* Specialized medical equipment shall include medically necessary items for personal use by consumers with a physical disability which provide for the health and safety of the consumer that are not covered by Medicaid, are not funded by vocational rehabilitation programs, and are not provided by voluntary means. This includes, but is not limited to: electronic aids and organizers, medicine-dispensing devices, communication devices, bath aids and noncovered environmental control units. This includes repair and maintenance of items purchased through the waiver in addition to the initial costs.

a. Consumers may receive specialized medical equipment once a month until a maximum yearly usage of $6,060 has been reached.

b. The need for specialized medical equipment shall be documented by a health care professional as necessary for the consumer's health and safety and shall be identified in the consumer's service plan.

78.46(5) *Transportation.* Transportation services may be provided for consumers to conduct business errands and essential shopping, to receive medical services when not reimbursed through Medicaid as medical transportation, to travel to and from work or day programs, and to reduce social isolation. A unit of service is either per mile, per trip, or the unit established by an area agency on aging.

78.46(6) *Consumer choices option.* The consumer choices option provides a consumer with a flexible monthly individual budget that is based on the consumer's service needs. With the individual budget, the consumer shall have the authority to purchase goods and services and may choose to employ providers of services and supports. Components of this service are set forth below.

a. *Agreement.* As a condition of participating in the consumer choices option, a consumer shall sign Form 470-4289, HCBS Consumer Choices Informed Consent and Risk Agreement, to document that the consumer has been informed of the responsibilities and risks of electing the consumer choices option.

b. *Individual budget amount.* A monthly individual budget amount shall be set for each consumer. The consumer's department service worker or Medicaid targeted case manager shall determine the amount of each consumer's individual budget, based on the services and supports authorized in the consumer's service plan. The consumer shall be informed of the individual budget amount during the development of the service plan.

(1) Services that may be included in determining the individual budget amount for a consumer in the HCBS physical disability waiver are:

1. Consumer-directed attendant care (unskilled).
2. Home and vehicle modification.
3. Specialized medical equipment.
4. Transportation.

(2) The department shall determine an average unit cost for each service listed in subparagraph (1) based on actual unit costs from the previous fiscal year plus a cost-of-living adjustment.

(3) In aggregate, costs for individual budget services shall not exceed the current costs of waiver program services. In order to maintain cost neutrality, the department shall apply a utilization adjustment factor to the amount of service authorized in the consumer's service plan when calculating the value of that service to be included in the individual budget.

(4) The department shall compute the utilization adjustment factor for each service by dividing the net costs of all claims paid for the service by the total of the authorized costs for that service, using at least 12 consecutive months of aggregate service data. The utilization adjustment factor shall be no

lower than 60 percent. The department shall analyze and adjust the utilization adjustment factor at least annually in order to maintain cost neutrality.

(5) Anticipated costs for home and vehicle modification are not subject to the average cost in subparagraph (2) or the utilization adjustment factor in subparagraph (3). Costs for home and vehicle modification may be released in a one-time payment.

(6) The individual budget amount may be changed only at the first of the month and shall remain fixed for the entire month.

c. Required service components. To participate in the consumer choices option, a consumer must hire an independent support broker and must work with a financial management service that is enrolled as a Medicaid HCBS physical disability waiver services provider.

(1) Before hiring the individual support broker, the consumer shall receive the results of the background check conducted pursuant to 441—subrule 77.30(14).

(2) If the consumer chooses to hire a person who has a criminal record or founded abuse report, the consumer shall acknowledge this information on Form 470-4289, HCBS Consumer Choices Informed Consent and Risk Agreement.

d. Optional service components. A consumer who elects the consumer choices option may purchase the following services and supports, which shall be provided in the consumer's home or at an integrated community setting:

(1) Self-directed personal care services. Self-directed personal care services are services or goods that provide a range of assistance in activities of daily living and incidental activities of daily living that help the consumer remain in the home and community.

(2) Self-directed community supports and employment. Self-directed community supports and employment are services that support the consumer in developing and maintaining independence and community integration.

(3) Individual-directed goods and services. Individual-directed goods and services are services, equipment, or supplies not otherwise provided through the Medicaid program that address a need identified in the consumer's service plan. The item or service shall decrease the consumer's need for other Medicaid services, promote the consumer's inclusion in the community, or increase the consumer's safety in the community.

e. Development of the individual budget. The individual support broker shall assist the consumer in developing and implementing the consumer's individual budget. The individual budget shall include:

(1) The costs of the financial management service.

(2) The costs of the independent support broker. The independent support broker may be compensated for up to 6 hours of service for assisting with the implementation of the initial individual budget. After the initial implementation, the independent support broker shall not be paid for more than 20 hours of service during a 12-month period without prior approval by the department.

(3) The costs of any services and supports chosen by the consumer as described in paragraph *"d."*

f. Budget authority. The consumer shall have authority over the individual budget authorized by the department to perform the following tasks:

(1) Contract with entities to provide services and supports as described in this subrule.

(2) Determine the amount to be paid for services with the exception of the independent support broker and the financial management service. Reimbursement rates for the independent support broker and the financial management service are subject to the limits in 441—subrule 79.1(2).

(3) Schedule the provision of services.

(4) Authorize payment for waiver goods and services identified in the individual budget. Consumers shall not use the individual budget to purchase room and board, sheltered workshop services, child care, or personal entertainment items.

(5) Reallocate funds among services included in the budget.

g. Delegation of budget authority. The consumer may delegate responsibility for the individual budget to a representative in addition to the independent support broker.

(1) The representative must be at least 18 years old.

(2) The representative shall not be a current provider of service to the consumer.

(3) The consumer shall sign a consent form that designates who the consumer has chosen as a representative and what responsibilities the representative shall have.

(4) The representative shall not be paid for this service.

h. Employer authority. The consumer shall have the authority to be the common-law employer of employees providing services and support under the consumer choices option. A common-law employer has the right to direct and control the performance of the services. The consumer may perform the following functions:

(1) Recruit employees.

(2) Select employees from a worker registry.

(3) Verify employee qualifications.

(4) Specify additional employee qualifications.

(5) Determine employee duties.

(6) Determine employee wages and benefits.

(7) Schedule employees.

(8) Train and supervise employees.

i. Employment agreement. Any person employed by the consumer to provide services under the consumer choices option shall sign an employment agreement with the consumer that outlines the employee's and consumer's responsibilities.

j. Responsibilities of the independent support broker. The independent support broker shall perform the services specified in 78.34(13)*"j."*

k. Responsibilities of the financial management service. The financial management service shall perform all of the services specified in 78.34(13)*"k."*

This rule is intended to implement Iowa Code section 249A.4.

441—78.47(249A) Pharmaceutical case management services. Payment will be approved for pharmaceutical case management services provided by an eligible physician and pharmacist for Medicaid recipients determined to be at high risk for medication-related problems. These services are designed to identify, prevent, and resolve medication-related problems and improve drug therapy outcomes.

78.47(1) *Medicaid recipient eligibility.* Patients are eligible for pharmaceutical case management services if they have active prescriptions for four or more regularly scheduled nontopical medications, are ambulatory, do not reside in a nursing facility, and have at least one of the eligible disease states of congestive heart disease, ischemic heart disease, diabetes mellitus, hypertension, hyperlipidemia, asthma, depression, atrial fibrillation, osteoarthritis, gastroesophageal reflux, or chronic obstructive pulmonary disease.

78.47(2) *Provider eligibility.* Physicians and pharmacists shall meet the following criteria to provide pharmaceutical case management services.

a. Physicians and pharmacists must be enrolled in the Iowa Medicaid program, have an Iowa Medicaid provider number, and receive training under the direction of the department regarding the provision of pharmaceutical case management services under the Iowa Medicaid program.

A copy of pharmaceutical case management records, including documentation of services provided, shall be maintained on file in each provider's facility and be made available for audit by the department on request.

b. Physicians shall be licensed to practice medicine.

c. Pharmacists shall present to the department evidence of competency including state licensure, submit five acceptable patient care plans, and have successfully completed professional training on patient-oriented, medication-related problem prevention and resolution. Pharmacists shall also maintain problem-oriented patient records, provide a private patient consultation area, and submit a statement indicating that the submitted patient care plans are representative of the pharmacists' usual patient care plans.

Acceptable professional training programs are:

(1) A doctor of pharmacy degree program.

(2) The Iowa Center for Pharmaceutical Care (ICPC) training program, which is a cooperative training initiative of the University of Iowa College of Pharmacy, Drake University College of Pharmacy and Health Sciences, and the Iowa Pharmacy Foundation.

(3) Other programs containing similar coursework and supplemental practice site evaluation and reengineering, approved by the department with input from a peer review advisory committee.

78.47(3) *Services.* Eligible patients may choose whether to receive the services. If patients elect to receive the services, they must receive the services from any eligible physician and pharmacist acting as a pharmaceutical case management (PCM) team. Usually the eligible physician and pharmacist will be the patient's primary physician and pharmacist. Pharmaceutical case management services are to be value-added services complementary to the basic medical services provided by the primary physician and pharmacist.

The PCM team shall provide the following services:

a. *Initial assessment.* The initial assessment shall consist of:

(1) A patient evaluation by the pharmacist, including:

1. Medication history;
2. Assessment of indications, effectiveness, safety, and compliance of medication therapy;
3. Assessment for the presence of untreated illness; and
4. Identification of medication-related problems such as unnecessary medication therapy, suboptimal medication selection, inappropriate compliance, adverse drug reactions, and need for additional medication therapy.

(2) A written report and recommendation from the pharmacist to the physician.

(3) A patient care action plan developed by the PCM team with the patient's agreement and implemented by the PCM team. Specific components of the action plan will vary based on patient needs and conditions but may include changes in medication regimen, focused patient or caregiver education, periodic assessment for changes in the patient's condition, periodic monitoring of the effectiveness of medication therapy, self-management training, provision of patient-specific educational and informational materials, compliance enhancement, and reinforcement of healthy lifestyles. An action plan must be completed for each initial assessment.

b. *New problem assessments.* These assessments are initiated when a new medication-related problem is identified. The action plan is modified and new components are implemented to address the new problem. This assessment may occur in the interim between scheduled follow-up assessments.

c. *Problem follow-up assessments.* These assessments are based on patient need and a problem identified by a prior assessment. The patient's status is evaluated at an appropriate interval. The effectiveness of the implemented action plan is determined and modifications are made as needed.

d. *Preventive follow-up assessments.* These assessments occur approximately every six months when no current medication-related problems have been identified in prior assessments. The patient is reassessed for newly developed medication-related problems and the action plan is reviewed.

This rule is intended to implement Iowa Code section 249A.4 and 2000 Iowa Acts, chapter 1228, section 9.

441—78.48(249A) Rehabilitation services for adults with chronic mental illness. Rescinded IAB 8/1/07, effective 9/5/07.

441—78.49(249A) Infant and toddler program services. Subject to the following subrules, payment shall be made for medical services provided to Medicaid eligible children by infant and toddler program providers under the infants and toddlers with disabilities program administered by the Iowa Child Health Specialty Clinics and the departments of education, public health, and human services.

78.49(1) *Covered services.* Covered services include, but are not limited to, audiology, psychological evaluation and counseling, health and nursing services, nutrition services, occupational therapy services, physical therapy services, developmental services, speech-language services, vision services, case management, and medical transportation.

78.49(2) *Case management services.* Payment shall also be approved for infant and toddler case management services subject to the following requirements:

a. Definition. "Case management" means services that will assist eligible children in gaining access to needed medical, social, educational, and other services. Case management is intended to address the complexities of coordinated service delivery for children with medical needs. The case manager should be the focus for coordinating and overseeing the effectiveness of all providers and programs in responding to the assessed need. Case management does not include the direct delivery of an underlying medical, educational, social, or other service to which an eligible child has been referred or any activities that are an integral part or an extension of the direct services.

b. Choice of provider. Children who also are eligible to receive targeted case management services under 441—Chapter 90 must choose whether to receive case management through the infant and toddler program or through 441—Chapter 90. The chosen provider must meet the requirements of this subrule.

(1) When a child resides in a medical institution, the institution is responsible for case management. The child is not eligible for any other case management services.— However, noninstitutional case management services may be provided during the last 14 days before the child's planned discharge if the child's stay in the institution has been less than 180 consecutive days. If the child has been in the institution 180 consecutive days or longer, the child may receive noninstitutional case management services during the last 60 days before the child's planned discharge.

(2) If the case management agency also provides direct services, the case management unit must be designed so that conflict of interest is addressed and does not result in self-referrals.

(3) If the costs of any part of case management services are reimbursable under another program, the costs must be allocated between those programs and Medicaid in accordance with OMB Circular No. A-87 or any related or successor guidance or regulations regarding allocation of costs.

(4) The case manager must complete a competency-based training program with content related to knowledge and understanding of eligible children, Early ACCESS rules, the nature and scope of services in Early ACCESS, and the system of payments for services, as well as case management responsibilities and strategies. The department of education or its designee shall determine whether a person has successfully completed the training.

c. Assessment. The case manager shall conduct a comprehensive assessment and periodic reassessment of an eligible child to identify all of the child's service needs, including the need for any medical, educational, social, or other services. Assessment activities are defined to include the following:

(1) Taking the child's history;

(2) Identifying the needs of the child;

(3) Gathering information from other sources, such as family members, medical providers, social workers, and educators, if necessary, to form a complete assessment of the child;

(4) Completing documentation of the information gathered and the assessment results; and

(5) Repeating the assessment every six months to determine whether the child's needs or preferences have changed.

d. Plan of care. The case manager shall develop a plan of care based on the information collected through the assessment or reassessment. The plan of care shall:

(1) Include the child's strengths and preferences;

(2) Consider the child's physical and social environment;

(3) Specify goals of providing services to the child; and

(4) Specify actions to address the child's medical, social, educational, and other service needs. These actions may include activities such as ensuring the active participation of the child and working with the child or the child's authorized health care decision maker and others to develop goals and identify a course of action to respond to the assessed needs of the child.

e. Other service components. Case management must include the following components:

(1) Contacts with the child and family. The case manager shall have face-to-face contact with the child and family within the first 30 days of service and every three months thereafter. In months in which

there is no face-to-face contact, a telephone contact between the service coordinator and the family is required.

(2) Referral and related activities to help a child obtain needed services. The case manager shall help to link the child with medical, social, or educational providers or other programs and services that are capable of providing needed services. Referral activities do not include provision of the direct services, program, or activity to which the child has been linked. Referral activities include:

1. Assisting the family in gaining access to the infant and toddler program services and other services identified in the child's plan of care.
2. Assisting the family in identifying available service providers and funding resources and documenting unmet needs and gaps in services.
3. Making referrals to providers for needed services.
4. Scheduling appointments for the child.
5. Facilitating the timely delivery of services.
6. Arranging payment for medical transportation.

(3) Monitoring and follow-up activities. Monitoring activities shall take place at least once annually for the duration of the child's eligibility, but may be conducted as frequently as necessary to ensure that the plan of care is effectively implemented and adequately addresses the needs of the child. Monitoring and follow-up activities may be with the child, family members, providers, or other entities. The purpose of these activities is to help determine:

1. Whether services are being furnished in accordance with the child's plan of care.
2. Whether the services in the plan of care are adequate to meet the needs of the child.
3. Whether there are changes in the needs or status of the child. If there are changes in the child's needs or status, follow-up activities shall include making necessary adjustments to the plan of care and to service arrangements with providers.

(4) Keeping records, including preparing reports, updating the plan of care, making notes about plan activities in the child's record, and preparing and responding to correspondence with the family and others.

f. *Documentation of case management.* For each child receiving case management, case records must document:

(1) The name of the child;
(2) The dates of case management services;
(3) The agency chosen by the family to provide the case management services;
(4) The nature, content, and units of case management services received;
(5) Whether the goals specified in the care plan have been achieved;
(6) Whether the family has declined services in the care plan;
(7) Time lines for providing services and reassessment; and
(8) The need for and occurrences of coordination with case managers of other programs.

78.49(3) *Child's eligibility.* Payable services must be provided to a child under the age of 36 months who is experiencing developmental delay or who has a condition that is known to have a high probability of resulting in developmental delay at a later date.

78.49(4) *Delivery of services.* Services must be delivered directly by the infant and toddler program provider or by a practitioner under contract with the infant and toddler program provider.

78.49(5) *Remission of nonfederal share of costs.* Payment for services shall be made only when the following conditions are met:

a. Rescinded IAB 5/10/06, effective 7/1/06.

b. The infant and toddler program provider has executed an agreement to remit the nonfederal share of the cost to the department.

c. The infant and toddler program provider shall sign and return Form 470-3816, Medicaid Billing Remittance, along with the funds remitted for the nonfederal share of the costs of the services specified on the form.

This rule is intended to implement Iowa Code section 249A.4.

441—78.50(249A) Local education agency services. Subject to the following subrules, payment shall be made for medical services provided by local education agency services providers to Medicaid members under the age of 21.

78.50(1) *Covered services.* Covered services include, but are not limited to, audiology services, behavior services, consultation services, medical transportation, nursing services, nutrition services, occupational therapy services, personal assistance, physical therapy services, psychologist services, speech-language services, social work services, vision services, and school-based clinic visit services.

a. Vaccines available through the Vaccines for Children program under Section 1928 of the Social Security Act are not covered as local education agency services. Agencies that wish to administer those vaccines to Medicaid members shall enroll in the Vaccines for Children program and obtain the vaccines from the department of public health. However, the administration of vaccines is a covered service.

b. Payment for supplies shall be approved when the supplies are incidental to the patient's care, e.g., syringes for injections, and do not exceed $25 per month. Durable medical equipment and other supplies are not covered as local education agency services.

c. To the extent that federal funding is not available under Title XIX of the Social Security Act, payment for transportation between home and school is not a covered service.

78.50(2) *Coordination services.* Rescinded IAB 12/3/08, effective 2/1/09.

78.50(3) *Delivery of services.* Services must be delivered directly by the local education agency services providers or by a practitioner under contract with the local education agency services provider.

78.50(4) *Remission of nonfederal share of costs.* Payment for services shall be made only when the following conditions are met:

a. Rescinded IAB 5/10/06, effective 7/1/06.

b. The local education agency services provider has executed an agreement to remit the nonfederal share of the cost to the department.

c. The local education agency provider shall sign and return Form 470-3816, Medicaid Billing Remittance, along with the funds remitted for the nonfederal share of the costs of the services as specified on the form.

This rule is intended to implement Iowa Code section 249A.4.

441—78.51(249A) Indian health service 638 facility services. Payment shall be made for all medically necessary services and supplies provided by a licensed practitioner at an Indian health service 638 facility, as defined at rule 441—77.45(249A), within the practitioner's scope of practice and subject to the limitations and exclusions set forth in subrule 78.1(1).

This rule is intended to implement Iowa Code section 249A.4.

441—78.52(249A) HCBS children's mental health waiver services. Payment will be approved for the following services to consumers eligible for the HCBS children's mental health waiver as established in 441—Chapter 83. All services shall be provided in accordance with the general standards in subrule 78.52(1), as well as standards provided specific to each waiver service in subrules 78.52(2) through 78.52(5).

78.52(1) *General service standards.* All children's mental health waiver services shall be provided in accordance with the following standards:

a. Services must be based on the consumer's needs as identified in the consumer's service plan developed pursuant to 441—83.127(249A).

(1) Services must be delivered in the least restrictive environment consistent with the consumer's needs.

(2) Services must include the applicable and necessary instruction, supervision, assistance and support as required by the consumer to achieve the consumer's goals.

b. Payment for services shall be made only upon departmental approval of the services. Waiver services provided before approval of the consumer's eligibility for the waiver shall not be paid.

c. Services or service components must not be duplicative.

(1) Reimbursement shall not be available under the waiver for any services that the consumer may obtain through the Iowa Medicaid program outside of the waiver.

(2) Reimbursement shall not be available under the waiver for any services that the consumer may obtain through natural supports or community resources.

(3) Services may not be simultaneously reimbursed for the same period as nonwaiver Medicaid services or other Medicaid waiver services.

(4) Costs for waiver services are not reimbursable while the consumer is in a medical institution.

78.52(2) *Environmental modifications and adaptive devices.*

a. Environmental modifications and adaptive devices include items installed or used within the consumer's home that address specific, documented health, mental health, or safety concerns.

b. A unit of service is one modification or device.

c. For each unit of service provided, the case manager shall maintain in the consumer's case file a signed statement from a mental health professional on the consumer's interdisciplinary team that the service has a direct relationship to the consumer's diagnosis of serious emotional disturbance.

78.52(3) *Family and community support services.* Family and community support services shall support the consumer and the consumer's family by the development and implementation of strategies and interventions that will result in the reduction of stress and depression and will increase the consumer's and the family's social and emotional strength.

a. Dependent on the needs of the consumer and the consumer's family members individually or collectively, family and community support services may be provided to the consumer, to the consumer's family members, or to the consumer and the family members as a family unit.

b. Family and community support services shall be provided under the recommendation and direction of a mental health professional who is a member of the consumer's interdisciplinary team pursuant to 441—83.127(249A).

c. Family and community support services shall incorporate recommended support interventions and activities, which may include the following:

(1) Developing and maintaining a crisis support network for the consumer and for the consumer's family.

(2) Modeling and coaching effective coping strategies for the consumer's family members.

(3) Building resilience to the stigma of serious emotional disturbance for the consumer and the family.

(4) Reducing the stigma of serious emotional disturbance by the development of relationships with peers and community members.

(5) Modeling and coaching the strategies and interventions identified in the consumer's crisis intervention plan as defined in 441—24.1(225C) for life situations with the consumer's family and in the community.

(6) Developing medication management skills.

(7) Developing personal hygiene and grooming skills that contribute to the consumer's positive self-image.

(8) Developing positive socialization and citizenship skills.

d. Family and community support services may include an amount not to exceed $1500 per consumer per year for transportation within the community and purchase of therapeutic resources. Therapeutic resources may include books, training materials, and visual or audio media.

(1) The interdisciplinary team must identify the transportation or therapeutic resource as a support need.

(2) The annual amount available for transportation and therapeutic resources must be listed in the consumer's service plan.

(3) The consumer's parent or legal guardian shall submit a signed statement that the transportation or therapeutic resource cannot be provided by the consumer or the consumer's family or legal guardian.

(4) The consumer's Medicaid targeted case manager shall maintain a signed statement that potential community resources are unavailable and shall list the community resources contacted to fund the transportation or therapeutic resource.

(5) The transportation or therapeutic resource must not be otherwise eligible for Medicaid reimbursement.

(6) Family and community support services providers shall maintain records to:

1. Ensure that the transportation and therapeutic resources provided to not exceed the maximum amount authorized; and

2. Support the annual reporting requirements in 441—subparagraph 79.1(15)*"a"*(1).

e. The following components are specifically excluded from family and community support services:

(1) Vocational services.

(2) Prevocational services.

(3) Supported employment services.

(4) Room and board.

(5) Academic services.

(6) General supervision and consumer care.

f. A unit of family and community support services is one hour.

78.52(4) *In-home family therapy.* In-home family therapy provides skilled therapeutic services to the consumer and family that will increase their ability to cope with the effects of serious emotional disturbance on the family unit and the familial relationships. The service must support the family by the development of coping strategies that will enable the consumer to continue living within the family environment.

a. The goal of in-home family therapy is to maintain a cohesive family unit.

b. In-home family therapy is exclusive of and cannot serve as a substitute for individual therapy, family therapy, or other mental health therapy that may be obtained through the Iowa Plan or other funding sources.

c. A unit of in-home family therapy service is one hour. Any period less than one hour shall be prorated.

78.52(5) *Respite care services.* Respite care services are services provided to the consumer that give temporary relief to the usual caregiver and provide all the necessary care that the usual caregiver would provide during that period. The "usual caregiver" means a person or persons who reside with the consumer and are available on a 24-hour-per-day basis to assume responsibility for the care of the consumer.

a. Respite care shall not be provided to consumers during the hours in which the usual caregiver is employed, except when the consumer is attending a camp.

b. The usual caregiver cannot be absent from the home for more than 14 consecutive days during respite provision.

c. Staff-to-consumer ratios shall be appropriate to the individual needs of the consumer as determined by the consumer's interdisciplinary team. The team shall determine the type of respite care to be provided according to these definitions:

(1) Basic individual respite is provided on a ratio of one staff to one consumer. The consumer does not have specialized medical needs that require the direct services of a registered nurse or licensed practical nurse.

(2) Specialized respite is provided on a ratio of one or more nursing staff to one consumer. The consumer has specialized medical needs that require the direct services of a registered nurse or licensed practical nurse.

(3) Group respite is provided on a ratio of one staff to two or more consumers receiving respite. These consumers do not have specialized medical needs that require the direct services of a registered nurse or licensed practical nurse.

d. Respite services provided for a period exceeding 24 consecutive hours to three or more consumers who require nursing care because of a mental or physical condition must be provided by a health care facility licensed under Iowa Code chapter 135C.

e. Respite services provided outside the consumer's home shall not be reimbursable if the living unit where respite care is provided is reserved for another person on a temporary leave of absence.

f. A unit of service is one hour.

This rule is intended to implement Iowa Code section 249A.4 and 2005 Iowa Acts, chapter 167, section 13, and chapter 117, section 3.

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1 Effective date of 78.3 and 78.31 delayed 70 days by the Administrative Rules Review Committee at its January 1, 1988 meeting.

2 Effective date of 4/1/90 delayed 70 days by the Administrative Rules Review Committee at its March 12, 1990, meeting.

3 Effective date of 4/1/91 delayed until adjournment of the 1991 session of the General Assembly by the Administrative Rules Review Committee at its meeting held February 12, 1991.

4 Effective date of 3/1/92 delayed until adjournment of the 1992 General Assembly by the Administrative Rules Review Committee at its meeting held February 3, 1992.

5 At a special meeting held January 24, 2002, the Administrative Rules Review Committee voted to delay until adjournment of the 2002 Session of the General Assembly the effective date of amendments published in the February 6, 2002, Iowa Administrative Bulletin as **ARC 1365B**.

6 Effective date of 12/15/02 delayed 70 days by the Administrative Rules Review Committee at its December 10, 2002, meeting.

7 July 1, 2009, effective date of amendments to 78.27(2)*"d"* delayed 70 days by the Administrative Rules Review Committee at a special meeting held June 25, 2009.

CHAPTER 79
OTHER POLICIES RELATING TO PROVIDERS OF MEDICAL AND REMEDIAL CARE

[Prior to 7/1/83, Social Services[770] Ch 79]

441—79.1(249A) Principles governing reimbursement of providers of medical and health services. The basis of payment for services rendered by providers of services participating in the medical assistance program is either a system based on the provider's allowable costs of operation or a fee schedule. Generally, institutional types of providers such as hospitals and nursing facilities are reimbursed on a cost-related basis, and practitioners such as physicians, dentists, optometrists, and similar providers are reimbursed on the basis of a fee schedule. Payments to health care providers that are owned or operated by Iowa state or non-state government entities shall not exceed the provider's cost of providing services to Medicaid members. Providers of service must accept reimbursement based upon the department's methodology without making any additional charge to the member.

79.1(1) *Types of reimbursement.*

a. Prospective cost-related. Providers are reimbursed on the basis of a per diem rate calculated prospectively for each participating provider based on reasonable and proper costs of operation. The rate is determined by establishing a base year per diem rate to which an annual index is applied.

b. Retrospective cost-related. Providers are reimbursed on the basis of a per diem rate calculated retrospectively for each participating provider based on reasonable and proper costs of operation with suitable retroactive adjustments based on submission of financial and statistical reports by the provider. The retroactive adjustment represents the difference between the amount received by the provider during the year for covered services and the amount determined in accordance with an accepted method of cost apportionment (generally the Medicare principles of apportionment) to be the actual cost of service rendered medical assistance recipients.

c. Fee schedules. Fees for the various procedures involved are determined by the department with advice and consultation from the appropriate professional group. The fees are intended to reflect the amount of resources (time, training, experience) involved in each procedure. Individual adjustments will be made periodically to correct any inequity or to add new procedures or eliminate or modify others. If product cost is involved in addition to service, reimbursement is based either on a fixed fee, wholesale cost, or on actual acquisition cost of the product to the provider, or product cost is included as part of the fee schedule. Providers on fee schedules are reimbursed the lower of:

(1) The actual charge made by the provider of service.

(2) The maximum allowance under the fee schedule for the item of service in question.

Payment levels for fee schedule providers of service will be increased on an annual basis by an economic index reflecting overall inflation as well as inflation in office practice expenses of the particular provider category involved to the extent data is available. Annual increases will be made beginning July 1, 1988.

There are some variations in this methodology which are applicable to certain providers. These are set forth below in subrules 79.1(3) to 79.1(9) and 79.1(15).

Fee schedules in effect for the providers covered by fee schedules can be obtained from the department's Web site at: http://www.ime.state.ia.us/Reports_Publications/FeeSchedules.html.

d. Fee for service with cost settlement. Effective July 1, 2009, providers of case management services shall be reimbursed on the basis of a payment rate for a 15-minute unit of service based on reasonable and proper costs for service provision. The fee will be determined by the department with advice and consultation from the appropriate professional group and will reflect the amount of resources involved in service provision.

(1) Providers are reimbursed throughout each fiscal year on the basis of a projected unit rate for each participating provider. The projected rate is based on reasonable and proper costs of operation, pursuant to federally accepted reimbursement principles (generally Medicare or OMB A-87 principles).

(2) Payments are subject to annual retrospective cost settlement based on submission of actual costs of operation and service utilization data by the provider on Form 470-0664, Financial and Statistical

Report. The cost settlement represents the difference between the amount received by the provider during the year for covered services and the amount supported by the actual costs of doing business, determined in accordance with an accepted method of cost appointment.

(3) The methodology for determining the reasonable and proper cost for service provision assumes the following:

1. The indirect administrative costs shall be limited to 20 percent of other costs.
2. Mileage shall be reimbursed at a rate no greater than the state employee rate.
3. The rates a provider may charge are subject to limits established at 79.1(2).
4. Costs of operation shall include only those costs that pertain to the provision of services which are authorized under rule 441—90.3(249A).

e. Retrospectively limited prospective rates. Providers are reimbursed on the basis of a rate for a unit of service calculated prospectively for each participating provider (and, for supported community living daily rates, for each consumer or site) based on projected or historical costs of operation, subject to the maximums listed in subrule 79.1(2) and to retrospective adjustment based on actual, current costs of operation so as not to exceed reasonable and proper costs by more than 2.5 percent.

The prospective rates for new providers who have not submitted six months of cost reports will be based on a projection of the provider's reasonable and proper costs of operation until the provider has submitted an annual cost report that includes a minimum of six months of actual costs. The prospective rates paid established providers who have submitted an annual report with a minimum of a six-month history are based on reasonable and proper costs in a base period and are adjusted annually for inflation. The prospective rates paid to both new and established providers are subject to the maximums listed in subrule 79.1(2) and to retrospective adjustment based on the provider's actual, current costs of operation as shown by financial and statistical reports submitted by the provider, so as not to exceed reasonable and proper costs actually incurred by more than 2.5 percent.

f. Contractual rate. Providers are reimbursed on a basis of costs incurred pursuant to a contract between the provider and subcontractor.

g. Retrospectively adjusted prospective rates. Critical access hospitals are reimbursed prospectively, with retrospective adjustments based on annual cost reports submitted by the hospital at the end of the hospital's fiscal year. The retroactive adjustment equals the difference between the reasonable costs of providing covered services to eligible fee-for-service Medicaid members (excluding members in managed care), determined in accordance with Medicare cost principles, and the Medicaid reimbursement received. Amounts paid that exceed reasonable costs shall be recovered by the department. See paragraphs 79.1(5)*"aa"* and 79.1(16)*"h."*

h. Indian health service 638 facilities. Indian health service 638 facilities as defined at rule 441—77.45(249A) are paid a special daily base encounter rate for all Medicaid-covered services rendered to American Indian or Alaskan native persons who are Medicaid-eligible. This rate is updated periodically and published in the Federal Register after being approved by the Office of Management and Budget. Indian health service 638 facilities may bill only one charge per patient per day for services provided to American Indians or Alaskan natives, which shall include all services provided on that day.

Services provided to Medicaid recipients who are not American Indians or Alaskan natives will be paid at the fee schedule allowed by Iowa Medicaid for the services provided and will be billed separately by CPT code on the CMS-1500 Health Insurance Claim Form. Claims for services provided to Medicaid recipients who are not American Indians or Alaskan natives must be submitted by the individual practitioner enrolled in the Iowa Medicaid program, but may be paid to the facility if the provider agreement so stipulates.

79.1(2) *Basis of reimbursement of specific provider categories.*

Provider category	Basis of reimbursement	Upper limit
Advanced registered nurse practitioners	Fee schedule	Fee schedule in effect 6/30/08 plus 1%.
Ambulance	Fee schedule	Ground ambulance: Fee schedule in effect 6/30/08 plus 1%. Air ambulance: Fee schedule in effect 6/30/08 plus 1%.
Ambulatory surgical centers	Fee schedule. See 79.1(3)	Fee schedule in effect 6/30/08 plus 1%.
Area education agencies	Fee schedule	Fee schedule in effect 6/30/00 plus 0.7%.
Audiologists	Fee schedule	Fee schedule in effect 6/30/08 plus 1%.
Behavioral health services	Fee schedule	Fee schedule.
Birth centers	Fee schedule	Fee schedule in effect 6/30/08 plus 1%.
Chiropractors	Fee schedule	Fee schedule in effect 6/30/08 plus 1%.
Clinics	Fee schedule	Maximum physician reimbursement rate.
Community mental health centers and providers of mental health services to county residents pursuant to a waiver approved under Iowa Code section 225C.7(3)	Retrospective cost-related. See 79.1(25)	100% of reasonable Medicaid cost as determined by Medicare cost reimbursement principles.
Dentists	Fee schedule	Fee schedule in effect 6/30/08 plus 1%.
Durable medical equipment, prosthetic devices and medical supply dealers	Fee schedule. See 79.1(4)	Fee schedule in effect 6/30/08 plus 1%.
Family planning clinics	Fee schedule	Beginning 2/1/10, fee schedule in effect 6/30/09 plus 5%.
Federally qualified health centers	Retrospective cost-related See 441—88.14(249A)	1. Prospective payment rate as required by the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA 2000) or an alternative methodology allowed thereunder, as specified in "2" below. 2. 100% of reasonable cost as determined by Medicare cost reimbursement principles. 3. In the case of services provided pursuant to a contract between an FQHC and a managed care organization (MCO), reimbursement from the MCO shall be supplemented to achieve "1" or "2" above.
HCBS waiver service providers, including:		Except as noted, limits apply to all waivers that cover the named provider.

Provider category	Basis of reimbursement	Upper limit
1. Adult day care	Fee schedule	For AIDS/HIV, brain injury, elderly, and ill and handicapped waivers: Veterans Administration contract rate or $22.12 per half-day, $44.03 per full day, or $66.03 per extended day if no Veterans Administration contract. For mental retardation waiver: County contract rate or, in the absence of a contract rate, $29.47 per half-day, $58.83 per full day, or $75.00 per extended day.
2. Emergency response system	Fee schedule	Initial one-time fee $49.53. Ongoing monthly fee $38.52.
3. Home health aides	Retrospective cost-related	For AIDS/HIV, elderly, and ill and handicapped waivers: Lesser of maximum Medicare rate in effect 6/30/08 plus 1% or maximum Medicaid rate in effect 6/30/08 plus 1%. For mental retardation waiver: Lesser of maximum Medicare rate in effect 6/30/08 plus 1% or maximum Medicaid rate in effect 6/30/08 plus 1%, converted to an hourly rate.
4. Homemakers	Fee schedule	Maximum of $19.81 per hour.
5. Nursing care	For elderly and mental retardation waivers: Fee schedule as determined by Medicare.	For elderly waiver: $82.92 per visit. For mental retardation waiver: Lesser of maximum Medicare rate in effect 6/30/08 plus 1% or maximum Medicaid rate in effect 6/30/08 plus 1%, converted to an hourly rate.
	For AIDS/HIV and ill and handicapped waivers: Agency's financial and statistical cost report and Medicare percentage rate per visit.	For AIDS/HIV and ill and handicapped waivers: Cannot exceed $82.92 per visit.
6. Respite care when provided by:		
Home health agency:		
Specialized respite	Cost-based rate for nursing services provided by a home health agency	Lesser of maximum Medicare rate in effect 6/30/08 plus 1% or maximum Medicaid rate in effect 6/30/08 plus 1%, converted to an hourly rate, not to exceed $296.94 per day.

Provider category	Basis of reimbursement	Upper limit
Basic individual respite	Cost-based rate for home health aide services provided by a home health agency	Lesser of maximum Medicare rate in effect 6/30/08 plus 1% or maximum Medicaid rate in effect 6/30/08 plus 1%, converted to an hourly rate, not to exceed $296.94 per day.
Group respite	Retrospectively limited prospective rates. See 79.1(15)	$13.12 per hour not to exceed $296.94 per day.
Home care agency:		
Specialized respite	Retrospectively limited prospective rates. See 79.1(15)	$33.75 per hour not to exceed $296.94 per day.
Basic individual respite	Retrospectively limited prospective rates. See 79.1(15)	$18.01 per hour not to exceed $296.94 per day.
Group respite	Retrospectively limited prospective rates. See 79.1(15)	$13.12 per hour not to exceed $296.94 per day.
Nonfacility care:		
Specialized respite	Retrospectively limited prospective rates. See 79.1(15)	$33.75 per hour not to exceed $296.94 per day.
Basic individual respite	Retrospectively limited prospective rates. See 79.1(15)	18.01 per hour not to exceed $296.94 per day.
Group respite	Retrospectively limited prospective rates. See 79.1(15)	$13.12 per hour not to exceed $296.94 per day.
Facility care:		
Hospital or nursing facility providing skilled care	Fee schedule	$13.12 per hour not to exceed daily per diem for skilled nursing facility level of care.
Nursing facility	Fee schedule	$13.12 per hour not to exceed daily per diem for nursing facility level of care.
Camps	Retrospectively limited prospective rates. See 79.1(15)	$13.12 per hour not to exceed $296.94 per day.
Adult day care	Fee schedule	$13.12 per hour not to exceed rate for regular adult day care services.
Intermediate care facility for the mentally retarded	Fee schedule	$13.12 per hour not to exceed daily per diem for ICF/MR level of care.
Residential care facilities for persons with mental retardation	Fee schedule	$13.12 per hour not to exceed contractual daily per diem.
Foster group care	Fee schedule	$13.12 per hour not to exceed daily per diem rate for child welfare services.
Child care facilities	Fee schedule	$13.12 per hour not to exceed contractual daily per diem.
7. Chore service	Fee schedule	$7.71 per half hour.
8. Home-delivered meals	Fee schedule	$7.71 per meal. Maximum of 14 meals per week.

Provider category	Basis of reimbursement	Upper limit
9. Home and vehicle modification	Fee schedule	For elderly waiver: $1010 lifetime maximum. For mental retardation waiver: $5050 lifetime maximum. For brain injury, ill and handicapped and physical disability waivers: $6060 per year.
10. Mental health outreach providers	Fee schedule	On-site Medicaid reimbursement rate for center or provider. Maximum of 1440 units per year.
11. Transportation	Fee schedule	County contract rate or, in the absence of a contract rate, the rate set by the area agency on aging.
12. Nutritional counseling	Fee schedule	$8.25 per unit.
13. Assistive devices	Fee schedule	$110.05 per unit.
14. Senior companion	Fee schedule	$6.59 per hour.
15. Consumer-directed attendant care provided by:		
Agency (other than an elderly waiver assisted living program)	Fee agreed upon by consumer and provider	$20.20 per hour not to exceed the daily rate of $116.72 per day.
Assisted living program (for elderly waiver only)	Fee agreed upon by consumer and provider	For elderly waiver only: $1,117 per calendar month. Rate must be prorated per day for a partial month, at a rate not to exceed $36.71 per day.
Individual	Fee agreed upon by consumer and provider	$13.47 per hour not to exceed the daily rate of $78.56 per day.
16. Counseling		
Individual:	Fee schedule	$10.79 per unit.
Group:	Fee schedule	$43.14 per hour.
17. Case management	Fee schedule with cost settlement. See 79.1(1)*"d."*	For brain injury waiver: Retrospective cost-settled rate. For elderly waiver: Quarterly revision of reimbursement rate as necessary to maintain projected expenditures within the amounts budgeted under the appropriations made for the medical assistance program for the fiscal year.
18. Supported community living	Retrospectively limited prospective rates. See 79.1(15)	$34.98 per hour, $78.88 per day not to exceed the maximum daily ICF/MR per diem.
19. Supported employment:		
Activities to obtain a job:		
Job development	Fee schedule	$909 per unit (job placement). Maximum of two units per 12 months.

Provider category	Basis of reimbursement	Upper limit
Employer development	Fee schedule	$909 per unit (job placement). Maximum of two units per 12 months.
Enhanced job search	Retrospectively limited prospective rates. See 79.1(15)	Maximum of $34.98 per hour and 26 hours per 12 months.
Supports to maintain employment	Retrospectively limited prospective rates. See 79.1(15)	Maximum of $34.98 per hour for all activities other than personal care and services in an enclave setting. Maximum of $19.81 per hour for personal care. Maximum of $6.19 per hour for services in an enclave setting. Total not to exceed $2,883.71 per month. Maximum of 40 units per week.
20. Specialized medical equipment	Fee schedule	$6060 per year.
21. Behavioral programming	Fee schedule	$10.79 per 15 minutes.
22. Family counseling and training	Fee schedule	$43.14 per hour.
23. Prevocational services	Fee schedule	For the brain injury waiver: $37.44 per day. For the mental retardation waiver: County contract rate or, in absence of a contract rate, $48.22 per day.
24. Interim medical monitoring and treatment:		
Home health agency (provided by home health aide)	Cost-based rate for home health aide services provided by a home health agency	Lesser of maximum Medicare rate in effect 6/30/08 plus 1% or maximum Medicaid rate in effect 6/30/08 plus 1%, converted to an hourly rate.
Home health agency (provided by nurse)	Cost-based rate for nursing services provided by a home health agency	Lesser of maximum Medicare rate in effect 6/30/08 plus 1% or maximum Medicaid rate in effect 6/30/08 plus 1%, converted to an hourly rate.
Child development home or center	Fee schedule	$13.12 per hour.
25. Residential-based supported community living	Retrospectively limited prospective rates. See 79.1(15)	The maximum daily per diem for ICF/MR.
26. Day habilitation	Fee schedule	County contract rate or, in the absence of a contract rate, $13.21 per hour, $32.15 per half-day, or $64.29 per day.
27. Environmental modifications and adaptive devices	Fee schedule	$6060 per year.
28. Family and community support services	Retrospectively limited prospective rates. See 79.1(15)	$34.98 per hour.
29. In-home family therapy	Fee schedule	$93.63 per hour.
30. Financial management services	Fee schedule	$65.65 per enrolled consumer per month.
31. Independent support broker	Rate negotiated by consumer	$15.15 per hour.

Provider category	Basis of reimbursement	Upper limit
32. Self-directed personal care	Rate negotiated by consumer	Determined by consumer's individual budget.
33. Self-directed community supports and employment	Rate negotiated by consumer	Determined by consumer's individual budget.
34. Individual-directed goods and services	Rate negotiated by consumer	Determined by consumer's individual budget.
Hearing aid dispensers	Fee schedule plus product acquisition cost	Fee schedule in effect 6/30/08 plus 1%.
Home- and community-based habilitation services:		
1. Case management	Fee schedule with cost settlement. See 79.1(1)*"d."*	Retrospective cost-settled rate.
2. Home-based habilitation	Retrospective cost-related. See 79.1(24)	$46.70 per hour or $105.97 per day.
3. Day habilitation	Retrospective cost-related. See 79.1(24)	$13.21 per hour, $32.15 per half-day, or $64.29 per day.
4. Prevocational habilitation	Retrospective cost-related. See 79.1(24)	$9.91 per hour, $24.11 per half-day, or $48.22 per day.
5. Supported employment:		
Activities to obtain a job:		
Job development	Fee schedule	$909 per unit (job placement). Maximum of two units per 12 months.
Employer development	Fee schedule	$909 per unit (job placement). Maximum of two units per 12 months.
Enhanced job search	Retrospective cost-related. See 79.1(24)	Maximum of $34.98 per hour and 26 hours per 12 months.
Supports to maintain employment	Retrospective cost-related. See 79.1(24)	$6.19 per hour for services in an enclave setting; $19.81 per hour for personal care; and $34.98 per hour for all other services. Total not to exceed $2,883.71 per month. Maximum of 40 units per week.
Home health agencies		
1. Skilled nursing, physical therapy, occupational therapy, home health aide, and medical social services; home health care for maternity patients and children	Retrospective cost-related	Lesser of maximum Medicare rate in effect 6/30/08 plus 1% or maximum Medicaid rate in effect 6/30/08 plus 1%.
2. Private duty nursing and personal care for persons aged 20 or under	Interim fee schedule with retrospective cost settlement	Medicaid rate in effect 6/30/08 plus 1%.
3. Administration of vaccines	Physician fee schedule	Physician fee schedule rate.
Hospices	Fee schedule as determined by Medicare	Medicare cap. (See 79.1(14)*"d"*)
Hospitals (Critical access)	Retrospectively adjusted prospective rates. See 79.1(1)*"g"* and 79.1(5)	The reasonable cost of covered services provided to medical assistance recipients or the upper limits for other hospitals, whichever is greater.

Provider category	Basis of reimbursement	Upper limit
Hospitals (Inpatient)	Prospective reimbursement. See 79.1(5)	Reimbursement rate in effect 6/30/08 plus 1%.
Hospitals (Outpatient)	Prospective reimbursement or hospital outpatient fee schedule. See 79.1(16)*"c"*	Ambulatory payment classification rate or hospital outpatient fee schedule rate in effect 7/01/08.
Independent laboratories	Fee schedule. See 79.1(6)	Medicare fee schedule. See 79.1(6)
Indian health service 638 facilities	1. Base rate as determined by the United States Office of Management and Budget for outpatient visits for American Indian and Alaskan native members.	1. Office of Management and Budget rate published in the Federal Register for outpatient visit rate.
	2. Fee schedule for service provided for all other Medicaid members.	2. Fee schedule.
Infant and toddler program providers	Fee schedule	Fee schedule.
Intermediate care facilities for the mentally retarded	Prospective reimbursement. See 441—82.5(249A)	Eightieth percentile of facility costs as calculated from annual cost reports.
Lead inspection agency	Fee schedule	Fee schedule in effect 6/30/08 plus 1%.
Local education agency services providers	Fee schedule	Fee schedule.
Maternal health centers	Reasonable cost per procedure on a prospective basis as determined by the department based on financial and statistical data submitted annually by the provider group	Fee schedule in effect 6/30/08 plus 1%.
Nursing facilities: 1. Nursing facility care	Prospective reimbursement. See 441—subrule 81.10(1) and 441—81.6(249A). The percentage of the median used to calculate the direct care excess payment allowance ceiling under 441—81.6(16)*"d"*(1)"1" and (2)"1" is 95% of the patient-day-weighted median. The percentage of the difference used to calculate the direct care excess payment allowance is 0%. The percentage of the median used to calculate the direct care excess payment allowance limit is 10% of the patient-day-weighted median. The percentage of the median used to calculate the non-direct care excess payment allowance ceiling under 441—81.6(16)*"d"*(1)"2" and (2)"2" is 96% of the patient-day-weighted median.	See 441—subrules 81.6(4) and 81.6(14) and paragraph 81.6(16)*"f."* The direct care rate component limit under 441—81.6(16)*"f"*(1) and (2) is 120% of the patient-day-weighted median. The non-direct care rate component limit under 441—81.6(16)*"f"* (1) and (2) is 110% of the patient-day-weighted median.

Provider category	Basis of reimbursement	Upper limit
	The percentage of the difference used to calculate the non-direct care excess payment allowance limit is 0%. The percentage of the median used to calculate the non-direct care excess payment allowance limit is 8% of the patient-day-weighted median.	
2. Hospital-based, Medicare-certified nursing care	Prospective reimbursement. See 441—subrule 81.10(1) and 441—81.6(249A). The percentage of the median used to calculate the direct care excess payment allowance ceiling under 441—81.6(16)*"d"*(3)"1" is 95% of the patient-day-weighted median. The percentage of the difference used to calculate the direct care excess payment allowance is 0%. The percentage of the median used to calculate the direct care excess payment allowance limit is 10% of the patient-day-weighted median. The percentage of the median used to calculate the non-direct care excess payment allowance ceiling under 441—81.6(16)*"d"*(3)"2" is 96% of the patient-day-weighted median. The percentage of the difference used to calculate the non-direct care excess payment allowance limit is 0%. The percentage of the median used to calculate the non-direct care excess payment allowance limit is 8% of the patient-day-weighted median.	See 441—subrules 81.6(4) and 81.6(14) and paragraph 81.6(16)*"f."* The direct care rate component limit under 441—81.6(16)*"f"*(3) is 120% of the patient-day-weighted median. The non-direct care rate component limit under 441—81.6(16)*"f"*(3) is 110% of the patient-day-weighted median.
Occupational therapists	Fee schedule	Medicare fee schedule.
Opticians	Fee schedule. Fixed fee for lenses and frames; other optical materials at product acquisition cost	Fee schedule in effect 6/30/08 plus 1%.
Optometrists	Fee schedule. Fixed fee for lenses and frames; other optical materials at product acquisition cost	Fee schedule in effect 6/30/08 plus 1%.
Orthopedic shoe dealers	Fee schedule	Fee schedule in effect 6/30/08 plus 1%.
Pharmaceutical case management	Fee schedule. See 79.1(18)	Refer to 79.1(18).
Physical therapists	Fee schedule	Fee schedule in effect 6/30/08 plus 1%.
Physicians (doctors of medicine or osteopathy)	Fee schedule. See 79.1(7)*"a"*	Fee schedule in effect 6/30/08 plus 1%.
Anesthesia services	Fee schedule	Fee schedule in effect 6/30/08 plus 1%.

Provider category	Basis of reimbursement	Upper limit
Podiatrists	Fee schedule	Fee schedule in effect 6/30/08 plus 1%.
Prescribed drugs	See 79.1(8)	$4.57 dispensing fee. (See 79.1(8)*"a," "b,"* and *"e."*)
Psychiatric medical institutions for children		
1. Inpatient	Retrospective cost-related	Effective July 1, 2009, actual cost not to exceed a maximum for non-state-owned providers of 103% of patient-day-weighted average costs of non-state-owned providers located within Iowa.
2. Outpatient day treatment	Fee schedule	Fee schedule in effect 6/30/08 plus 1%.
Psychologists	Fee schedule	Fee schedule in effect 6/30/08 plus 1%.
Rehabilitation agencies	Fee schedule	Medicare fee schedule; refer to 79.1(21).
Remedial services	Retrospective cost-related plus 1%. See 79.1(23)	110% of average cost.
Rural health clinics	Retrospective cost-related See 441—88.14(249A)	1. Prospective payment rate as required by the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA 2000) or an alternative methodology allowed thereunder, as specified in "2" below. 2. 100% of reasonable cost as determined by Medicare cost reimbursement principles. 3. In the case of services provided pursuant to a contract between an RHC and a managed care organization (MCO), reimbursement from the MCO shall be supplemented to achieve "1" or "2" above.
Screening centers	Fee schedule	Reimbursement rate for center in effect 6/30/08 plus 1%.
State-operated institutions	Retrospective cost-related	
Targeted case management providers	Fee for service with cost settlement. See 79.1(1)*"d."*	Retrospective cost-settled rate.

79.1(3) *Ambulatory surgical centers.*

a. Payment is made for facility services on a fee schedule determined by the department and published on the department's Web site. These fees are grouped into nine categories corresponding to the difficulty or complexity of the surgical procedure involved.

b. Services of the physician or the dentist are reimbursed on the basis of a fee schedule (see paragraph 79.1(1)*"c"*). This payment is made directly to the physician or dentist.

79.1(4) *Durable medical equipment, prosthetic devices, medical supply dealers.* Fees for durable medical appliances, prosthetic devices and medical supplies are developed from several pricing sources

and are based on pricing appropriate to the date of service; prices are developed using prior calendar year price information. The average wholesale price from all available sources is averaged to determine the fee for each item. Payment for used equipment will be no more than 80 percent of the purchase allowance. For supplies, equipment, and servicing of standard wheelchairs, standard hospital beds, enteral nutrients, and enteral and parenteral supplies and equipment, the fee for payment shall be the lowest price for which the devices are widely and consistently available in a locality.

79.1(5) *Reimbursement for hospitals.*

a. Definitions.

"Adolescent" shall mean a Medicaid patient 17 years or younger.

"Adult" shall mean a Medicaid patient 18 years or older.

"Average daily rate" shall mean the hospital's final payment rate multiplied by the DRG weight and divided by the statewide average length of stay for a DRG.

"Base year cost report," for rates effective October 1, 2005, shall mean the hospital's cost report with fiscal year end on or after January 1, 2004, and before January 1, 2005, except as noted in 79.1(5)*"x."* Cost reports shall be reviewed using Medicare's cost reporting and cost reimbursement principles for those cost reporting periods.

"Blended base amount" shall mean the case-mix-adjusted, hospital-specific operating cost per discharge associated with treating Medicaid patients, plus the statewide average case-mix-adjusted operating cost per Medicaid discharge, divided by two. This base amount is the value to which payments for inflation and capital costs are added to form a final payment rate. The costs of hospitals receiving reimbursement as critical access hospitals during any of the period included in the base-year cost report shall not be used in determining the statewide average case-mix-adjusted operating cost per Medicaid discharge.

For purposes of calculating the disproportionate share rate only, a separate blended base amount shall be determined for any hospital that qualifies for a disproportionate share payment only as a children's hospital based on a distinct area or areas serving children. This separate amount shall be determined using only the case-mix-adjusted operating cost per discharge associated with treating Medicaid patients in the distinct area or areas of the hospital where services are provided predominantly to children under 18 years of age.

"Blended capital costs" shall mean case-mix-adjusted hospital-specific capital costs, plus statewide average capital costs, divided by two. The costs of hospitals receiving reimbursement as critical access hospitals during any of the period of time included in the base-year cost report shall not be used in determining the statewide average capital costs.

For purposes of calculating the disproportionate share rate only, separate blended capital costs shall be determined for any hospital that qualifies for a disproportionate share payment only as a children's hospital based on a distinct area or areas serving children, using only the capital costs related to the distinct area or areas of the hospital where services are provided predominantly to children under 18 years of age.

"Capital costs" shall mean an add-on to the blended base amount, which shall compensate for Medicaid's portion of capital costs. Capital costs for buildings, fixtures and movable equipment are defined in the hospital's base year cost report, are case-mix adjusted, are adjusted to reflect 80 percent of allowable costs, and are adjusted to be no greater than one standard deviation off the mean Medicaid blended capital rate.

For purposes of calculating the disproportionate share rate only, separate capital costs shall be determined for any hospital that qualifies for a disproportionate share payment only as a children's hospital based on a distinct area or areas serving children, using only the base year cost report information related to the distinct area or areas of the hospital where services are provided predominantly to children under 18 years of age.

"Case-mix adjusted" shall mean the division of the hospital-specific base amount or other applicable components of the final payment rate by the hospital-specific case-mix index. For purposes of calculating the disproportionate share rate only, a separate case-mix adjustment shall be determined for any hospital that qualifies for a disproportionate share payment only as a children's hospital based on a distinct area

or areas serving children, using the base amount or other applicable component for the distinct area or areas of the hospital where services are provided predominantly to children under 18 years of age.

"Case-mix index" shall mean an arithmetical index measuring the relative average costliness of cases treated in a hospital compared to the statewide average. For purposes of calculating the disproportionate share rate only, a separate case-mix index shall be determined for any hospital that qualifies for a disproportionate share payment only as a children's hospital based on a distinct area or areas serving children, using the average costliness of cases treated in the distinct area or areas of the hospital where services are provided predominantly to children under 18 years of age.

"Children's hospitals" shall mean hospitals with inpatients predominantly under 18 years of age. For purposes of qualifying for disproportionate share payments from the graduate medical education and disproportionate share fund, a children's hospital is defined as a duly licensed hospital that:

1. Either provides services predominantly to children under 18 years of age or includes a distinct area or areas that provide services predominantly to children under 18 years of age, and
2. Is a voting member of the National Association of Children's Hospitals and Related Institutions.

"Cost outlier" shall mean cases which have an extraordinarily high cost as established in 79.1(5)*"f,"* so as to be eligible for additional payments above and beyond the initial DRG payment.

"Critical access hospital" or *"CAH"* means a hospital licensed as a critical access hospital by the department of inspections and appeals pursuant to rule 481—51.52(135B).

"Diagnosis-related group (DRG)" shall mean a group of similar diagnoses combined based on patient age, procedure coding, comorbidity, and complications.

"Direct medical education costs" shall mean costs directly associated with the medical education of interns and residents or other medical education programs, such as a nursing education program or allied health programs, conducted in an inpatient setting, that qualify for payment as medical education costs under the Medicare program. The amount of direct medical education costs is determined from the hospital base year cost reports and is inflated and case-mix adjusted in determining the direct medical education rate. Payment for direct medical education costs shall be made from the graduate medical education and disproportionate share fund and shall not be added to the reimbursement for claims.

For purposes of calculating the disproportionate share rate only, separate direct medical education costs shall be determined for any hospital that qualifies for a disproportionate share payment only as a children's hospital based on a distinct area or areas serving children, using only costs associated with the distinct area or areas in the hospital where services are provided predominantly to children under 18 years of age.

"Direct medical education rate" shall mean a rate calculated for a hospital reporting medical education costs on the Medicare cost report (CMS 2552). The rate is calculated using the following formula: Direct medical education costs are multiplied by inflation factors. The result is divided by the hospital's case-mix index, then is further divided by net discharges.

For purposes of calculating the disproportionate share rate only, a separate direct medical education rate shall be determined for any hospital that qualifies for a disproportionate share payment only as a children's hospital based on a distinct area or areas serving children, using the direct medical education costs, case-mix index, and net discharges of the distinct area or areas in the hospital where services are provided predominantly to children under 18 years of age.

"Disproportionate share payment" shall mean a payment that shall compensate for treatment of a disproportionate share of poor patients. On or after July 1, 1997, the disproportionate share payment shall be made directly from the graduate medical education and disproportionate share fund and shall not be added to the reimbursement for claims with discharge dates on or after July 1, 1997.

"Disproportionate share percentage" shall mean either (1) the product of 2½ percent multiplied by the number of standard deviations by which the hospital's own Medicaid inpatient utilization rate exceeds the statewide mean Medicaid inpatient utilization rate for all hospitals, or (2) 2½ percent. (See 79.1(5)*"y"*(7).)

A separate disproportionate share percentage shall be determined for any hospital that qualifies for a disproportionate share payment only as a children's hospital, using the Medicaid inpatient utilization

rate for children under 18 years of age at the time of admission in all distinct areas of the hospital where services are provided predominantly to children under 18 years of age.

"Disproportionate share rate" shall mean the sum of the blended base amount, blended capital costs, direct medical education rate, and indirect medical education rate multiplied by the disproportionate share percentage.

"DRG weight" shall mean a number that reflects relative resource consumption as measured by the relative charges by hospitals for cases associated with each DRG. That is, the Iowa-specific DRG weight reflects the relative charge for treating cases classified in a particular DRG compared to the average charge for treating all Medicaid cases in all DRGs in Iowa hospitals.

"Final payment rate" shall mean the aggregate sum of the two components (the blended base amount and capital costs) that, when added together, form the final dollar value used to calculate each provider's reimbursement amount when multiplied by the DRG weight. These dollar values are displayed on the rate table listing.

"Full DRG transfer" shall mean that a case, coded as a transfer to another hospital, shall be considered to be a normal claim for recalibration or rebasing purposes if payment is equal to or greater than the full DRG payment.

"Graduate medical education and disproportionate share fund" shall mean a reimbursement fund developed as an adjunct reimbursement methodology to directly reimburse qualifying hospitals for the direct and indirect costs associated with the operation of graduate medical education programs and the costs associated with the treatment of a disproportionate share of poor, indigent, nonreimbursed or nominally reimbursed patients for inpatient services.

"Indirect medical education rate" shall mean a rate calculated as follows: The statewide average case-mix adjusted operating cost per Medicaid discharge, divided by two, is added to the statewide average capital costs, divided by two. The resulting sum is then multiplied by the ratio of the number of full-time equivalent interns and residents serving in a Medicare-approved hospital teaching program divided by the number of beds included in hospital departments served by the interns' and residents' program, and is further multiplied by 1.159.

For purposes of calculating the disproportionate share rate only, a separate indirect medical education rate shall be determined for any hospital that qualifies for a disproportionate share payment only as a children's hospital based on a distinct area or areas serving children, using the number of full-time equivalent interns and residents and the number of beds in the distinct area or areas in the hospital where services are provided predominantly to children under 18 years of age.

"Inlier" shall mean those cases where the length of stay or cost of treatment falls within the actual calculated length of stay criteria, or the cost of treating a patient is within the cost boundaries of a DRG payment.

"Long stay outlier" shall mean cases which have an associated length of stay that is greater than the calculated length of stay parameters as defined within the length of stay calculations for that DRG. Payment is as established in 79.1(5)*"f."*

"Low-income utilization rate" shall mean the ratio of gross billings for all Medicaid, bad debt, and charity care patients, including billings for Medicaid enrollees of managed care organizations and primary care case management organizations, to total billings for all patients. Gross billings do not include cash subsidies received by the hospital for inpatient hospital services except as provided from state or local governments.

A separate low-income utilization rate shall be determined for any hospital qualifying or seeking to qualify for a disproportionate share payment as a children's hospital, using only billings for patients under 18 years of age at the time of admission in the distinct area or areas in the hospital where services are provided predominantly to children under 18 years of age.

"Medicaid inpatient utilization rate" shall mean the number of total Medicaid days, including days for Medicaid enrollees of managed care organizations and primary care case management organizations, both in-state and out-of-state, and Iowa state indigent patient days divided by the number of total inpatient days for both in-state and out-of-state recipients. Children's hospitals, including hospitals qualifying for

disproportionate share as a children's hospital, receive twice the percentage of inpatient hospital days attributable to Medicaid patients.

A separate Medicaid inpatient utilization rate shall be determined for any hospital qualifying or seeking to qualify for a disproportionate share payment as a children's hospital, using only Medicaid days, Iowa state indigent patient days, and total inpatient days attributable to patients under 18 years of age at the time of admission in all distinct areas of the hospital where services are provided predominantly to children under 18 years of age.

"Neonatal intensive care unit" shall mean a designated level II or level III neonatal unit.

"Net discharges" shall mean total discharges minus transfers and short stay outliers.

"Quality improvement organization" or *"QIO"* shall mean the organization that performs medical peer review of Medicaid claims, including review of validity of hospital diagnosis and procedure coding information; completeness, adequacy and quality of care; appropriateness of admission, discharge and transfer; and appropriateness of prospective payment outlier cases. These activities undertaken by the QIO may be included in a contractual relationship with the Iowa Medicaid enterprise.

"Rate table listing" shall mean a schedule of rate payments for each provider. The rate table listing is defined as the output that shows the final payment rate by hospital before being multiplied by the appropriate DRG weight.

"Rebasing" shall mean the redetermination of the blended base amount or other applicable components of the final payment rate from more recent Medicaid cost report data.

"Recalibration" shall mean the adjustment of all DRG weights to reflect changes in relative resource consumption.

"Short stay day outlier" shall mean cases which have an associated length of stay that is less than the calculated length of stay parameters as defined within the length of stay calculations. Payment rates are established in 79.1(5)*"f."*

b. Determination of final payment rate amount. The hospital DRG final payment amount reflects the sum of inflation adjustments to the blended base amount plus an add-on for capital costs. This blended base amount plus the add-on is multiplied by the set of Iowa-specific DRG weights to establish a rate schedule for each hospital. Federal DRG definitions are adopted except as provided below:

(1) Substance abuse units certified pursuant to 79.1(5)*"r."* Three sets of DRG weights are developed for DRGs concerning rehabilitation of substance abuse patients. The first set of weights is developed from charges associated with treating adults in certified substance abuse units. The second set of weights reflects charges associated with treating adolescents in mixed-age certified substance abuse units. The third set of weights reflects charges associated with treating adolescents in designated adolescent-only certified substance abuse units.

Hospitals with these units are reimbursed using the weight that reflects the age of each patient. Out-of-state hospitals may not receive reimbursement for the rehabilitation portion of substance abuse treatment.

(2) Neonatal intensive care units certified pursuant to 79.1(5)*"r."* Three sets of weights are developed for DRGs concerning treatment of neonates. One set of weights is developed from charges associated with treating neonates in a designated level III neonatal intensive care unit for some portion of their hospitalization. The second set of weights is developed from charges associated with treating neonates in a designated level II neonatal intensive care unit for some portion of their hospitalization. The third set of weights reflects charges associated with neonates not treated in a designated level II or level III setting. Hospitals are reimbursed using the weight that reflects the setting for neonate treatment.

(3) Psychiatric units. Rescinded IAB 8/29/07, effective 8/10/07.

c. Calculation of Iowa-specific weights and case-mix index. Using all applicable claims for the period January 1, 2003, through December 31, 2004, and paid through March 31, 2005, the recalibration for rates effective October 1, 2005, will use all normal inlier claims, discard short stay outliers, discard transfers where the final payment is less than the full DRG payment, include transfers where the full payment is greater than or equal to the full DRG payment, and use only the estimated charge for the inlier portion of long stay outliers and cost outliers for weighting calculations. These are referred to as trimmed claims.

(1) Iowa-specific weights are calculated from Medicaid charge data on discharge dates occurring from January 1, 2003, to December 31, 2004, and paid through March 31, 2005. Medicaid charge data for hospitals receiving reimbursement as critical access hospitals during any of the period included in the base-year cost report shall not be used in calculating Iowa-specific weights. One weight is determined for each DRG with noted exceptions. Weights are determined through the following calculations:

1. Determine the statewide geometric mean charge for all cases classified in each DRG.

2. Compute the statewide aggregate geometric mean charge for each DRG by multiplying the statewide geometric mean charge for each DRG by the total number of cases classified in that DRG.

3. Sum the statewide aggregate geometric mean charges for all DRGs and divide by the total number of cases for all DRGs to determine the weighted average charge for all DRGs.

4. Divide the statewide geometric mean charge for each DRG by the weighted average charge for all DRGs to derive the Iowa-specific weight for each DRG.

5. Normalize the weights so that the average case has a weight of one.

(2) The hospital-specific case-mix index is computed by taking each hospital's trimmed claims that match the hospital's 2004 fiscal year and paid through March 31, 2005, summing the assigned DRG weights associated with those claims and dividing by the total number of Medicaid claims associated with that specific hospital for that period. Case-mix indices are not computed for hospitals receiving reimbursement as critical access hospitals.

For purposes of calculating the disproportionate share rate only, a separate hospital-specific case-mix index shall be computed for any hospital that qualifies for a disproportionate share payment only as a children's hospital, using claims and associated DRG weights only for services provided to patients under 18 years of age at the time of admission in all distinct areas of the hospital where services are provided predominantly to children under 18 years of age.

d. Calculation of blended base amount. The DRG blended base amount reflects a 50/50 blend of statewide and hospital-specific base amounts.

(1) Calculation of statewide average case-mix-adjusted cost per discharge. The statewide average cost per discharge is calculated by subtracting from the statewide total Iowa Medicaid inpatient expenditures:

1. The total calculated dollar expenditures based on hospitals' base-year cost reports for capital costs and medical education costs, and

2. The actual payments made for additional transfers, outliers, physical rehabilitation services, psychiatric services rendered on or after October 1, 2006, and indirect medical education.

Cost report data for hospitals receiving reimbursement as critical access hospitals during any of the period of time included in the base-year cost report is not used in calculating the statewide average cost per discharge. The remaining amount (which has been case-mix adjusted and adjusted to reflect inflation if applicable) is divided by the statewide total number of Iowa Medicaid discharges reported in the Medicaid management information system (MMIS) less an actual number of nonfull DRG transfers and short stay outliers.

(2) Calculation of hospital-specific case-mix-adjusted average cost per discharge. The hospital-specific case-mix-adjusted average cost per discharge is calculated by subtracting from the lesser of total Iowa Medicaid costs or covered reasonable charges, as determined by the hospital's base-year cost report or MMIS claims system, the actual dollar expenditures for capital costs, direct medical education costs, and the payments made for nonfull DRG transfers, outliers, physical rehabilitation services, and psychiatric services rendered on or after October 1, 2006, if applicable. The remaining amount is case-mix adjusted, multiplied by inflation factors, and divided by the total number of Iowa Medicaid discharges from the MMIS claims system for that hospital during the applicable base year, less the nonfull DRG transfers and short stay outliers.

For purposes of calculating the disproportionate share rate only, a separate hospital-specific case-mix-adjusted average cost per discharge shall be calculated for any hospital that qualifies for a disproportionate share payment only as a children's hospital based on a distinct area or areas serving children, using the costs, charges, expenditures, payments, discharges, transfers, and outliers attributable

to the distinct area or areas in the hospital where services are provided predominantly to children under 18 years of age.

(3) Calculation of the blended statewide and hospital-specific base amount. The hospital-specific case-mix adjusted average cost per discharge is added to the case-mix adjusted statewide average cost per discharge and divided by two to arrive at a 50/50 blended base amount.

e. Add-ons to the base amount.

(1) One payment for capital costs is added on to the blended base amount.

Capital costs are included in the rate table listing and added to the blended base amount before the final payment rate schedule is set. This add-on reflects a 50/50 blend of the statewide average case-mix-adjusted capital cost per discharge and the case-mix-adjusted hospital-specific base-year capital cost per discharge attributed to Iowa Medicaid patients.

Allowable capital costs are determined by multiplying the capital amount from the base-year cost report by 80 percent. Cost report data for hospitals receiving reimbursement as critical access hospitals during any of the period of time included in the base-year cost report is not used in calculating the statewide average case-mix-adjusted capital cost per discharge.

The 50/50 blend is calculated by adding the case-mix-adjusted hospital-specific per discharge capital cost to the statewide average case-mix-adjusted per discharge capital costs and dividing by two. Hospitals whose blended capital add-on exceeds one standard deviation off the mean Medicaid blended capital rate will be subject to a reduction in their capital add-on to equal the first standard deviation.

For purposes of calculating the disproportionate share rate only, a separate add-on to the base amount for capital costs shall be calculated for any hospital that qualifies for a disproportionate share payment only as a children's hospital based on a distinct area or areas serving children, using the case-mix-adjusted hospital-specific base-year capital cost per discharge attributed to Iowa Medicaid patients in the distinct area or areas in the hospital where services are provided predominantly to children under 18 years of age.

(2) Rescinded IAB 7/6/05, effective 7/1/05.

f. Outlier payment policy. Additional payment is made for approved cases meeting or exceeding Medicaid criteria for day and cost outliers for each DRG. Effective for claims with dates of services ending July 1, 1993, and after, 100 percent of outlier costs will be paid to facilities at the time of claim reimbursement. The QIO shall perform retrospective outlier reviews in accordance with the terms in the contract between the department and the QIO. The QIO contract is available for review at the Iowa Medicaid Enterprise, 100 Army Post Road, Des Moines, Iowa.

(1) Long stay outliers. Long stay outliers are incurred when a patient's stay exceeds the upper day limit threshold. This threshold is defined as the lesser of the arithmetically calculated average length of stay plus 23 days of care or two standard deviations above the average statewide length of stay for a given DRG, calculated geometrically. Reimbursement for long stay outliers is calculated at 60 percent of the average daily rate for the given DRG for each approved day of stay beyond the upper day limit. Payment for long stay outliers shall be paid at 100 percent of the calculated amount and made at the time the claim is originally paid.

(2) Short stay outliers. Short stay outliers are incurred when a patient's length of stay is greater than two standard deviations from the geometric mean below the average statewide length of stay for a given DRG, rounded to the next highest whole number of days. Payment for short stay outliers will be 200 percent of the average daily rate for each day the patient qualifies up to the full DRG payment. Short stay outlier claims will be subject to QIO review and payment denied for inappropriate admissions.

(3) Cost outliers. Cases qualify as cost outliers when costs of service in a given case, not including any add-on amounts for direct or indirect medical education or disproportionate share costs exceed the cost threshold. This cost threshold is determined to be the greater of two times the statewide average DRG payment for that case or the hospital's individual DRG payment for that case plus $16,000. Costs are calculated using hospital-specific cost-to-charge ratios determined in the base-year cost reports. Additional payment for cost outliers is 80 percent of the excess between the hospital's cost for the discharge and the cost threshold established to define cost outliers. Payment of cost outlier amounts shall be paid at 100 percent of the calculated amount and made at the time the claim is paid.

Those hospitals that are notified of any outlier review initiated by the QIO must submit all requested supporting data to the QIO within 60 days of the receipt of outlier review notification, or outlier payment will be forfeited and recouped. In addition, any hospital may request a review for outlier payment by submitting documentation to the QIO within 365 days of receipt of the outlier payment. If requests are not filed within 365 days, the provider loses the right to appeal or contest that payment.

(4) Day and cost outliers. Cases qualifying as both day and cost outliers are given additional payment as cost outliers only.

g. Billing for patient transfers and readmissions.

(1) Transfers between hospitals. When a Medicaid patient is transferred the initial hospital or unit is paid 100 percent of the average daily rate of the transferring hospital's payment for each day the patient remained in that hospital or unit, up to 100 percent of the entire DRG payment. The hospital or unit that received the transferred patient receives the entire DRG payment.

(2) Substance abuse units. When a patient is discharged to or from an acute care hospital and is admitted to or from a substance abuse unit certified pursuant to paragraph 79.1(5)*"r,"* both the discharging and admitting hospitals will receive 100 percent of the DRG payment.

(3) Physical rehabilitation hospitals or units. When a patient requiring physical rehabilitation is discharged from an acute care hospital and admitted to a rehabilitation hospital or unit certified pursuant to 79.1(5)*"r,"* and the admission is medically appropriate, then payment for time spent in the unit is through a per diem. The discharging hospital will receive 100 percent of the DRG payment. When a patient is discharged from a certified physical rehabilitation hospital or unit and admitted to an acute care hospital, the acute care hospital will receive 100 percent of the DRG payment.

When a patient requiring physical rehabilitation is discharged from a facility other than an acute care hospital and admitted to a rehabilitation hospital or unit certified pursuant to 79.1(5)*"r,"* and the admission is medically appropriate, then payment for time spent in the unit is based on a per diem. The other facility will receive payment in accordance with rules governing that facility. When a patient is discharged from a certified physical rehabilitation hospital or unit and admitted to a facility other than an acute care hospital, the other facility will receive payment in accordance with rules governing that facility.

(4) Psychiatric units. When a patient is discharged to or from an acute care hospital before October 1, 2006, and is admitted to or from a psychiatric unit certified pursuant to paragraph 79.1(5)*"r,"* both the discharging and admitting hospitals will receive 100 percent of the DRG payment.

Effective October 1, 2006, when a patient requiring psychiatric care is discharged from an acute care hospital and admitted to a psychiatric unit certified pursuant to paragraph 79.1(5)*"r,"* and the admission is medically appropriate, then payment for time spent in the unit is through a per diem. The discharging hospital will receive 100 percent of the DRG payment. When a patient is discharged from a certified psychiatric unit and is admitted to an acute care hospital, the acute care hospital will receive 100 percent of the DRG payment.

When a patient requiring psychiatric care is discharged from a facility other than an acute care hospital on or after October 1, 2006, and is admitted to a psychiatric unit certified pursuant to paragraph 79.1(5)*"r,"* and the admission is medically appropriate, then payment for time spent in the unit is based on a per diem. The other facility will receive payment in accordance with rules governing that facility. When a patient is discharged from a certified psychiatric unit on or after October 1, 2006, and is admitted to a facility other than an acute care hospital, the other facility will receive payment in accordance with rules governing that facility.

h. Covered DRGs. Medicaid DRGs cover services provided in acute care general hospitals, with the exception of services provided in physical rehabilitation hospitals and units certified pursuant to paragraph 79.1(5)*"r,"* and services provided on or after October 1, 2006, in psychiatric units certified pursuant to paragraph 79.1(5)*"r,"* which are paid per diem, as specified in paragraph 79.1(5)*"i."*

i. Payment for certified physical rehabilitation hospitals and units and psychiatric units. Payment for services provided by a physical rehabilitation hospital or unit certified pursuant to paragraph 79.1(5)*"r"* and for services provided on or after October 1, 2006, in a psychiatric unit certified pursuant

to paragraph 79.1(5)*"r"* is prospective. The payment is based on a per diem rate calculated for each hospital by establishing a base-year per diem rate to which an annual index is applied.

(1) Per diem calculation. The base rate shall be the medical assistance per diem rate as determined by the individual hospital's base-year cost report pursuant to paragraph 79.1(5)*"a."* No recognition will be given to the professional component of the hospital-based physicians except as noted under paragraph 79.1(5)*"j."*

(2) Rescinded IAB 5/12/93, effective 7/1/93.

(3) Per diem reimbursement. Hospitals shall be reimbursed the lower of actual charges or the medical assistance cost per diem rate. The determination of the applicable rate shall be based on the hospital fiscal year aggregate of actual charges and medical assistance cost per diem rate. If an overpayment exists, the hospital will refund or have the overpayment deducted from subsequent billings.

(4) Per diem recalculation. Hospital prospective reimbursement rates shall be established as of October 1, 1987, for the remainder of the applicable hospital fiscal year. Beginning July 1, 1988, all updated rates shall be established based on the state's fiscal year.

(5) Per diem billing. The current method for submitting billing and cost reports shall be maintained. All cost reports will be subject to desk review audit and, if necessary, a field audit.

j. Services covered by DRG payments. Medicaid adopts the Medicare definition of inpatient hospital services covered by the DRG prospective payment system except as indicated herein. As a result, combined billing for physician services is eliminated unless the hospital has approval from Medicare to combine bill the physician and hospital services. Teaching hospitals having Medicare's approval to receive reasonable cost reimbursement for physician services under 42 CFR 415.58 as amended to November 25, 1991, are eligible for combined billing status if they have the Medicare approval notice on file with Iowa Medicaid as verification. Reasonable cost settlement will be made during the year-end settlement process. Services provided by certified nurse anesthetists (CRNAs) employed by a physician are covered by the physician reimbursement. Payment for the services of CRNAs employed by the hospital are included in the hospital's reimbursement.

The cost for hospital-based ambulance transportation that results in an inpatient admission and hospital-based ambulance services performed while the recipient is an inpatient, in addition to all other inpatient services, is covered by the DRG payment. If, during the inpatient stay at the originating hospital, it becomes necessary to transport but not transfer the patient to another hospital or provider for treatment, with the patient remaining an inpatient at the originating hospital after that treatment, the originating hospital shall bear all costs incurred by that patient for the medical treatment or the ambulance transportation between the originating hospital and the other provider. The services furnished to the patient by the other provider shall be the responsibility of the originating hospital. Reimbursement to the originating hospital for all services is under the DRG payment. (See 441—subrule 78.11(4).)

k. Inflation factors, rebasing, and recalibration.

(1) Inflation factors shall be set annually at levels that ensure payments that are consistent with efficiency, economy, and quality of care and that are sufficient to enlist enough providers so that care and services are available at least to the extent that such care and services are available to the general population in the geographic area.

(2) Base amounts shall be rebased and weights recalibrated in 2005 and every three years thereafter. Cost reports used in rebasing shall be the hospital fiscal year-end Form CMS 2552, Hospital and Healthcare Complex Cost Report, as submitted to Medicare in accordance with Medicare cost report submission time lines for the hospital fiscal year ending during the preceding calendar year. If a hospital does not provide this cost report to the Iowa Medicaid enterprise provider cost audits and rate-setting unit by May 31 of a year in which rebasing occurs, the most recent submitted cost report will be used with the addition of a hospital market basket index inflation factor.

(3) The graduate medical education and disproportionate share fund shall be updated as provided in subparagraphs 79.1(5)*"y"*(3), (6), and (9).

(4) Hospitals receiving reimbursement as critical access hospitals shall not receive inflation of base payment amounts and shall not have base amounts rebased or weights recalibrated pursuant to this paragraph.

l. Eligibility and payment. When a client is eligible for Medicaid for less than or equal to the average length of stay for that DRG, then payment equals 100 percent of the hospital's average daily rate times the number of eligible hospital stay days up to the amount of the DRG payment. When a Medicaid client is eligible for greater than the average length of stay but less than the entire stay, then payment is treated as if the client were eligible for the entire length of stay.

Long stay outlier days are determined as the number of Medicaid eligible days beyond the outlier limits. The date of patient admission is the first date of service. Long stay outlier costs are accrued only during eligible days.

m. Payment to out-of-state hospitals. Payment made to out-of-state hospitals providing care to beneficiaries of Iowa's Medicaid program is equal to either the Iowa statewide average blended base amount plus the statewide average capital cost add-on, multiplied by the DRG weight, or blended base and capital rates calculated by using 80 percent of the hospital's submitted capital costs. Hospitals that submit a cost report no later than May 31 in the most recent rebasing year will receive a case-mix-adjusted blended base rate using hospital-specific, Iowa-only Medicaid data and the Iowa statewide average cost per discharge amount.

(1) Capital costs will be reimbursed at either the statewide average rate in place at the time of discharge, or the blended capital rate computed by using submitted cost report data.

(2) Hospitals that qualify for disproportionate share payment based on the definition established by their state's Medicaid agency for the calculation of the Medicaid inpatient utilization rate will be eligible to receive disproportionate share payments according to paragraph *"y."*

(3) If a hospital qualifies for reimbursement for direct medical education or indirect medical education under Medicare guidelines, it shall be reimbursed according to paragraph *"y."*

n. Preadmission, preauthorization, or inappropriate services. Medicaid adopts most Medicare QIO regulations to control increased admissions or reduced services. Exceptions to the Medicare review practice are that the QIO reviews Medicaid short stay outliers and all Medicaid patients readmitted within 31 days. Payment can be denied if either admissions or discharges are performed without medical justification as determined by the QIO. Inpatient or outpatient services which require preadmission or preprocedure approval by the QIO are updated yearly by the department and are listed in the provider manual. Preauthorization for any of these services is transmitted directly from the QIO to the Iowa Medicaid enterprise and no additional information needs to be submitted as part of the claim filing for inpatient or outpatient services. To safeguard against these and other inappropriate practices, the department through the QIO will monitor admission practices and quality of care. If an abuse of the prospective payment system is identified, payments for abusive practices may be reduced or denied. In reducing or denying payment, Medicaid adopts the Medicare QIO regulations.

o. Hospital billing. Hospitals shall normally submit claims for DRG reimbursement to the Iowa Medicaid enterprise after a patient's discharge.

(1) Payment for outlier days or costs is determined when the claim is paid by the Iowa Medicaid enterprise, as described in paragraph *"f."*

(2) When a Medicaid patient requires acute care in the same facility for a period of no less than 120 days, a request for partial payment may be made. Written requests for this interim DRG payment shall be addressed to the Iowa Medicaid Enterprise, Attention: Provider Services Unit, P.O. Box 36450, Des Moines, Iowa 50315. A request for interim payment shall include:

1. The patient's name, state identification number, and date of admission;
2. A brief summary of the case;
3. A current listing of charges; and
4. A physician's attestation that the recipient has been an inpatient for 120 days and is expected to remain in the hospital for a period of no less than 60 additional days.

A departmental representative will then contact the facility to assist the facility in filing the interim claim.

p. Determination of inpatient admission. A person is considered to be an inpatient when a formal inpatient admission occurs, when a physician intends to admit a person as an inpatient, or when a physician determines that a person being observed as an outpatient in an observation or holding bed should be admitted to the hospital as an inpatient.

(1) In cases involving outpatient observation status, the determinant of patient status is not the length of time the patient was being observed, but rather that the observation period was medically necessary for the physician to determine whether a patient should be released from the hospital or admitted to the hospital as an inpatient.

(2) Outpatient observation lasting greater than a 24-hour period will be subject to review by the Iowa Medicaid Enterprise (IME) Medical Services Unit to determine the medical necessity of each case. For those outpatient observation cases where medical necessity is not established by the IME, reimbursement shall be denied for the services found to be unnecessary for the provision of that care, such as the use of the observation room.

q. Inpatient admission after outpatient services. A patient may be admitted to the hospital as an inpatient after receiving outpatient services. If the patient is admitted as an inpatient within three days of the day outpatient services were rendered, all outpatient services related to the principal diagnosis are considered inpatient services for billing purposes. The day of formal admission as an inpatient is considered as the first day of hospital inpatient services.

r. Certification for reimbursement as a special unit or physical rehabilitation hospital. Certification for Medicaid reimbursement as a substance abuse unit under subparagraph 79.1(5)*"b"*(1), a neonatal intensive care unit under subparagraph 79.1(5)*"b"*(2), a psychiatric unit under paragraph 79.1(5)*"i,"* or a physical rehabilitation hospital or unit under paragraph 79.1(5)*"i"* shall be awarded as provided in this paragraph.

(1) Certification procedure. All hospital special units and physical rehabilitation hospitals must be certified by the Iowa Medicaid enterprise to qualify for Medicaid reimbursement as a special unit or physical rehabilitation hospital. Hospitals shall submit requests for certification to Iowa Medicaid Enterprise, Attention: Provider Services Unit, P.O. Box 36450, Des Moines, Iowa 50315, with documentation that the certification requirements are met. The provider services unit will notify the facility of any additional documentation needed after review of the submitted documentation.

Upon certification, reimbursement as a special unit or physical rehabilitation hospital shall be retroactive to the first day of the month during which the Iowa Medicaid enterprise received the request for certification. No additional retroactive payment adjustment shall be made when a hospital fails to make a timely request for certification.

(2) Certification criteria for substance abuse units. An in-state substance abuse unit may be certified for Medicaid reimbursement under 79.1(5)*"b"*(1) if the unit's program is licensed by the Iowa department of public health as a substance abuse treatment program in accordance with Iowa Code chapter 125 and 643—Chapter 3. In addition to documentation of the license, an in-state hospital must submit documentation of the specific substance abuse programs available at the facility with a description of their staffing, treatment standards, and population served.

An out-of-state substance abuse unit may be certified for Medicaid reimbursement under 79.1(5)*"b"*(1) if it is excluded from the Medicare prospective payment system as a psychiatric unit pursuant to 42 Code of Federal Regulations, Sections 412.25 and 412.27, as amended to September 1, 1994. An out-of-state hospital requesting reimbursement as a substance abuse unit must initially submit a copy of its current Medicare prospective payment system exemption notice, unless the facility had certification for reimbursement as a substance abuse unit before July 1, 1993. All out-of-state hospitals certified for reimbursement for substance abuse units must submit copies of new Medicare prospective payment system exemption notices as they are issued, at least annually.

(3) Certification criteria for neonatal intensive care units. A neonatal intensive care unit may be certified for Medicaid reimbursement under 79.1(5)*"b"*(2) if it is certified as a level II or level III neonatal unit and the hospital where it is located is accredited by the Joint Commission on Accreditation of Healthcare Organizations or the American Osteopathic Association. The Iowa Medicaid enterprise shall verify the unit's certification as a level II or level III neonatal unit in accordance with recommendations

set forth by the American Academy of Pediatrics for newborn care. Neonatal units in Iowa shall be certified by the Iowa department of public health pursuant to 641—Chapter 150. Out-of-state units shall submit proof of level II or level III certification.

(4) Certification criteria for psychiatric units. A psychiatric unit may be certified for Medicaid reimbursement under paragraph 79.1(5)*"i"* if it is excluded from the Medicare prospective payment system as a psychiatric unit pursuant to 42 Code of Federal Regulations, Sections 412.25 and 412.27 as amended to August 1, 2002.

(5) Certification criteria for physical rehabilitation hospitals and units. A physical rehabilitation hospital or unit may be certified for Medicaid reimbursement under 79.1(5)*"i"* if it receives or qualifies to receive Medicare reimbursement as a rehabilitative hospital or unit pursuant to 42 Code of Federal Regulations, Sections 412.600 through 412.632 (Subpart P), as amended to January 1, 2002, and the hospital is accredited by the Joint Commission on Accreditation of Healthcare Organizations or the American Osteopathic Association.

s. *Cost report adjustments.* Rescinded IAB 6/11/03, effective 7/16/03.

t. *Limitations and application of limitations on payment.* Diagnosis related group payments are subject to the upper payment limits as stated in 42 CFR 447.271 and 42 CFR 447.272 as amended to September 5, 2001.

Payment limits as stated in subparagraphs (1) and (2) below are applied in the aggregate during the cost settlement process at the completion of the hospital's fiscal year end. The payment limit stated in subparagraph (3) is applied to aggregate Medicaid payments at the end of the state's fiscal year.

(1) The department may not pay a provider more for inpatient hospital services under Medicaid than the provider's customary charges to the general public for the services.

(2) Payments to a hospital that is owned or operated by state or non-state government shall not exceed the hospital's actual medical assistance program costs. The department shall perform a cost settlement annually after the desk review or audit of the hospital's cost report. The department shall determine the aggregate payments made to the hospital under the diagnosis-related group methodology and compare this amount to the hospital's actual medical assistance program costs as determined from the audit or desk review of the hospital's cost report. For purposes of this determination, payments shall include amounts received from the Medicaid program, including graduate medical education payments and outlier payments, as well as patient and third-party payments up to the Medicaid-allowed amount. If the payments exceed the hospital's actual medical assistance program costs, the amount by which payments exceed actual costs shall be requested and collected from the hospital.

(3) Aggregate payments to hospitals and state-operated hospitals may not exceed the amount that can reasonably be estimated would have been paid for those services under Medicare payment principles.

u. *Determination of payment amounts for outpatient hospitalization.* Rescinded IAB 7/6/94, effective 7/1/94.

v. *Reimbursement of malpractice costs.* Rescinded IAB 5/30/01, effective 8/1/01.

w. *Rate adjustments for hospital mergers.* When one or more hospitals merge to form a distinctly different legal entity, the base rate plus applicable add-ons will be revised to reflect this new entity. Financial information from the original cost reports and original rate calculations will be added together and averaged to form the new rate for that entity.

x. For cost reporting periods beginning on or after July 1, 1993, reportable Medicaid administrative and general expenses are allowable only to the extent that they are defined as allowable using Medicare Reimbursement Principles or Health Insurance Reimbursement Manual 15 (HIM-15). Appropriate, reportable costs are those that meet the Medicare (or HIM-15) principles, are reasonable, and are directly related to patient care. In instances where costs are not directly related to patient care or are not in accord with Medicare Principles of Reimbursement, inclusion of those costs in the cost report would not be appropriate. Examples of administrative and general costs that must be related to patient care to be included as a reportable cost in the report are:

(1) Advertising.

(2) Promotional items.

(3) Feasibility studies.

(4) Administrative travel and entertainment.
(5) Dues, subscriptions, or membership costs.
(6) Contributions made to other organizations.
(7) Home office costs.
(8) Public relations items.
(9) Any patient convenience items.
(10) Management fees for administrative services.
(11) Luxury employee benefits (i.e., country club dues).
(12) Motor vehicles for other than patient care.
(13) Reorganization costs.

y. Graduate medical education and disproportionate share fund. Payment shall be made to all hospitals qualifying for direct medical education, indirect medical education, or disproportionate share payments directly from the graduate medical education and disproportionate share fund. The requirements to receive payments from the fund, the amounts allocated to the fund, and the methodology used to determine the distribution amounts from the fund are as follows:

(1) Qualifying for direct medical education. Hospitals qualify for direct medical education payments if direct medical education costs that qualify for payment as medical education costs under the Medicare program are contained in the hospital's base year cost report and in the most recent cost report submitted before the start of the state fiscal year for which payments are being made.

(2) Allocation to fund for direct medical education. Except as reduced pursuant to subparagraph 79.1(5)*"y"*(3), the total amount of funding that is allocated to the graduate medical education and disproportionate share fund for direct medical education related to inpatient services for July 1, 2008, through June 30, 2009, is $8,642,112.

(3) Distribution to qualifying hospitals for direct medical education. Distribution of the amount in the fund for direct medical education shall be on a monthly basis. To determine the amount to be distributed to each qualifying hospital for direct medical education, the following formula is used:

1. Multiply the total of all DRG weights for claims paid from July 1, 2005, through June 30, 2006, for each hospital reporting direct medical education costs that qualify for payment as medical education costs under the Medicare program in the hospital's base year cost report by each hospital's direct medical education rate to obtain a dollar value.

2. Sum the dollar values for each hospital, then divide each hospital's dollar value by the total dollar value, resulting in a percentage.

3. Multiply each hospital's percentage by the amount allocated for direct medical education to determine the payment to each hospital.

Effective for payments from the fund for July 2006, the state fiscal year used as the source of DRG weights shall be updated to July 1, 2005, through June 30, 2006. Thereafter, the state fiscal year used as the source of DRG weights shall be updated by a three-year period effective for payments from the fund for July of every third year.

If a hospital fails to qualify for direct medical education payments from the fund because it does not report direct medical education costs that qualify for payment as medical education costs under the Medicare program in the most recent cost report submitted before the start of the state fiscal year for which payments are being made, the amount of money that would have been paid to that hospital shall be removed from the fund.

(4) Qualifying for indirect medical education. Hospitals qualify for indirect medical education payments from the fund when they receive a direct medical education payment from Iowa Medicaid and qualify for indirect medical education payments from Medicare. Qualification for indirect medical education payments is determined without regard to the individual components of the specific hospital's teaching program, state ownership, or bed size.

(5) Allocation to fund for indirect medical education. Except as reduced pursuant to subparagraph 79.1(5)*"y"*(6), the total amount of funding that is allocated to the graduate medical education and disproportionate share fund for indirect medical education related to inpatient services for July 1, 2008, through June 30, 2009, is $15,174,101.

(6) Distribution to qualifying hospitals for indirect medical education. Distribution of the amount in the fund for indirect medical education shall be on a monthly basis. To determine the amount to be distributed to each qualifying hospital for indirect medical education, the following formula is used:

1. Multiply the total of all DRG weights for claims paid from July 1, 2005, through June 30, 2006, for each hospital reporting direct medical education costs that qualify for payment as medical education costs under the Medicare program in the hospital's base year cost report by each hospital's indirect medical education rate to obtain a dollar value.

2. Sum the dollar values for each hospital, then divide each hospital's dollar value by the total dollar value, resulting in a percentage.

3. Multiply each hospital's percentage by the amount allocated for indirect medical education to determine the payment to each hospital.

Effective for payments from the fund for July 2006, the state fiscal year used as the source of DRG weights shall be updated to July 1, 2005, through June 30, 2006. Thereafter, the state fiscal year used as the source of DRG weights shall be updated by a three-year period effective for payments from the fund for July of every third year.

If a hospital fails to qualify for indirect medical education payments from the fund because it does not report direct medical education costs that qualify for payment as medical education costs under the Medicare program in the most recent cost report submitted before the start of the state fiscal year for which payments are being made, the amount of money that would have been paid to that hospital shall be removed from the fund.

(7) Qualifying for disproportionate share. For months beginning with July 2002, hospitals qualify for disproportionate share payments from the fund when the hospital's low-income utilization rate exceeds 25 percent, when the hospital's Medicaid inpatient utilization rate exceeds one standard deviation from the statewide average Medicaid utilization rate, or when the hospital qualifies as a children's hospital under subparagraph (10).

For those hospitals that qualify for disproportionate share under both the low-income utilization rate definition and the Medicaid inpatient utilization rate definition, the disproportionate share percentage shall be the greater of (1) the product of 2½ percent multiplied by the number of standard deviations by which the hospital's own Medicaid inpatient utilization rate exceeds the statewide mean Medicaid inpatient utilization rate for all hospitals, or (2) 2½ percent.

For those hospitals that qualify for disproportionate share under the low-income utilization rate definition, but do not qualify under the Medicaid inpatient utilization rate definition, the disproportionate share percentage shall be 2½ percent.

For those hospitals that qualify for disproportionate share under the Medicaid inpatient utilization rate definition, but do not qualify under the low-income utilization rate definition, the disproportionate share percentage shall be the product of 2½ percent multiplied by the number of standard deviations by which the hospital's own Medicaid inpatient utilization rate exceeds the statewide mean Medicaid inpatient utilization rate for all hospitals.

For those hospitals that qualify for disproportionate share as a children's hospital, the disproportionate share percentage shall be the greater of (1) the product of 2½ percent multiplied by the number of standard deviations by which the Medicaid inpatient utilization rate for children under 18 years of age at the time of admission in all areas of the hospital where services are provided predominantly to children under 18 years of age exceeds the statewide mean Medicaid inpatient utilization rate for all hospitals, or (2) 2½ percent.

Information contained in the hospital's available 2004 submitted Medicare cost report is used to determine the hospital's low-income utilization rate and the hospital's Medicaid inpatient utilization rate.

Additionally, a qualifying hospital other than a children's hospital must also have at least two obstetricians who have staff privileges at the hospital and who have agreed to provide obstetric services to Medicaid-eligible persons who are in need of obstetric services. In the case of a hospital located in a rural area as defined in Section 1886 of the Social Security Act, the term "obstetrician" includes any physician with staff privileges at the hospital to perform nonemergency obstetric procedures.

Out-of-state hospitals serving Iowa Medicaid patients qualify for disproportionate share payments from the fund based on their state Medicaid agency's calculation of the Medicaid inpatient utilization rate. The disproportionate share percentage is calculated using the number of standard deviations by which the hospital's own state Medicaid inpatient utilization rate exceeds the hospital's own statewide mean Medicaid inpatient utilization rate.

Hospitals qualify for disproportionate share payments from the fund without regard to the facility's status as a teaching facility or bed size.

Hospitals receiving reimbursement as critical access hospitals shall not qualify for disproportionate share payments from the fund.

(8) Allocation to fund for disproportionate share. The total amount of funding that is allocated to the graduate medical education and disproportionate share fund for disproportionate share payments for July 1, 2008, through June 30, 2009, is $7,253,641.

(9) Distribution to qualifying hospitals for disproportionate share. Distribution of the amount in the fund for disproportionate share shall be on a monthly basis. To determine the amount to be distributed to each qualifying hospital for disproportionate share, the following formula is used:

1. Multiply the total of all DRG weights for claims paid July 1, 2005, through June 30, 2006, for each hospital that met the qualifications during the fiscal year used to determine the hospital's low-income utilization rate and Medicaid utilization rate (or for children's hospitals, during the preceding state fiscal year) by each hospital's disproportionate share rate to obtain a dollar value. For any hospital that qualifies for a disproportionate share payment only as a children's hospital, only the DRG weights for claims paid for services rendered to patients under 18 years of age at the time of admission in all distinct areas of the hospital where services are provided predominantly to children under 18 years of age shall be used in this calculation.

2. Sum the dollar values for each hospital, then divide each hospital's dollar value by the total dollar value, resulting in a percentage.

3. Multiply each hospital's percentage by the amount allocated for disproportionate share to determine the payment to each hospital.

Effective for payments from the fund for July 2006, the state fiscal year used as the source of DRG weights shall be updated to July 1, 2005, through June 30, 2006. Thereafter, the state fiscal year used as the source of DRG weights shall be updated by a three-year period effective for payments from the fund for July of every third year. In compliance with Medicaid Voluntary Contribution and Provider-Specific Tax Amendments of 1991 (Public Law 102-234) and 1992 Iowa Acts, chapter 1246, section 13, the total of disproportionate share payments from the fund and supplemental disproportionate share payments pursuant to paragraph 79.1(5)*"ab"* cannot exceed the amount of the federal cap under Public Law 102-234. If a hospital fails to qualify for disproportionate share payments from the fund due to closure or for any other reason, the amount of money that would have been paid to that hospital shall be removed from the fund.

(10) Qualifying for disproportionate share as a children's hospital. A licensed hospital qualifies for disproportionate share payments as a children's hospital if the hospital provides services predominantly to children under 18 years of age or includes a distinct area or areas providing services predominantly to children under 18 years of age, is a voting member of the National Association of Children's Hospitals and Related Institutions, and has Medicaid utilization and low-income utilization rates of 1 percent or greater for children under 18 years of age at the time of admission in all distinct areas of the hospital where services are provided predominantly to children under 18 years of age.

A hospital wishing to qualify for disproportionate share payments as a children's hospital for any state fiscal year beginning on or after July 1, 2002, must provide the following information to the Iowa Medicaid enterprise provider cost audits and rate-setting unit within 20 business days of a request by the department:

1. Base year cost reports.

2. Medicaid claims data for children under the age of 18 at the time of admission to the hospital in all distinct areas of the hospital where services are provided predominantly to children under 18 years of age.

3. Other information needed to determine a disproportionate share rate encompassing the periods used to determine the disproportionate share rate and distribution amounts.

z. Adjustments to the graduate medical education and disproportionate share fund for changes in utilization. Rescinded IAB 10/31/01, effective 1/1/02.

aa. Retrospective adjustment for critical access hospitals. Payments to critical access hospitals pursuant to paragraphs 79.1(5)*"a"* to *"z"* are subject to a retrospective adjustment equal to the difference between the reasonable costs of covered services provided to eligible fee-for-service Medicaid members (excluding members in managed care), based on the hospital's annual cost reports and Medicare cost principles, and the Medicaid fee-for-service reimbursement received pursuant to paragraphs 79.1(5)*"a"* to *"z."* Amounts paid before adjustment that exceed reasonable costs shall be recovered by the department.

(1) The base rate upon which the DRG payment is built shall be changed after any retrospective adjustment to reflect, as accurately as is possible, the reasonable costs of providing the covered service to eligible fee-for-service Medicaid members for the coming year using the most recent utilization as submitted to the Iowa Medicaid enterprise provider cost audit and rate-setting unit and Medicare cost principles.

(2) Once a hospital begins receiving reimbursement as a critical access hospital, the prospective DRG base rate is not subject to inflation factors, rebasing, or recalibration as provided in paragraph 79.1(5)*"k."*

ab. Enhanced disproportionate-share payments. In addition to payments from the graduate medical education and disproportionate share fund pursuant to paragraph 79.1(5)*"y,"* payment shall be made to all Iowa hospitals qualifying for enhanced disproportionate-share payments. Interim payments based on estimated allowable costs will be paid to qualifying hospitals under this paragraph. Final payments under this paragraph will be determined as follows:

(1) Qualifying criteria for enhanced disproportionate-share payments. A hospital qualifies for enhanced disproportionate-share payments if it qualifies for payments for disproportionate share from the graduate medical education and disproportionate-share fund pursuant to paragraph 79.1(5)*"y"* and meets one of the following conditions:

1. Is an Iowa state-owned hospital with more than 500 beds and eight or more distinct residency specialty or subspecialty programs recognized by the American College of Graduate Medical Education.

2. Is a non-state government-owned acute-care teaching hospital located in a county with a population over 350,000.

3. Is an Iowa state-owned hospital for persons with mental illness.

(2) Amount of payment. The total amount of disproportionate-share payments from the graduate medical education and disproportionate share fund and enhanced disproportionate share shall not exceed the amount of the state's allotment under Public Law 102-234. In addition, the total amount of disproportionate-share payments from the graduate medical education and disproportionate share fund and enhanced disproportionate-share payments shall not exceed the hospital-specific disproportionate-share caps under Public Law 103-666.

The amount available for enhanced disproportionate-share payments shall be the federal allotment less disproportionate-share payments from the graduate medical education and disproportionate share fund. In the event that the disproportionate-share allotment for enhanced payments is insufficient to pay 100 percent of the cost that is eligible for disproportionate-share payments, the allotment shall be allocated among qualifying hospitals using their eligible cost as an allocation basis.

(3) Final disproportionate-share adjustment. The department's total year-end disproportionate-share obligation to a qualifying hospital shall be calculated following completion of the desk review or audit of the hospital's Form CMS 2552, Hospital and Hospital Health Care Complex Cost Report.

ac. Enhanced graduate medical education payments. In addition to payments from the graduate medical education and disproportionate share fund pursuant to paragraph 79.1(5)*"y,"* payment shall be made to all Iowa hospitals qualifying for enhanced graduate medical education payments. Interim payments based on estimated allowable costs will be paid to qualifying hospitals under this paragraph. Final payments under this paragraph will be determined as follows:

(1) Qualifying for enhanced graduate medical education payments. A hospital shall qualify for enhanced graduate medical education payments if it qualifies to receive both direct and indirect medical education payments from the graduate medical education and disproportionate share fund pursuant to paragraph 79.1(5)*"y"* and meets one of the following conditions:

1. Is an Iowa state-owned hospital with more than 500 beds and eight or more distinct residency specialty or subspecialty programs recognized by the American College of Graduate Medical Education; or

2. Is a non-state government-owned acute-care teaching hospital located in a county with a population over 350,000.

(2) Amount of payment. The total amount of graduate medical education payments from the graduate medical education and disproportionate share fund and enhanced graduate medical education shall not exceed each hospital's actual medical assistance program graduate medical education costs. The amount paid to each qualifying hospital for enhanced graduate medical education payments shall be the hospital's actual medical assistance program graduate medical education costs less the graduate medical education payments from the graduate medical education and disproportionate share fund.

(3) Final graduate medical education adjustment. The department's total year-end graduate medical education obligation to a qualifying hospital shall be calculated following completion of the desk review or audit of the hospital's Form CMS 2552, Hospital and Hospital Health Care Complex Cost Report.

79.1(6) *Independent laboratories.* The maximum payment for clinical diagnostic laboratory tests performed by an independent laboratory will be the areawide fee schedule established by the Centers for Medicare and Medicaid Services (CMS). The fee schedule is based on the definition of laboratory procedures from the Physician's Current Procedural Terminology (CPT) published by the American Medical Association. The fee schedules are adjusted annually by CMS to reflect changes in the Consumer Price Index for All Urban Consumers.

79.1(7) *Physicians.*

a. *Fee schedule.* The fee schedule is based on the definitions of medical and surgical procedures given in the most recent edition of Physician's Current Procedural Terminology (CPT). Refer to 441—paragraph 78.1(2)*"e"* for the guidelines for immunization replacement.

b. *Supplemental payments.* Rescinded IAB 7/6/05, effective 7/1/05.

79.1(8) *Drugs.* The amount of payment shall be based on several factors, subject to the upper limits in 42 CFR 447.500 to 447.520 as amended to October 7, 2008. The Medicaid program relies on information published by Medi-Span to classify drugs as brand-name or generic. Specialty drugs include biological drugs, blood-derived products, complex molecules, and select oral, injectable, and infused medications identified by the department and published on the specialty drug list.

a. Reimbursement for covered generic prescription drugs shall be the lowest of the following, as of the date of dispensing:

(1) The estimated acquisition cost, defined:

1. For covered nonspecialty generic prescription drugs, as the average wholesale price as published by Medi-Span less 12 percent, plus the professional dispensing fee specified in paragraph *"g"*; or

2. For covered specialty generic prescription drugs, as the average wholesale price as published by Medi-Span less 17 percent, plus the professional dispensing fee specified in paragraph *"g."*

(2) The maximum allowable cost (MAC), defined as the upper limit for multiple source drugs established in accordance with the methodology of Centers for Medicare and Medicaid Services as described in 42 CFR 447.514, plus the professional dispensing fee specified in paragraph *"g."*

(3) The state maximum allowable cost (SMAC), defined as the average wholesale acquisition cost for a generic drug (the average price pharmacies pay to obtain the generic drug as evidenced by purchase records) adjusted by a multiplier of 1.2, plus the professional dispensing fee specified in paragraph *"g."*

(4) The submitted charge, representing the provider's usual and customary charge for the drug.

b. Reimbursement for covered brand-name prescription drugs shall be the lower of the following, as of the date of dispensing:

(1) The estimated acquisition cost, defined:

1. For covered nonspecialty brand-name prescription drugs, as the average wholesale price as published by Medi-Span less 12 percent, plus the professional dispensing fee specified in paragraph *"g"*; or

2. For covered specialty brand-name prescription drugs, as the average wholesale price as published by Medi-Span less 17 percent, plus the professional dispensing fee specified in paragraph *"g."*

(2) The submitted charge, representing the provider's usual and customary charge for the drug.

c. No payment shall be made for sales tax.

d. All hospitals that wish to administer vaccines which are available through the vaccines for children program to Medicaid members shall enroll in the vaccines for children program. In lieu of payment, vaccines available through the vaccines for children program shall be accessed from the department of public health for Medicaid members. Hospitals receive reimbursement for the administration of vaccines to Medicaid members through the DRG reimbursement for inpatients and APC reimbursement for outpatients.

e. The basis of payment for nonprescription drugs shall be the same as specified in paragraph *"a"* except that the department shall establish a maximum allowable reimbursable cost for these drugs using the average wholesale prices of the chemically equivalent products available. The department shall set the maximum allowable reimbursable cost at the median of those average wholesale prices. No exceptions for higher reimbursement will be approved.

f. An additional reimbursement amount of one cent per dose shall be added to the allowable ingredient cost of a prescription for an oral solid if the drug is dispensed to a patient in a nursing home in unit dose packaging prepared by the pharmacist.

g. The professional dispensing fee is $4.57 or the pharmacy's usual and customary fee, whichever is lower, except for the period from December 1, 2009, to June 30, 2010, during which the professional dispensing fee shall be $4.34.

h. For purposes of this subrule, "equivalent products" shall be those that meet therapeutic equivalent standards as published in the federal Food and Drug Administration document, "Approved Prescription Drug Products With Therapeutic Equivalence Evaluations."

i. Pharmacies and providers that are enrolled in the Iowa Medicaid program shall make available drug acquisition cost information, product availability information, and other information deemed necessary by the department to assist the department in monitoring and revising reimbursement rates subject to 79.1(8)*"a"*(3) and 79.1(8)*"c"* and for the efficient operation of the pharmacy benefit.

(1) Pharmacies and providers shall produce and submit the requested information in the manner and format requested by the department or its designee at no cost to the department or its designee.

(2) Pharmacies and providers shall submit information to the department or its designee within 30 days following receipt of a request for information unless the department or its designee grants an extension upon written request of the pharmacy or provider.

j. Savings in Medicaid reimbursements attributable to the SMAC shall be used to pay costs associated with determination of the SMAC, before reversion to Medicaid.

79.1(9) *HCBS consumer choices financial management.*

a. Monthly allocation. A financial management service provider shall receive a monthly fee as established in subrule 79.1(2) for each consumer electing to work with that provider under the HCBS consumer choices option. The financial management service provider shall also receive monthly the consumer's individual budget amount as determined under 441—paragraph 78.34(13)*"b,"*78.37(16)*"b,"*78.38(9)*"b,"*78.41(15)*"b,"*78.43(15)*"b,"* or 78.46(6)*"b."*

b. Cost settlement. The financial management service shall pay from the monthly allocated individual budget amount for independent support broker service, self-directed personal care services, individual-directed goods and services, and self-directed community supports and employment as authorized by the consumer. On a quarterly basis during the federal fiscal year, the department shall perform a cost settlement. The cost settlement represents the difference between the amount received for the allocated individual budget and the amount actually utilized.

c. Start-up grants. A qualifying financial management service provider may be reimbursed up to $10,000 for the costs associated for starting the service.

(1) Start-up reimbursement shall be issued as long as funds for this purpose are available from the Robert Wood Johnson Foundation or until September 30, 2007.

(2) Funds will not be distributed until the provider meets all of the following criteria:

1. The provider shall meet the requirements to be certified to participate in an HCBS waiver program as set forth in 441—subrule 77.30(13), 77.33(16), 77.34(9), 77.37(28), 77.39(26), or 77.41(7), including successful completion of a readiness review as approved by the department.

2. The provider shall enter into an agreement with the department to provide statewide coverage for not less than one year from the date that the funds are distributed.

3. The provider shall submit to the department for approval a budget identifying the costs associated with starting financial management service.

(3) If the provider fails to continue to meet these qualifications after the funds have been distributed, the department may recoup all or part of the funds paid to the provider.

79.1(10) *Prohibition against reassignment of claims.* No payment under the medical assistance program for any care or service provided to a patient by any health care provider shall be made to anyone other than the providers. However with respect to physicians, dentists or other individual practitioners direct payment may be made to the employer of the practitioner if the practitioner is required as a condition of employment to turn over fees to the employer; or where the care or service was provided in a facility, to the facility in which the care or service was provided if there is a contractual arrangement between the practitioner and the facility whereby the facility submits the claim for reimbursement; or to a foundation, plan or similar organization including a health maintenance organization which furnishes health care through an organized health care delivery system if there is a contractual agreement between organization and the person furnishing the service under which the organization bills or receives payment for the person's services. Payment may be made in accordance with an assignment from the provider to a government agency or an assignment made pursuant to a court order. Payment may be made to a business agent, such as a billing service or accounting firm, which renders statements and receives payment in the name of the provider when the agent's compensation for this service is (1) reasonably related to the cost or processing the billing; (2) not related on a percentage or other basis to the dollar amounts to be billed or collected; and (3) not dependent upon the actual collection of payment. Nothing in this rule shall preclude making payment to the estate of a deceased practitioner.

79.1(11) *Prohibition against factoring.* Payment under the medical assistance program for any care or service furnished to an individual by providers as specified in 79.1(1) shall not be made to or through a factor either directly or by virtue of power of attorney given by the provider to the factor. A factor is defined as an organization, collection agency, or service bureau which, or an individual who, advances money to a provider for accounts receivable which have been assigned or sold or otherwise transferred including transfer through the use of power of attorney to the organization or individual for an added fee or reduction of a portion of the accounts receivable. The term factor does not include business representatives such as billing agents or accounting firms which render statements and receive payments in the name of the individual provider provided that the compensation of the business representative for the service is reasonably related to the cost of processing the billings and is not related on a percentage or other basis to the dollar amounts to be billed or collected.

79.1(12) *Reasonable charges for services, supplies, and equipment.* For selected medical services, supplies, and equipment, including equipment servicing, which in the judgment of the Secretary of the Department of Health and Human Services generally do not vary significantly in quality from one provider to another, the upper limits for payments shall be the lowest charges for which the devices are widely and consistently available in a locality. For those selected services and items furnished under part B of Medicare and Medicaid, the upper limits shall be the lowest charge levels recognized under Medicare. For those selected services and items furnished only under Medicaid, the upper limits shall be the lowest charge levels determined by the department according to the Medicare reimbursement method.

a. For any noninstitutional item or service furnished under both Medicare and Medicaid, the department shall pay no more than the reasonable charge established for that item or service by the part

B Medicare carrier serving part or all of Iowa. Noninstitutional services do not include practitioner's services, such as physicians, pharmacies, or out-patient hospital services.

b. For all other noninstitutional items or services furnished only under Medicaid, the department shall pay no more than the customary charge for a provider or the prevailing charges in the locality for comparable items or services under comparable circumstances, whichever is lower.

79.1(13) *Copayment by member.* A copayment in the amount specified shall be charged to members for the following covered services:

a. The member shall pay a copayment for each covered prescription or refill of any covered drug as follows:

(1) One dollar for generic drugs and preferred brand-name drugs. Any brand-name drug that is not subject to prior approval based on nonpreferred status on the preferred drug list published by the department pursuant to Iowa Code section 249A.20A shall be treated as a preferred brand-name drug.

(2) Rescinded IAB 7/6/05, effective 7/1/05.

(3) One dollar for nonpreferred brand-name drugs for which the cost to the state is less than $25.

(4) Two dollars for nonpreferred brand-name drugs for which the cost to the state is $25.01 to $50.

(5) Three dollars for nonpreferred brand-name drugs for which the cost to the state is $50.01 or more.

(6) For the purpose of this paragraph, the cost to the state is determined without regard to federal financial participation in the Medicaid program or to any rebates received.

b. The member shall pay $1 copayment for total covered service rendered on a given date for podiatrists' services, chiropractors' services, and services of independently practicing physical therapists.

c. The member shall pay $2 copayment for total covered services rendered on a given date for medical equipment and appliances, prosthetic devices and medical supplies as defined in 441—78.10(249A), orthopedic shoes, services of audiologists, services of hearing aid dealers except the hearing aid, services of optometrists, opticians, rehabilitation agencies, and psychologists, and ambulance services.

d. The member shall pay $3 copayment for:

(1) Total covered service rendered on a given date for dental services and hearing aids.

(2) All covered services rendered in a physician office visit on a given date. For the purposes of this subparagraph, "physician" means either a doctor of allopathic medicine (M.D.) or a doctor of osteopathic medicine (D.O.), as defined under rule 441—77.1(249A).

e. Copayment charges are not applicable to persons under age 21.

f. Copayment charges are not applicable to family planning services or supplies.

g. Copayment charges are not applicable for a member receiving care in a hospital, nursing facility, state mental health institution, or other medical institution if the person is required, as a condition of receiving services in the institution, to spend for costs of necessary medical care all but a minimal amount of income for personal needs.

h. The member shall pay $1 for each federal Medicare Part B crossover claim submitted to the Medicaid program when the services provided have a Medicaid copayment as set forth above.

i. Copayment charges are not applicable to services furnished pregnant women.

j. All providers are prohibited from offering or providing copayment related discounts, rebates, or similar incentives for the purpose of soliciting the patronage of Medicaid members.

k. Copayment charges are not applicable for emergency services. Emergency services are defined as services provided in a hospital, clinic, office, or other facility that is equipped to furnish the required care, after the sudden onset of a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain), that the absence of immediate medical attention could reasonably be expected to result in:

(1) Placing the patient's health in serious jeopardy,

(2) Serious impairment to bodily functions, or

(3) Serious dysfunction of any bodily organ or part.

l. Copayment charges are not applicable for services rendered by a health maintenance organization in which the member is enrolled.

m. No provider of service participating in the Medicaid program may deny care or services to a person eligible for care or services under the program because of the person's inability to pay a copayment. However, this rule does not change the fact that a member is liable for the charges and it does not preclude the provider from attempting to collect them.

79.1(14) *Reimbursement for hospice services.*

a. Medicaid hospice rates. The Medicaid hospice rates are based on the methodology used in setting Medicare rates, adjusted to disregard cost offsets attributable to Medicare coinsurance amounts, and with application of the appropriate area wage adjustments for the categories of care provided.

Hospices are reimbursed at one of four predetermined rates based on the level of care furnished to the individual for that day. Payments to a hospice for inpatient care are subject to the limitations imposed by Medicare. The levels of care into which each day of care is classified are as follows:

(1) Routine home care.

(2) Continuous home care.

(3) Inpatient respite care.

(4) General inpatient care.

b. Adjustment to hospice rates. An adjustment to hospice reimbursement is made when a recipient residing in a nursing facility elects the hospice benefit. The adjustment will be a room and board rate that is equal to the rate at which the facility is paid for reserved bed days or 95 percent of the facility's Medicaid reimbursement rate, whichever is greater. Room and board services include the performance of personal care services, including assistance in activities of daily living, socializing activities, administration of medication, maintaining the cleanliness of a resident's room and supervising and assisting in the use of durable medical equipment and prescribed therapies.

For hospice recipients entering a nursing facility the adjustment will be effective the date of entry. For persons in nursing facilities prior to hospice election, the adjustment rate shall be effective the date of election.

For individuals who have client participation amounts attributable to their cost of care, the adjustment to the hospice will be reduced by the amount of client participation as determined by the department. The hospice will be responsible for collecting the client participation amount due the hospice unless the hospice and the nursing facility jointly determine the nursing facility is to collect the client participation.

c. Payment for day of discharge. For the day of discharge from an inpatient unit, the appropriate home care rate is to be paid unless the recipient dies as an inpatient. When the recipient is discharged as deceased, the inpatient rate (general or respite) is to be paid for the discharge date.

d. Hospice cap. Overall aggregate payments made to a hospice during a hospice cap period are limited or capped. The hospice cap year begins November 1 and ends October 31 of the next year. The cap amount for each hospice is calculated by multiplying the number of beneficiaries electing hospice care from that hospice during the cap period by the base statutory amount, adjusted to reflect the percentage increase or decrease in the medical care expenditure category of the Consumer Price Index for all urban consumers published by the Bureau of Labor Statistics. Payments made to a hospice but not included in the cap include room and board payment to a nursing home. Any payment in excess of the cap must be refunded to the department by the hospice.

e. Limitation of payments for inpatient care. Payments to a hospice for inpatient care shall be limited according to the number of days of inpatient care furnished to Medicaid patients. During the 12-month period beginning November 1 of each year and ending October 31, the aggregate number of inpatient days (both for general inpatient care and inpatient respite care) shall not exceed 20 percent of the aggregate total number of days of hospice care provided to all Medicaid recipients during that same period. Medicaid recipients afflicted with acquired immunodeficiency syndrome (AIDS) are excluded in calculating this inpatient care limitation. This limitation is applied once each year, at the end of the hospices' "cap period" (November 1 to October 31). For purposes of this computation, if it is determined that the inpatient rate should not be paid, any days for which the hospice receives payment at a home care rate will not be counted as inpatient days. The limitation is calculated as follows:

(1) The maximum allowable number of inpatient days will be calculated by multiplying the total number of days of Medicaid hospice care by 0.2.

(2) If the total number of days of inpatient care furnished to Medicaid hospice patients is less than or equal to the maximum, no adjustment will be necessary.

(3) If the total number of days of inpatient care exceeded the maximum allowable number, the limitation will be determined by:

1. Calculating a ratio of the maximum allowable days to the number of actual days of inpatient care, and multiplying this ratio by the total reimbursement for inpatient care (general inpatient and inpatient respite reimbursement) that was made.

2. Multiplying excess inpatient care days by the routine home care rate.

3. Adding together the amounts calculated in "1" and "2."

4. Comparing the amount in "3" with interim payments made to the hospice for inpatient care during the "cap period."

Any excess reimbursement shall be refunded by the hospice.

f. Location of services. Claims must identify the geographic location where the service is provided (as distinct from the location of the hospice).

79.1(15) *HCBS retrospectively limited prospective rates.* This methodology applies to reimbursement for HCBS supported community living; HCBS family and community support services; HCBS supported employment enhanced job search activities; HCBS interim medical monitoring and treatment when provided by an HCBS-certified supported community agency; HCBS respite when provided by nonfacility providers, camps, home care agencies, or providers of residential-based supported community living; and HCBS group respite provided by home health agencies.

a. Reporting requirements.

(1) Providers shall submit cost reports for each waiver service provided using Form 470-0664, Financial and Statistical Report for Purchase of Service, and Form 470-3449, Supplemental Schedule. The cost reporting period is from July 1 to June 30. The completed cost reports shall be submitted to the IME Provider Cost Audits and Rate-Setting Unit, P.O. Box 36450, Des Moines, Iowa 50315, or by electronic mail to costaudit@dhs.state.ia.us, by September 30 of each year.

(2) If a provider chooses to leave the HCBS program or terminates a service, a final cost report shall be submitted within 60 days of termination for retrospective adjustment.

(3) Costs reported under the waiver shall not be reported as reimbursable costs under any other funding source. Costs incurred for other services shall not be reported as reimbursable costs under the waiver.

(4) Financial information shall be based on the agency's financial records. When the records are not kept on an accrual basis of accounting, the provider shall make the adjustments necessary to convert the information to an accrual basis for reporting. Providers which are multiple program agencies shall submit a cost allocation schedule, prepared in accordance with generally accepted accounting principles.

(5) Failure to maintain records to support the cost reports may result in termination of the provider's HCBS certification.

(6) The department may require that an opinion of a certified public accountant or public accountant accompany the report when adjustments made to prior reports indicate noncompliance with reporting instructions.

(7) A 30-day extension for submitting the cost reports due by September 30 may be obtained by submitting a letter to the bureau of long-term care by September 30. No extensions will be granted beyond 30 days.

(8) Failure to submit a report that meets the requirements of this paragraph by September 30 or an extended deadline granted per subparagraph (7) shall reduce payment to 76 percent of the current rate. The reduced rate shall be paid for not longer than three months, after which time no further payments will be made.

b. Home- and community-based general rate criteria.

(1) To receive reimbursement for services, a certified provider shall enter into an agreement with the department on Form 470-2918, HCBS Waiver Agreement, and have an approved service plan for the consumer.

(2) The rates a provider may charge are subject to limits established in subrule 79.1(2).

(3) Indirect administrative costs shall be limited to 20 percent of other costs.

(4) Mileage costs shall be reimbursed according to state employee rate.

(5) Consumer transportation, consumer consulting, consumer instruction, consumer environmental modification and repairs and consumer environmental furnishings shall not exceed $1,570 per consumer per year for supported community living services.

(6) For respite care provided in the consumer's home, only the cost of care is reimbursed.

(7) For respite care provided outside the consumer's home, charges may include room and board.

(8) Transportation and therapeutic resources reimbursement shall not exceed $1,500 per child per year for family and community support services.

c. Prospective rates for new providers other than respite.

(1) Providers who have not submitted an annual report including at least 6 months of actual, historical costs shall be paid prospective rates based on projected reasonable and proper costs of operation for a 12-month period reported in Form SS-1703-0, Financial and Statistical Report, and Form 470-3449, Supplemental Schedule.

(2) Prospective rates shall be subject to retrospective adjustment as provided in paragraph *"e."*

(3) After a provider has submitted an annual report including at least six months of actual, historical costs, prospective rates shall be determined as provided in paragraph *"d."*

d. Prospective rates for established providers other than respite.

(1) Providers who have submitted an annual report including at least six months of actual, historical costs shall be paid prospective rates based on reasonable and proper costs in a base period, as adjusted for inflation.

(2) The base period shall be the period covered by the first Form SS-1703-0, Financial and Statistical Report, and Form 470-3449, Supplemental Schedule, submitted to the department after 1997 that includes at least six months of actual, historical costs.

(3) Reasonable and proper costs in the base period shall be inflated by a percentage of the increase in the consumer price index for all urban consumers for the preceding 12-month period ending June 30, based on the months included in the base period, to establish the initial prospective rate for an established provider.

(4) After establishment of the initial prospective rate for an established provider, the rate will be adjusted annually, effective for the third month after the month during which the annual cost report is submitted to the department. The provider's new rate shall be the actual reconciled rate or the previously established rate adjusted by the consumer price index for all urban consumers for the preceding 12-month period ending June 30, whichever is less.

(5) Prospective rates for services other than respite shall be subject to retrospective adjustment as provided in paragraph *"f."*

e. Prospective rates for respite. Prospective rates for respite shall be agreed upon between the consumer, interdisciplinary team and the provider up to the maximum, subject to retrospective adjustment as provided in paragraph *"f."*

f. Retrospective adjustments.

(1) Retrospective adjustments shall be made based on reconciliation of provider's reasonable and proper actual service costs with the revenues received for those services as reported on Form 470-3449, Supplemental Schedule, accompanying Form SS-1703-0, Financial and Statistical Report for Purchase of Service.

(2) Revenues exceeding adjusted actual costs by more than 2.5 percent shall be remitted to the department. Payment will be due upon notice of the new rates and retrospective adjustment.

(3) Providers who do not reimburse revenues exceeding 2.5 percent of actual costs 30 days after notice is given by the department will have the revenues over 2.5 percent of the actual costs deducted from future payments.

g. Supported community living daily rate. For purposes of determining the daily rate for supported community living services, providers are treated as new providers until they have submitted an annual report including at least six months of actual costs for the same consumers at the same site with no significant change in any consumer's needs, or if there is a subsequent change in the consumers at a site or in any consumer's needs. Individual prospective daily rates are determined for each consumer. These rates may be adjusted no more than once every three months if there is a vacancy at the site for over 30 days or the consumer's needs have significantly changed. Rates adjusted on this basis will become effective the month a new cost report is submitted. Retrospective adjustments of the prospective daily rates are based on each site's average costs.

79.1(16) *Outpatient reimbursement for hospitals.*

a. Definitions.

"Allowable costs" means the costs defined as allowable in 42 CFR, Chapter IV, Part 413, as amended to October 1, 2007, except for the purposes of calculating direct medical education costs, where only the reported costs of the interns and residents are allowed. Further, costs are allowable only to the extent that they relate to patient care; are reasonable, ordinary, and necessary; and are not in excess of what a prudent and cost-conscious buyer would pay for the given service or item.

"Ambulatory payment classification" or *"APC"* means an outpatient service or group of services for which a single rate is set. The services or groups of services are determined according to the typical clinical characteristics, the resource use, and the costs associated with the service or services.

"Ambulatory payment classification relative weight" or *"APC relative weight"* means the relative value assigned to each APC.

"Ancillary service" means a supplemental service that supports the diagnosis or treatment of the patient's condition. Examples include diagnostic testing or screening services and rehabilitative services such as physical or occupational therapy.

"APC service" means a service that is priced and paid using the APC system.

"Base-year cost report," for rates effective July 1, 2008, shall mean the hospital's cost report with fiscal year end on or after January 1, 2006, and before January 1, 2007. Cost reports shall be reviewed using Medicare's cost-reporting and cost reimbursement principles for those cost-reporting periods.

"Blended base APC rate" shall mean the hospital-specific base APC rate, plus the statewide base APC rate, divided by two. The costs of hospitals receiving reimbursement as critical access hospitals during any of the period included in the base-year cost report shall not be used in determining the statewide base APC rate.

"Case-mix index" shall mean an arithmetical index measuring the relative average costliness of outpatient cases treated in a hospital, compared to the statewide average.

"Cost outlier" shall mean services provided during a single visit that have an extraordinarily high cost as established in paragraph *"g"* and are therefore eligible for additional payments above and beyond the base APC payment.

"Current procedural terminology—fourth edition (CPT-4)" is the systematic listing and coding of procedures and services provided by physicians or other related health care providers. The CPT-4 coding is maintained by the American Medical Association and is updated yearly.

"Diagnostic service" means an examination or procedure performed to obtain information regarding the medical condition of an outpatient.

"Direct medical education costs" shall mean costs directly associated with the medical education of interns and residents or other medical education programs, such as a nursing education program or allied health programs, conducted in an outpatient setting, that qualify for payment as medical education costs under the Medicare program. The amount of direct medical education costs is determined from the hospital base-year cost reports and is inflated in determining the direct medical education rate.

"Direct medical education rate" shall mean a rate calculated for a hospital reporting medical education costs on the Medicare cost report (CMS 2552). The rate is calculated using the following formula: Direct medical education costs are multiplied by the percentage of valid claims to total claims, further multiplied by inflation factors, then divided by outpatient visits.

"Discount factor" means the percentage discount applied to additional APCs when more than one APC is provided during the same visit (including the same APC provided more than once). Not all APCs are subject to a discount factor.

"Graduate medical education and disproportionate share fund" shall mean a reimbursement fund developed as an adjunct reimbursement methodology to directly reimburse qualifying hospitals for the direct costs of interns and residents associated with the operation of graduate medical education programs for outpatient services.

"Healthcare common procedures coding system" or *"HCPCS"* means the national uniform coding method that is maintained by the Centers for Medicare and Medicaid Services (CMS) and that incorporates the American Medical Association publication Physicians Current Procedural Terminology (CPT) and the three HCPCS unique coding levels I, II, and III.

"Hospital-based clinic" means a clinic that is owned by the hospital, operated by the hospital under its hospital license, and on the premises of the hospital.

"International classifications of diseases—fourth edition, ninth revision (ICD-9)" is a systematic method used to classify and provide standardization to coding practices which are used to describe the diagnosis, symptom, complaint, condition or cause of a person's injury or illness.

"Modifier" means a two-character code that is added to the procedure code to indicate the type of service performed. The modifier allows the reporting hospital to indicate that a performed service or procedure has been altered by some specific circumstance. The modifier may affect payment or may be used for information only.

"Multiple significant procedure discounting" means a reduction of the standard payment amount for an APC to recognize that the marginal cost of providing a second APC service to a patient during a single visit is less than the cost of providing that service by itself.

"Observation services" means a set of clinically appropriate services, such as ongoing short-term treatment, assessment, and reassessment, that is provided before a decision can be made regarding whether a patient needs further treatment as a hospital inpatient or is able to be discharged from the hospital.

"Outpatient hospital services" means preventive, diagnostic, therapeutic, observation, rehabilitation, or palliative services provided to an outpatient by or under the direction of a physician, dentist, or other practitioner by an institution that:

1. Is licensed or formally approved as a hospital by the officially designated authority in the state where the institution is located; and
2. Meets the requirements for participation in Medicare as a hospital.

"Outpatient prospective payment system" or *"OPPS"* means the payment methodology for hospital outpatient services established by this subrule and based on Medicare's outpatient prospective payment system mandated by the Balanced Budget Refinement Act of 1999 and the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000.

"Outpatient visit" shall mean those hospital-based outpatient services which are billed on a single claim form.

"Packaged service" means a service that is secondary to other services but is considered an integral part of another service.

"Pass-through" means certain drugs, devices, and biologicals for which providers are entitled to payment separate from any APC.

"Quality improvement organization" or *"QIO"* shall mean the organization that performs medical peer review of Medicaid claims, including review of validity of hospital diagnosis and procedure coding information; completeness, adequacy and quality of care; and appropriateness of prospective payments for outlier cases and nonemergent use of the emergency room. These activities undertaken by the QIO may be included in a contractual relationship with the Iowa Medicaid enterprise.

"Rebasing" shall mean the redetermination of the blended base APC rate using more recent Medicaid cost report data.

"Significant procedure" shall mean the procedure, therapy, or service provided to a patient that constitutes the primary reason for the visit and dominates the time and resources expended during the visit.

"Status indicator" or *"SI"* means a payment indicator that identifies whether a service represented by a CPT or HCPCS code is payable under the OPPS APC or another payment system. Only one status indicator is assigned to each CPT or HCPCS code.

b. Outpatient hospital services. Medicaid adopts the Medicare categories of hospitals and services subject to and excluded from the hospital outpatient prospective payment system (OPPS) at 42 CFR 419.20 through 419.22 as amended to October 1, 2007, except as indicated in this subrule.

(1) A teaching hospital that has approval from the Centers for Medicare and Medicaid Services to receive reasonable cost reimbursement for physician services under 42 CFR 415.160 through 415.162 as amended to October 1, 2007, is eligible for combined billing status if the hospital has filed the approval notice with the Iowa Medicaid enterprise provider cost audit and rate-setting unit. If a teaching hospital elects to receive reasonable cost payment for physician direct medical and surgical services furnished to Medicaid members, those services and the supervision of interns and residents furnishing the care to members are covered as hospital services and are combined with the bill for hospital service. Cost settlement for the reasonable costs related to physician direct medical and surgical services shall be made after receipt of the hospital's financial and statistical report.

(2) A hospital-based ambulance service must be an enrolled Medicaid ambulance provider and must bill separately for ambulance services. EXCEPTION: If the member's condition results in an inpatient admission to the hospital, the reimbursement for ambulance services is included in the hospital's DRG reimbursement rate for the inpatient services.

(3) All psychiatric services for members who have a primary diagnosis of mental illness and are enrolled in the Iowa Plan program under 441—Chapter 88 shall be the responsibility of the Iowa Plan contractor and shall not be otherwise payable by Iowa Medicaid. The only exceptions to this policy are reference laboratory and radiology services, which will be payable by fee schedule or APC.

(4) Emergency psychiatric evaluations for members who are covered by the Iowa Plan shall be the responsibility of the Iowa Plan contractor. For members who are not covered by the Iowa Plan, services shall be payable under the APC for emergency psychiatric evaluation.

(5) Substance abuse services for persons enrolled in the Iowa Plan program under 441—Chapter 88 shall be the responsibility of the Iowa Plan contractor and shall not be otherwise payable by Iowa Medicaid. The only exceptions to this policy are reference laboratory and radiology services, which will be payable by fee schedule or APC.

c. Payment for outpatient hospital services.

(1) Outpatient hospital services shall be reimbursed according to the first of the following methodologies that applies to the service:

1. Any specific rate or methodology established by rule for the particular service.
2. The OPPS APC rates established pursuant to this subrule.
3. Fee schedule rates established pursuant to paragraph 79.1(1)*"c."*

(2) Except as provided in paragraph 79.1(16)*"h,"* outpatient hospital services that have been assigned to an APC with an assigned weight shall be reimbursed based on the APC to which the services provided are assigned. For dates of services beginning on or after July 1, 2008, the department adopts and incorporates by reference the OPPS APCs and relative weights effective January 1, 2008, published on November 27, 2007, as final by the Centers for Medicare and Medicaid Services in the Federal Register at Volume 72, No. 227, page 66579. Relative weights shall be updated pursuant to paragraph 79.1(16)*"j."*

(3) The APC payment is calculated as follows:

1. The applicable APC relative weight is multiplied by the blended base APC rate determined according to paragraph 79.1(16)*"e."*
2. The resulting APC payment is multiplied by a discount factor of 50 percent and by units of service when applicable.

3. For a procedure started but discontinued before completion, the department will pay 50 percent of the APC for the service.

(4) The OPPS APC payment status indicators show whether a service represented by a CPT or HCPCS code is payable under an OPPS APC or under another payment system and whether particular OPPS policies apply to the code. The following table lists the status indicators and definitions for both services that are paid under an OPPS APC and services that are not paid under an OPPS APC.

Indicator	Item, Code, or Service	OPPS Payment Status
A	Services furnished to a hospital outpatient that are paid by Medicare under a fee schedule or payment system other than OPPS, such as: ● Ambulance services. ● Clinical diagnostic laboratory services. ● Diagnostic mammography. ● Screening mammography. ● Nonimplantable prosthetic and orthotic devices. ● Physical, occupational, and speech therapy. ● Erythropoietin for end-stage renal dialysis (ESRD) patients. ● Routine dialysis services provided for ESRD patients in a certified dialysis unit of a hospital.	If covered by Iowa Medicaid as an outpatient hospital service, the service is not paid under OPPS APC, but is paid based on the Iowa Medicaid fee schedule for outpatient hospital services established pursuant to 79.1(1)*"c."* If not covered by Iowa Medicaid as an outpatient hospital service, the service is not paid under OPPS APC, but may be paid under the specific rate or methodology established by other rules (other than outpatient hospital).
B	Codes that are not paid by Medicare on an outpatient hospital basis	Not paid under OPPS APC. ● May be paid when submitted on a bill type other than outpatient hospital. ● An alternate code that is payable when submitted on an outpatient hospital bill type (13x) may be available.
C	Inpatient procedures	If covered by Iowa Medicaid as an outpatient hospital service, the service is not paid under OPPS APC, but is paid based on the Iowa Medicaid fee schedule for outpatient hospital services established pursuant to 79.1(1)*"c."* If not covered by Iowa Medicaid as an outpatient hospital service, the service is not paid under OPPS APC. Admit the patient and bill as inpatient care.
D	Discontinued codes	Not paid under OPPS APC or any other Medicaid payment system.
E	Items, codes, and services: ● That are not covered by Medicare based on statutory exclusion and may or may not be covered by Iowa Medicaid; or ● That are not covered by Medicare for reasons other than statutory exclusion and may or may not be covered by Iowa Medicaid; or ● That are not recognized by Medicare but for which an alternate code for the same item or service may be available under Iowa Medicaid; or ● For which separate payment is not provided by Medicare but may be provided by Iowa Medicaid.	If covered by Iowa Medicaid, the item, code, or service is not paid under OPPS APC, but is paid based on the Iowa Medicaid fee schedule for outpatient hospital services established pursuant to 79.1(1)*"c."* If not covered by Iowa Medicaid, the item, code, or service is not paid under OPPS APC or any other Medicaid payment system.

F	Certified registered nurse anesthetist services Corneal tissue acquisition Hepatitis B vaccines	If covered by Iowa Medicaid, the item or service is not paid under OPPS APC, but is paid based on the Iowa Medicaid fee schedule for outpatient hospital services established pursuant to 79.1(1)*"c."* If not covered by Iowa Medicaid, the item or service is not paid under OPPS APC or any other Medicaid payment system.
G	Pass-through drugs and biologicals	If covered by Iowa Medicaid, the item is not paid under OPPS APC, but is paid based on the Iowa Medicaid fee schedule for outpatient hospital services established pursuant to 79.1(1)*"c."* If not covered by Iowa Medicaid, the item is not paid under OPPS APC or any other Medicaid payment system.
H	Pass-through device categories	If covered by Iowa Medicaid, the device is not paid under OPPS APC, but is paid based on the Iowa Medicaid fee schedule for outpatient hospital services established pursuant to 79.1(1)*"c."* If not covered by Iowa Medicaid, the device is not paid under OPPS APC or any other Medicaid payment system.
K	Blood and blood products Brachytherapy sources Non-pass-through drugs and biologicals Therapeutic radiopharmaceuticals	If covered by Iowa Medicaid, the item is: ● Paid under OPPS APC with a separate APC payment when both an APC and an APC weight are established. ● Paid based on the Iowa Medicaid fee schedule for outpatient hospital services established pursuant to 79.1(1)*"c"* when either no APC or APC weight is established. If not covered by Iowa Medicaid, the item is not paid under OPPS APC or any other Medicaid payment system.
L	Influenza vaccine Pneumococcal pneumonia vaccine	If covered by Iowa Medicaid, the vaccine is not paid under OPPS APC, but is paid based on the Iowa Medicaid fee schedule for outpatient hospital services established pursuant to 79.1(1)*"c."* If not covered by Iowa Medicaid, the vaccine is not paid under OPPS APC or any other Medicaid payment system.
M	Items and services not billable to the Medicare fiscal intermediary	If covered by Iowa Medicaid, the item or service is not paid under OPPS APC, but is paid based on the Iowa Medicaid fee schedule for outpatient hospital services established pursuant to 79.1(1)*"c."* If not covered by Iowa Medicaid, the item or service is not paid under OPPS APC or any other Medicaid payment system.

N	Packaged services not subject to separate payment under Medicare OPPS payment criteria	Paid under OPPS APC. Payment, including outliers, is included with payment for other services; therefore, no separate payment is made.
P	Partial hospitalization	Not a covered service under Iowa Medicaid.
Q	Packaged services subject to separate payment under Medicare OPPS payment criteria	Paid under OPPS APC in a separate APC payment based on Medicare OPPS payment criteria. If criteria are not met, payment, including outliers, is packaged into payment for other services; therefore, no separate APC payment is made.
S	Significant procedure, not discounted when multiple	If covered by Iowa Medicaid, the procedure is paid under OPPS APC with separate APC payment. If not covered by Iowa Medicaid, the procedure is not paid under OPPS APC or any other Medicaid payment system.
T	Significant procedure, multiple reduction applies	If covered by Iowa Medicaid, the procedure is paid under OPPS APC with separate APC payment subject to multiple reduction. If not covered by Iowa Medicaid, the procedure is not paid under OPPS APC or any other Medicaid payment system.
V	Clinic or emergency department visit	If covered by Iowa Medicaid, the service is paid under OPPS APC with separate APC payment. If not covered by Iowa Medicaid, the service is not paid under OPPS APC or any other Medicaid payment system.
X	Ancillary services	If covered by Iowa Medicaid, the service is paid under OPPS APC with separate APC payment. If not covered by Iowa Medicaid, the service is not paid under OPPS APC or any other Medicaid payment system.

d. Calculation of case-mix indices. Hospital-specific and statewide case-mix indices shall be calculated using all applicable claims with dates of service occurring in the period July 1, 2006, through June 30, 2007, paid through September 10, 2007.

(1) Hospital-specific case-mix indices are calculated by summing the relative weights for each APC service at that hospital and dividing the total by the number of APC services for that hospital.

(2) The statewide case-mix index is calculated by summing the relative weights for each APC service for all claims and dividing the total by the statewide total number of APC services. Claims for hospitals receiving reimbursement as critical access hospitals during any of the period included in the base-year cost report are not used in calculating the statewide case-mix index.

e. Calculation of the hospital-specific base APC rates.

(1) Using the hospital's base-year cost report, hospital-specific outpatient cost-to-charge ratios are calculated for each ancillary and outpatient cost center of the Medicare cost report, Form CMS 2552-96.

(2) The cost-to-charge ratios are applied to each line item charge reported on claims with dates of service occurring in the period July 1, 2006, through June 30, 2007, paid through September 10, 2007, to calculate the Medicaid cost per service. The hospital's total outpatient Medicaid cost is the sum of the Medicaid cost per service for all line items.

(3) The following items are subtracted from the hospital's total outpatient Medicaid costs:

1. The total calculated Medicaid direct medical education cost for interns and residents based on the hospital's base-year cost report.

2. The total calculated Medicaid cost for services listed at 441—subrule 78.31(1), paragraphs *"g"* to *"n."*

3. The total calculated Medicaid cost for ambulance services.

4. The total calculated Medicaid cost for services paid based on the Iowa Medicaid fee schedule.

(4) The remaining amount is multiplied by a factor to limit aggregate expenditures to available funding, divided by the hospital-specific case-mix index, and then divided by the total number of APC services for that hospital during the period July 1, 2006, through June 30, 2007, that were paid through September 10, 2007.

(5) Hospital-specific base APC rates are not computed for hospitals receiving reimbursement as critical access hospitals during any of the period included in the base-year cost report.

f. Calculation of statewide base APC rate.

(1) The statewide average base APC rate is calculated by summing the outpatient Medicaid cost for all hospitals and subtracting the following:

1. The total calculated Medicaid direct medical education cost for interns and residents for all hospitals.

2. The total calculated Medicaid cost for services listed at 441—subrule 78.31(1), paragraphs *"g"* to *"n,"* for all hospitals.

3. The total calculated Medicaid cost for ambulance services for all hospitals.

4. The total calculated Medicaid cost for services paid based on the Iowa Medicaid fee schedule for all hospitals.

(2) The resulting amount is multiplied by a factor to limit aggregate expenditures to available funding, divided by the statewide case-mix index, and then divided by the statewide total number of APC services for the period July 1, 2006, through June 30, 2007, that were paid through September 10, 2007.

(3) Data for hospitals receiving reimbursement as critical access hospitals during any of the period included in the base-year cost report is not used in calculating the statewide average base APC rate.

g. Cost outlier payment policy. Additional payment is made for services provided during a single visit that exceed the following Medicaid criteria of cost outliers for each APC. Outlier payments are determined on an APC-by-APC basis.

(1) An APC qualifies as a cost outlier when the cost of the service exceeds both the multiple threshold and the fixed-dollar threshold.

(2) The multiple threshold is met when the cost of furnishing an APC service exceeds 1.75 times the APC payment amount.

(3) The fixed-dollar threshold is met when the cost of furnishing an APC service exceeds the APC payment amount plus $2,000.

(4) If both the multiple threshold and the fixed-dollar threshold are met, the outlier payment is calculated as 50 percent of the amount by which the hospital's cost of furnishing the APC service or procedure exceeds the multiple threshold.

(5) The cost of furnishing the APC service or procedure is calculated using a single overall hospital-specific cost-to-charge ratio determined from the base-year cost report. Costs appearing on a claim that are attributable to packaged APC services for which no separate payment is made are allocated to all nonpackaged APC services that appear on that claim. The amount allocated to each nonpackaged APC service is based on the proportion the APC payment rate for that APC service bears to the total APC rates for all nonpackaged APC services on the claim.

h. Payment to critical access hospitals. Initial, interim payments to critical access hospitals as defined in paragraph 79.1(5)*"a"* shall be the hospital's line-item charge multiplied by the hospital's Medicaid outpatient cost-to-charge ratio. These interim payments are subject to annual retrospective adjustment equal to the difference between the reasonable costs of covered services provided to eligible fee-for-service Medicaid members (excluding members in managed care) and the Medicaid reimbursement received. The department shall determine the reasonable costs of services based on the

hospital's annual cost reports and Medicare cost principles. When the interim amounts paid exceed reasonable costs, the department shall recover the difference.

(1) After any retrospective adjustment, the department shall update the cost-to-charge ratio to reflect as accurately as is possible the reasonable costs of providing the covered service to eligible fee-for-service Medicaid members for the coming year. The department shall base these changes on the most recent utilization as submitted to the Iowa Medicaid enterprise provider cost audit and rate-setting unit and Medicare cost principles.

(2) Once a hospital begins receiving reimbursement as a critical access hospital, the cost-to-charge ratio is not subject to rebasing as provided in paragraph 79.1(16)*"j."*

i. Cost-reporting requirements. Hospitals shall prepare annual cost reports in accordance with generally accepted accounting principles as defined by the American Institute of Certified Public Accountants and in accordance with Medicare Provider Reimbursement Manual, CMS Publication 15, subject to the exceptions and limitations provided in this rule.

(1) Using electronic media, each hospital shall submit the following:

1. The hospital's Medicare cost report (Form CMS 2552-96, Hospitals and Healthcare Complex Cost Report);

2. Either Form 470-4515, Critical Access Hospital Supplemental Cost Report, or Form 470-4514, Hospital Supplemental Cost Report; and

3. A copy of the revenue code crosswalk used to prepare the Medicare cost report.

(2) The cost reports and supporting documentation shall be sent to the Iowa Medicaid Enterprise, Provider Cost Audit and Rate Setting Unit, 100 Army Post Road, P.O. Box 36450, Des Moines, Iowa 50315.

(3) The cost reports shall be submitted on or before the last day of the fifth calendar month following the close of the period covered by the report. For fiscal periods ending on a day other than the last day of the month, cost reports are due 150 days after the last day of the cost-reporting period. Extensions of the due date for filing a cost report granted by the Medicare fiscal intermediary shall be accepted by Iowa Medicaid.

j. Rebasing.

(1) Effective January 1, 2009, and annually thereafter, the department shall update the OPPS APC relative weights using the most current calendar update as published by the Centers for Medicare and Medicaid Services.

(2) Effective January 1, 2009, and every three years thereafter, blended base APC rates shall be rebased. Cost reports used in rebasing shall be the hospital fiscal year-end Form CMS 2552-96, Hospital and Healthcare Complex Cost Report, as submitted to Medicare in accordance with Medicare cost report submission time lines for the hospital fiscal year ending during the preceding calendar year. If a hospital does not provide this cost report, including the Medicaid cost report and revenue code crosswalk, to the Iowa Medicaid enterprise provider cost audit and rate-setting unit by May 31 of a year in which rebasing occurs, the most recent submitted cost report will be used.

(3) Effective January 1, 2009, and every three years thereafter, case-mix indices shall be recalculated using valid claims most nearly matching each hospital's fiscal year end.

(4) The graduate medical education and disproportionate share fund shall be updated as provided in subparagraph 79.1(16)*"v"*(3).

k. Payment to out-of-state hospitals. Out-of-state hospitals providing care to members of Iowa's Medicaid program shall be reimbursed in the same manner as Iowa hospitals, except that APC payment amounts for out-of-state hospitals may be based on either the Iowa statewide base APC rate or the Iowa blended base APC rate for the out-of-state hospital.

(1) For out-of-state hospitals that submit a cost report no later than May 31 in the most recent rebasing year, APC payment amounts will be based on the blended base APC rate using hospital-specific, Iowa-only Medicaid data. For other out-of-state hospitals, APC payment amounts will be based on the Iowa statewide base APC rate.

(2) If an out-of-state hospital qualifies for reimbursement for direct medical education under Medicare guidelines, it shall qualify for such reimbursement from the Iowa Medicaid program for services to Iowa Medicaid members.

l. Preadmission, preauthorization or inappropriate services. Inpatient or outpatient services that require preadmission or preprocedure approval by the quality improvement organization (QIO) are updated yearly and are available from the QIO.

(1) The hospital shall provide the QIO authorization number on the claim form to receive payment. Claims for services requiring preadmission or preprocedure approval that are submitted without this authorization number will be denied.

(2) To safeguard against other inappropriate practices, the department, through the QIO, will monitor admission practices and quality of care. If an abuse of the prospective payment system is identified, payments for abusive practices may be reduced or denied. In reducing or denying payment, Medicaid adopts the Medicare QIO regulations.

m. Hospital billing. Rescinded IAB 07/02/08, effective 07/01/08.

n. Determination of inpatient admission. A person is considered to be an inpatient when a formal inpatient admission occurs, when a physician intends to admit a person as an inpatient, or when a physician determines that a person being observed as an outpatient in an observation or holding bed should be admitted to the hospital as an inpatient. In cases involving outpatient observation status, the determinant of patient status is not the length of time the patient was being observed, rather whether the observation period was medically necessary to determine whether a patient should be admitted to the hospital as an inpatient. Outpatient observation lasting greater than a 24-hour period will be subject to review by the QIO to determine the medical necessity of each case. For those outpatient observation cases where medical necessity is not established, reimbursement shall be denied for the services found to be unnecessary for the provision of that care, such as the use of the observation room.

o. Inpatient admission after outpatient services. If a patient is admitted as an inpatient within three days of the day in which outpatient services were rendered, all outpatient services related to the principal diagnosis are considered inpatient services for billing purposes. The day of formal admission as an inpatient is considered as the first day of hospital inpatient services. EXCEPTION: This requirement does not apply to critical access hospitals.

p. Cost report adjustments. Rescinded IAB 6/11/03, effective 7/16/03.

q. Determination of payment amounts for mental health noninpatient (NIP) services. Mental health NIP services are limited as set forth at 441—78.31(4)*"d"*(7) and are reimbursed on a fee schedule basis. Mental health NIP services are the responsibility of the managed mental health care and substance abuse (Iowa Plan) contractor for persons eligible for managed mental health care.

r. Payment for outpatient services delivered in the emergency room. Rescinded IAB 07/02/08, effective 07/01/08.

s. Limit on payments. Payments under the ambulatory payment classification (APC) methodology, as well as other payments for outpatient services, are subject to upper limit rules set forth in 42 CFR 447.321 as amended to September 5, 2001, and 447.325 as amended to January 26, 1993. Requirements under these sections state that, in general, Medicaid may not make payments to providers that would exceed the amount that would be payable to providers under comparable circumstances under Medicare.

t. Government-owned facilities. Payments to a hospital that is owned or operated by state or non-state government shall not exceed the hospital's actual medical assistance program costs.

(1) The department shall perform a cost settlement annually after the desk review or audit of the hospital's cost report.

(2) The department shall determine the aggregate payments made to the hospital under the APC methodology and shall compare this amount to the hospital's actual medical assistance program costs as determined from the audit or desk review of the hospital's cost report. For purposes of this determination, aggregate payments shall include amounts received from the Medicaid program, including graduate medical education payments and outlier payments, as well as patient and third-party payments up to the Medicaid-allowed amount.

(3) If the aggregate payments exceed the hospital's actual medical assistance program costs, the amount by which payments exceed actual costs shall be requested and collected from the hospital.

u. QIO review. The QIO will review a yearly random sample of hospital outpatient service cases performed for Medicaid members and identified on claims data from all Iowa and bordering state hospitals in accordance with the terms in the contract between the department and the QIO. The QIO contract is available for review at the Iowa Medicaid Enterprise Office, 100 Army Post Road, Des Moines, Iowa 50315.

v. Graduate medical education and disproportionate share fund. Payment shall be made to all hospitals qualifying for direct medical education directly from the graduate medical education and disproportionate share fund. The requirements to receive payments from the fund, the amount allocated to the fund and the methodology used to determine the distribution amounts from the fund are as follows:

(1) Qualifying for direct medical education. Hospitals qualify for direct medical education payments if direct medical education costs that qualify for payment as medical education costs under the Medicare program are contained in the hospital's base year cost report and in the most recent cost report submitted before the start of the state fiscal year for which payments are being made.

(2) Allocation to fund for direct medical education. Except as reduced pursuant to subparagraph 79.1(16)*"v"*(3), the total amount of funding that is allocated to the graduate medical education and disproportionate share fund for direct medical education related to outpatient services for July 1, 2008, through June 30, 2009, is $2,922,460.

(3) Distribution to qualifying hospitals for direct medical education. Distribution of the amount in the fund for direct medical education shall be on a monthly basis. To determine the amount to be distributed to each qualifying hospital for direct medical education, the following formula is used:

1. Multiply the total count of outpatient visits for claims paid from July 1, 2005, through June 30, 2006, for each hospital reporting direct medical education costs that qualify for payment as medical education costs under the Medicare program in the hospital's base year cost report by each hospital's direct medical education rate to obtain a dollar value.

2. Sum the dollar values for each hospital, then divide each hospital's dollar value by the total dollar value, resulting in a percentage.

3. Multiply each hospital's percentage by the amount allocated for direct medical education to determine the payment to each hospital.

Effective for payments from the fund for July 2006, the state fiscal year used as the source of the count of outpatient visits shall be updated to July 1, 2005, through June 30, 2006. Thereafter, the state fiscal year used as the source of the count of outpatient visits shall be updated by a three-year period effective for payments from the fund for July of every third year.

If a hospital fails to qualify for direct medical education payments from the fund because it does not report direct medical education costs that qualify for payment as medical education costs under the Medicare program in the most recent cost report submitted before the start of the state fiscal year for which payments are being made, the amount of money that would have been paid to that hospital shall be removed from the fund.

w. Adjustments to the graduate medical education and disproportionate share fund for changes in utilization. Rescinded IAB 10/29/03, effective 1/1/04.

79.1(17) *Reimbursement for home- and community-based services home and vehicle modification.* Payment is made for home and vehicle modifications at the amount of payment to the subcontractor provided in the contract between the supported community living provider and subcontractor. All contracts shall be awarded through competitive bidding, shall be approved by the department, and shall be justified by the consumer's service plan. Payment for completed work shall be made to the supported community living provider.

79.1(18) *Pharmaceutical case management services reimbursement.* Pharmacist and physician pharmaceutical case management (PCM) team members shall be equally reimbursed for participation in each of the four services described in rule 441—78.47(249A). The following table contains the amount each team member shall be reimbursed for the services provided and the maximum number of payments

for each type of assessment. Payment for services beyond the maximum number of payments shall be considered on an individual basis after peer review of submitted documentation of medical necessity.

Service	Payment amount	Number of payments
Initial assessment	$75	One per patient
New problem assessment	$40	Two per patient per 12 months
Problem follow-up assessment	$40	Four per patient per 12 months
Preventative follow-up assessment	$25	One per patient per 6 months

79.1(19) *Reimbursement for translation and interpretation services.* Reimbursement for translation and interpretation services shall be made to providers based on the reimbursement methodology for the provider category as defined in subrule 79.1(2).

a. For those providers whose basis of reimbursement is cost-related, translation and interpretation services shall be considered an allowable cost.

b. For those providers whose basis of reimbursement is a fee schedule, a fee shall be established for translation and interpretation services, which shall be treated as a reimbursable service. In order for translation or interpretation to be covered, it must be provided by separate employees or contractors solely performing translation or interpretation activities.

79.1(20) *Dentists.* The dental fee schedule is based on the definitions of dental and surgical procedures given in the Current Dental Terminology, Third Edition (CDT-3).

79.1(21) *Rehabilitation agencies.* Subject to the Medicaid upper limit in 79.1(2), payments to rehabilitation agencies shall be made as provided in the areawide fee schedule established for Medicare by the Centers for Medicare and Medicaid Services (CMS). The Medicare fee schedule is based on the definitions of procedures from the physicians' Current Procedural Terminology (CPT) published by the American Medical Association. CMS adjusts the fee schedules annually to reflect changes in the consumer price index for all urban customers.

79.1(22) *Medicare crossover claims for inpatient and outpatient hospital services.* Subject to approval of a state plan amendment by the federal Centers for Medicare and Medicaid Services, payment for crossover claims shall be made as follows.

a. *Definitions.* For purposes of this subrule:

"Crossover claim" means a claim for Medicaid payment for Medicare-covered inpatient or outpatient hospital services rendered to a Medicare beneficiary who is also eligible for Medicaid. Crossover claims include claims for services rendered to beneficiaries who are eligible for Medicaid in any category, including, but not limited to, qualified Medicare beneficiaries and beneficiaries who are eligible for full Medicaid coverage.

"Medicaid-allowed amount" means the Medicaid prospective reimbursement for the services rendered (including any portion to be paid by the Medicaid beneficiary as copayment or spenddown), as determined under state and federal law and policies.

"Medicaid reimbursement" means any amount to be paid by the Medicaid beneficiary as a Medicaid copayment or spenddown and any amount to be paid by the department after application of any applicable Medicaid copayment or spenddown.

"Medicare payment amount" means the Medicare reimbursement rate for the services rendered in a crossover claim, excluding any Medicare coinsurance or deductible amounts to be paid by the Medicare beneficiary.

b. *Reimbursement of crossover claims.* Crossover claims for inpatient or outpatient hospital services covered under Medicare and Medicaid shall be reimbursed as follows.

(1) If the Medicare payment amount for a crossover claim exceeds or equals the Medicaid-allowed amount for that claim, Medicaid reimbursement for the crossover claim shall be zero.

(2) If the Medicaid-allowed amount for a crossover claim exceeds the Medicare payment amount for that claim, Medicaid reimbursement for the crossover claim shall be the lesser of:

1. The Medicaid-allowed amount minus the Medicare payment amount; or
2. The Medicare coinsurance and deductible amounts applicable to the claim.

c. Additional Medicaid payment for crossover claims uncollectible from Medicare. Medicaid shall reimburse hospitals for the portion of crossover claims not covered by Medicaid reimbursement pursuant to paragraph *"b"* and not reimbursable by Medicare as an allowable bad debt pursuant to 42 CFR 413.80, as amended June 13, 2001, up to a limit of 30 percent of the amount not paid by Medicaid pursuant to paragraph *"b."* The department shall calculate these amounts for each provider on a calendar-year basis and make payment for these amounts by March 31 of each year for the preceding calendar year.

d. Application of savings. Savings in Medicaid reimbursements attributable to the limits on inpatient and outpatient crossover claims established by this subrule shall be used to pay costs associated with development and implementation of this subrule before reversion to Medicaid.

79.1(23) *Reimbursement for remedial services.* Reimbursement for remedial services shall be made on the basis of a unit rate that is calculated retrospectively for each provider, considering reasonable and proper costs of operation. The unit rate shall not exceed the established unit-of-service limit on reasonable costs pursuant to subparagraph 79.1(23)*"c"*(1). The unit of service may be a quarter-hour, a half-hour, an hour, a half-day, or a day, depending on the service provided.

a. Interim rate. Providers shall be reimbursed through a prospective interim rate equal to the previous year's retrospectively calculated unit-of-service rate. On an interim basis, pending determination of remedial services provider costs, the provider may bill for and shall be reimbursed at a unit-of-service rate that the provider and the Iowa Medicaid enterprise may reasonably expect to produce total payments to the provider for the provider's fiscal year that are consistent with Medicaid's obligation to reimburse that provider's reasonable costs. The interim unit-of-service rate is subject to the established unit-of-service limit on reasonable costs pursuant to subparagraph 79.1(23)*"c"*(1).

b. Cost reports. Reasonable and proper costs of operation shall be determined based on cost reports submitted by the provider.

(1) Financial information shall be based on the provider's financial records. When the records are not kept on an accrual basis of accounting, the provider shall make the adjustments necessary to convert the information to an accrual basis for reporting. Failure to maintain records to support the cost report may result in termination of the provider's Medicaid enrollment.

(2) The provider shall complete Form 470-4414, Financial and Statistical Report for Remedial Services, and submit it to the IME Provider Cost Audit and Rate Setting Unit, P.O. Box 36450, Des Moines, Iowa 50315, within three months of the end of the provider's fiscal year.

(3) A provider may obtain a 30-day extension for submitting the cost report by sending a letter to the IME provider cost audit and rate setting unit before the cost report due date. No extensions will be granted beyond 30 days.

(4) Providers of services under multiple programs shall submit a cost allocation schedule, prepared in accordance with the generally accepted accounting principles and requirements specified in OMB Circular A-87. Costs reported under remedial services shall not be reported as reimbursable costs under any other funding source. Costs incurred for other services shall not be reported as reimbursable costs under remedial services.

(5) If a provider fails to submit a cost report that meets the requirement of this paragraph, the department shall reduce payment to 76 percent of the current rate. The reduced rate shall be paid for not longer than three months, after which time no further payments will be made.

(6) A projected cost report shall be submitted when a new remedial services provider enters the program or an existing remedial services provider adds a new service code. A prospective interim rate shall be established using the projected cost report. The effective date of the rate shall be the day the provider becomes certified as a Medicaid provider or the day the new service is added.

c. Rate determination. Cost reports as filed shall be subject to review and audit by the Iowa Medicaid enterprise to determine the actual cost of services rendered to Medicaid members, using an accepted method of cost apportionment (as specified in OMB Circular A-87).

(1) A reasonable cost for a member is one that does not exceed 110 percent of the average allowable costs reported by Iowa Medicaid providers for providing similar remedial services to members who have similar diagnoses and live in similar settings.

(2) When the reasonable and proper costs of operation are determined, a retroactive adjustment shall be made. The retroactive adjustment represents the difference between the amount received by the provider through an interim rate during the year for covered services and the reasonable and proper costs of operation determined in accordance with this subrule.

79.1(24) *Reimbursement for home- and community-based habilitation services.* Reimbursement for case management, job development, and employer development is based on a fee schedule developed using the methodology described in paragraph 79.1(1)*"d."* Reimbursement for home-based habilitation, day habilitation, prevocational habilitation, enhanced job search and supports to maintain employment is based on a retrospective cost-related rate calculated using the methodology in this subrule. All rates are subject to the upper limits established in subrule 79.1(2).

a. Units of service.

(1) Effective July 1, 2009, a unit of case management is 15 minutes.

(2) A unit of home-based habilitation is one hour. EXCEPTIONS:

1. A unit of service is one day when a member receives direct supervision for 14 or more hours per day, averaged over a calendar month. The member's comprehensive service plan must identify and reflect the need for this amount of supervision. The provider's documentation must support the number of direct support hours identified in the comprehensive service plan.

2. When cost-effective, a daily rate may be developed for members needing fewer than 14 hours of direct supervision per day. The provider must obtain approval from the Iowa Medicaid enterprise for a daily rate for fewer than 14 hours of service per day.

(3) A unit of day habilitation is an hour, a half-day (1 to 4 hours), or a full day (4 to 8 hours).

(4) A unit of prevocational habilitation is an hour, a half-day (1 to 4 hours), or a full day (4 to 8 hours).

(5) A unit of supported employment habilitation for activities to obtain a job is:

1. One job placement for job development and employer development.

2. One hour for enhanced job search.

(6) A unit of supported employment habilitation supports to maintain employment is one hour.

b. Submission of cost reports. The department shall determine reasonable and proper costs of operation for home-based habilitation, day habilitation, prevocational habilitation, and supported employment based on cost reports submitted by the provider on Form 470-4425, Financial and Statistical Report for HCBS Habilitation Services.

(1) Financial information shall be based on the provider's financial records. When the records are not kept on an accrual basis of accounting, the provider shall make the adjustments necessary to convert the information to an accrual basis for reporting. Failure to maintain records to support the cost report may result in termination of the provider's Medicaid enrollment.

(2) For home-based habilitation, the provider's cost report shall reflect all staff-to-member ratios and costs associated with members' specific support needs for travel and transportation, consulting, and instruction, as determined necessary by the interdisciplinary team for each consumer. The specific support needs must be identified in the member's comprehensive service plan. The total costs shall not exceed $1570 per consumer per year. The provider must maintain records to support all expenditures.

(3) The provider shall submit the complete cost report to the IME Provider Cost Audit and Rate Setting Unit, P.O. Box 36450, Des Moines, Iowa 50315, within three months of the end of the provider's fiscal year. The submission must include a working trial balance. Cost reports submitted without a working trial balance will be considered incomplete.

(4) A provider may obtain a 30-day extension for submitting the cost report by sending a letter to the IME provider cost audit and rate setting unit before the cost report due date. No extensions will be granted beyond 30 days.

(5) A provider of services under multiple programs shall submit a cost allocation schedule, prepared in accordance with the generally accepted accounting principles and requirements specified in OMB Circular A-87. Costs reported under habilitation services shall not be reported as reimbursable costs under any other funding source. Costs incurred for other services shall not be reported as reimbursable costs under habilitation services.

(6) If a provider fails to submit a cost report that meets the requirement of paragraph 79.1(24)*"b,"* the department shall reduce payment to 76 percent of the current rate. The reduced rate shall be paid for not longer than three months, after which time no further payments will be made.

(7) A projected cost report shall be submitted when a new habilitation services provider enters the program or an existing habilitation services provider adds a new service code. A prospective interim rate shall be established using the projected cost report. The effective date of the rate shall be the day the provider becomes certified as a Medicaid provider or the day the new service is added.

c. Rate determination based on cost reports. Reimbursement shall be made using a unit rate that is calculated retrospectively for each provider, considering reasonable and proper costs of operation.

(1) Interim rates. Providers shall be reimbursed through a prospective interim rate equal to the previous year's retrospectively calculated unit-of-service rate. Pending determination of habilitation services provider costs, the provider may bill for and shall be reimbursed at a unit-of-service rate that the provider and the Iowa Medicaid enterprise may reasonably expect to produce total payments to the provider for the provider's fiscal year that are consistent with Medicaid's obligation to reimburse that provider's reasonable costs.

(2) Audit of cost reports. Cost reports as filed shall be subject to review and audit by the Iowa Medicaid enterprise to determine the actual cost of services rendered to Medicaid members, using an accepted method of cost apportionment (as specified in OMB Circular A-87).

(3) Retroactive adjustment. When the reasonable and proper costs of operation are determined, a retroactive adjustment shall be made. The retroactive adjustment represents the difference between the amount that the provider received during the year for covered services through an interim rate and the reasonable and proper costs of operation determined in accordance with this subrule.

79.1(25) *Reimbursement for community mental health centers and providers of mental health services to county residents pursuant to a waiver approved under Iowa Code section 225C.7(3).*

a. Reimbursement methodology. Effective for services rendered on or after October 1, 2006, community mental health centers and providers of mental health services to county residents pursuant to a waiver approved under Iowa Code section 225C.7(3) that provide clinic services are paid on a reasonable-cost basis as determined by Medicare reimbursement principles. Rates are initially paid on an interim basis and then are adjusted retroactively based on submission of a financial and statistical report.

(1) Until a provider that was enrolled int he Medicaid program before October 1, 2006, submits a cost report in order to develop a provider-specific interim rate, the Iowa Medicaid enterprise shall make interim payments to the provider based upon 105 percent of the greater of:

1. The statewide fee schedule for community mental health centers effective July 1, 2006, or

2. The average Medicaid managed care contracted fee amounts for community mental health centers effective July 1, 2006.

(2) For a provider that enrolls in the Medicaid program on or after October 1, 2006, until a provider-specific interim rate is developed, the Iowa Medicaid enterprise shall make interim payments based upon the average statewide interim rates for community mental health centers at the time services are rendered. A new provider may submit a projected cost report that the Iowa Medicaid enterprise will use to develop a provider-specific interim rate.

(3) Cost reports as filed are subject to review and audit by the Iowa Medicaid enterprise. The Iowa Medicaid enterprise shall determine each provider's actual, allowable costs in accordance with generally accepted accounting principles and in accordance with Medicare cost principles, subject to the exceptions and limitations in the department's administrative rules.

(4) The Iowa Medicaid enterprise shall make retroactive adjustment of the interim rate after the submission of annual cost reports. The adjustment represents the difference between the amount the provider received during the year through interim payments for covered services and the amount determined to be the actual, allowable cost of service rendered to Medicaid members.

(5) The Iowa Medicaid enterprise shall use each annual cost report to develop a provider-specific interim fee schedule to be paid prospectively. The effective date of the fee schedule change is the first day of the month following completion of the cost settlement.

b. Reporting requirements. All providers shall submit cost reports using Form 470-4419, Financial and Statistical Report. A hospital-based provider shall also submit the Medicare cost report, CMS Form 2552-96.

(1) Financial information shall be based on the provider's financial records. When the records are not kept on an accrual basis of accounting, the provider shall make the adjustments necessary to convert the information to an accrual basis for reporting. Failure to maintain records to support the cost report may result in termination of the provider's enrollment with the Iowa Medicaid program.

(2) Providers that offer multiple programs shall submit a cost allocation schedule prepared in accordance with generally accepted accounting principles and requirements as specified in OMB Circular A-87 adopted in federal regulations at 2 CFR Part 225 as amended to August 31, 2005.

(3) Costs reported for community mental health clinic services shall not be reported as reimbursable costs under any other funding source. Costs incurred for other services shall not be reported as reimbursable costs under community mental health clinic services.

(4) Providers shall submit completed cost reports to the IME Provider Cost Audit and Rate Setting Unit, P.O. Box 36450, Des Moines, Iowa 50315. A provider that is not hospital-based shall submit Form 470-4419 on or before the last day of the third month after the end of the provider's fiscal year. A hospital-based provider shall submit both Form 470-4419 and CMS Form 2552-96 on or before the last day of the fifth month after the end of the provider's fiscal year.

(5) A provider may obtain a 30-day extension for submitting the cost report by submitting a letter to the IME provider cost audit and rate setting unit before the cost report due date. No extensions will be granted beyond 30 days.

(6) If a provider fails to submit a cost report that meets the requirements of this paragraph, the Iowa Medicaid enterprise shall reduce the provider's interim payments to 76 percent of the current interim rate. The reduced interim rate shall be paid for not longer than three months, after which time no further payments will be made.

This rule is intended to implement Iowa Code section 249A.4.

[**ARC 7835B**, IAB 6/3/09, effective 7/8/09; **ARC 7937B**, IAB 7/1/09, effective 7/1/09; **ARC 7957B**, IAB 7/15/09, effective 7/1/09 (See Delay note at end of chapter); **ARC 8205B**, IAB 10/7/09, effective 11/11/09; **ARC 8206B**, IAB 10/7/09, effective 11/11/09; **ARC 8344B**, IAB 12/2/09, effective 12/1/09; **ARC 8643B**, IAB 4/7/10, effective 3/11/10; **ARC 8647B**, IAB 4/7/10, effective 3/11/10; **ARC 8649B**, IAB 4/7/10, effective 3/11/10]

441—79.2(249A) Sanctions against provider of care. The department reserves the right to impose sanctions against any practitioner or provider of care who has violated the requirements for participation in the medical assistance program.

79.2(1) *Definitions.*

"Affiliates" means persons having an overt or covert relationship such that any one of them directly or indirectly controls or has the power to control another.

"Iowa Medicaid enterprise" means the entity comprised of department staff and contractors responsible for the management and reimbursement of Medicaid services.

"Person" means any natural person, company, firm, association, corporation, or other legal entity.

"Probation" means a specified period of conditional participation in the medical assistance program.

"Provider" means an individual, firm, corporation, association, or institution which is providing or has been approved to provide medical assistance to a recipient pursuant to the state medical assistance program.

"Suspension from participation" means an exclusion from participation for a specified period of time.

"Suspension of payments" means the withholding of all payments due a provider until the resolution of the matter in dispute between the provider and the department.

"Termination from participation" means a permanent exclusion from participation in the medical assistance program.

"Withholding of payments" means a reduction or adjustment of the amounts paid to a provider on pending and subsequently submitted bills for purposes of offsetting overpayments previously made to the provider.

79.2(2) *Grounds for sanctioning providers.* Sanctions may be imposed by the department against a provider for any one or more of the following reasons:

a. Presenting or causing to be presented for payment any false or fraudulent claim for services or merchandise.

b. Submitting or causing to be submitted false information for the purpose of obtaining greater compensation than that to which the provider is legally entitled, including charges in excess of usual and customary charges.

c. Submitting or causing to be submitted false information for the purpose of meeting prior authorization requirements.

d. Failure to disclose or make available to the department or its authorized agent, records of services provided to medical assistance recipients and records of payments made for those services.

e. Failure to provide and maintain the quality of services to medical assistance recipients within accepted medical community standards as adjudged by professional peers.

f. Engaging in a course of conduct or performing an act which is in violation of state or federal regulations of the medical assistance program, or continuing that conduct following notification that it should cease.

g. Failure to comply with the terms of the provider certification on each medical assistance check endorsement.

h. Overutilization of the medical assistance program by inducing, furnishing or otherwise causing the recipient to receive services or merchandise not required or requested by the recipient.

i. Rebating or accepting a fee or portion of a fee or a charge for medical assistance patient referral.

j. Violating any provision of Iowa Code chapter 249A, or any rule promulgated pursuant thereto.

k. Submission of a false or fraudulent application for provider status under the medical assistance program.

l. Violations of any laws, regulations, or code of ethics governing the conduct of occupations or professions or regulated industries.

m. Conviction of a criminal offense relating to performance of a provider agreement with the state or for negligent practice resulting in death or injury to patients.

n. Failure to meet standards required by state or federal law for participation, for example, licensure.

o. Exclusion from Medicare because of fraudulent or abusive practices.

p. Documented practice of charging recipients for covered services over and above that paid for by the department, except as authorized by law.

q. Failure to correct deficiencies in provider operations after receiving notice of these deficiencies from the department.

r. Formal reprimand or censure by an association of the provider's peers for unethical practices.

s. Suspension or termination from participation in another governmental medical program such as workers' compensation, crippled children's services, rehabilitation services or Medicare.

t. Indictment for fraudulent billing practices, or negligent practice resulting in death or injury to the provider's patients.

79.2(3) *Sanctions.* The following sanctions may be imposed on providers based on the grounds specified in 79.2(2).

a. A term of probation for participation in the medical assistance program.

b. Termination from participation in the medical assistance program.

c. Suspension from participation in the medical assistance program. This includes when the department is notified by the Centers for Medicare and Medicaid Services, Department of Health and Human Services, that a practitioner has been suspended from participation under the Medicare program. These practitioners shall be suspended from participation in the medical assistance program effective on the date established by the Centers for Medicare and Medicaid Services and at least for the period of time of the Medicare suspension.

d. Suspension or withholding of payments to provider.

e. Referral to peer review.

f. Prior authorization of services.

g. One hundred percent review of the provider's claims prior to payment.

h. Referral to the state licensing board for investigation.

i. Referral to appropriate federal or state legal authorities for investigation and prosecution under applicable federal or state laws.

j. Providers with a total Medicaid credit balance of more than $500 for more than 60 consecutive days without repaying or reaching written agreement to repay the balance shall be charged interest at 10 percent per year on each overpayment. The interest shall begin to accrue retroactively to the first full month that the provider had a credit balance over $500.

Nursing facilities shall make repayment or reach agreement with the division of medical services. All other providers shall make repayment or reach agreement with the Iowa Medicaid enterprise. Overpayments and interest charged may be withheld from future payments to the provider.

79.2(4) *Imposition and extent of sanction.*

a. The decision on the sanction to be imposed shall be the commissioner's or designated representative's except in the case of a provider terminated from the Medicare program.

b. The following factors shall be considered in determining the sanction or sanctions to be imposed:

(1) Seriousness of the offense.

(2) Extent of violations.

(3) History of prior violations.

(4) Prior imposition of sanctions.

(5) Prior provision of provider education.

(6) Provider willingness to obey program rules.

(7) Whether a lesser sanction will be sufficient to remedy the problem.

(8) Actions taken or recommended by peer review groups or licensing boards.

79.2(5) *Scope of sanction.*

a. The sanction may be applied to all known affiliates of a provider, provided that each decision to include an affiliate is made on a case-by-case basis after giving due regard to all relevant facts and circumstances. The violation, failure, or inadequacy of performance may be imputed to a person with whom the violator is affiliated where the conduct was accomplished in the course of official duty or was effectuated with the knowledge or approval of that person.

b. Suspension or termination from participation shall preclude the provider from submitting claims for payment, whether personally or through claims submitted by any clinic, group, corporation, or other association, for any services or supplies except for those services provided before the suspension or termination.

c. No clinic, group, corporation, or other association which is the provider of services shall submit claims for payment for any services or supplies provided by a person within the organization who has been suspended or terminated from participation in the medical assistance program except for those services provided before the suspension or termination.

d. When the provisions of paragraph 79.2(5)*"c"* are violated by a provider of services which is a clinic, group, corporation, or other association, the department may suspend or terminate the organization, or any other individual person within the organization who is responsible for the violation.

79.2(6) *Notice of sanction.* When a provider has been sanctioned, the department shall notify as appropriate the applicable professional society, board of registration or licensure, and federal or state agencies of the findings made and the sanctions imposed.

79.2(7) *Notice of violation.* Should the department have information that indicates that a provider may have submitted bills or has been practicing in a manner inconsistent with the program requirements, or may have received payment for which the provider may not be properly entitled, the department shall notify the provider of the discrepancies noted. Notification shall set forth:

a. The nature of the discrepancies or violations,

b. The known dollar value of the discrepancies or violations,

c. The method of computing the dollar value,

d. Notification of further actions to be taken or sanctions to be imposed by the department, and

e. Notification of any actions required of the provider. The provider shall have 15 days subsequent to the date of the notice prior to the department action to show cause why the action should not be taken.

79.2(8) *Suspension or withholding of payments pending a final determination.* Where the department has notified a provider of a violation pursuant to 79.2(7) or an overpayment, the department may withhold payments on pending and subsequently received claims in an amount reasonably calculated to approximate the amounts in question or may suspend payment pending a final determination. Where the department intends to withhold or suspend payments it shall notify the provider in writing.

This rule is intended to implement Iowa Code section 249A.4.

441—79.3(249A) Maintenance of records by providers of service. A provider of a service that is charged to the medical assistance program shall maintain complete and legible records as required in this rule. Failure to maintain records or failure to make records available to the department or to its authorized representative timely upon request may result in claim denial or recoupment.

79.3(1) *Financial (fiscal) records.*

a. A provider of service shall maintain records as necessary to:

(1) Support the determination of the provider's reimbursement rate under the medical assistance program; and

(2) Support each item of service for which a charge is made to the medical assistance program. These records include financial records and other records as may be necessary for reporting and accountability.

b. A financial record does not constitute a medical record.

79.3(2) *Medical (clinical) records.* A provider of service shall maintain complete and legible medical records for each service for which a charge is made to the medical assistance program. Required records shall include any records required to maintain the provider's license in good standing.

a. Definition. "Medical record" (also called "clinical record") means a tangible history that provides evidence of:

(1) The provision of each service and each activity billed to the program; and

(2) First and last name of the member receiving the service.

b. Purpose. The medical record shall provide evidence that the service provided is:

(1) Medically necessary;

(2) Consistent with the diagnosis of the member's condition; and

(3) Consistent with professionally recognized standards of care.

c. Components.

(1) Identification. Each page or separate electronic document of the medical record shall contain the member's first and last name. In the case of electronic documents, the member's first and last name must appear on each screen when viewed electronically and on each page when printed. As part of the medical record, the medical assistance identification number and the date of birth must also be identified and associated with the member's first and last name.

(2) Basis for service—general rule. General requirements for all services are listed herein. For the application of these requirements to specific services, see paragraph 79.3(2)*"d."* The medical record shall reflect the reason for performing the service or activity, substantiate medical necessity, and demonstrate the level of care associated with the service. The medical record shall include the items specified below unless the listed item is not routinely received or created in connection with a particular service or activity and is not required to document the reason for performing the service or activity, the medical necessity of the service or activity, or the level of care associated with the service or activity:

1. The member's complaint, symptoms, and diagnosis.
2. The member's medical or social history.
3. Examination findings.
4. Diagnostic test reports, laboratory test results, or X-ray reports.
5. Goals or needs identified in the member's plan of care.

6. Physician orders and any prior authorizations required for Medicaid payment.
7. Medication records, pharmacy records for prescriptions, or providers' orders.
8. Related professional consultation reports.
9. Progress or status notes for the services or activities provided.
10. All forms required by the department as a condition of payment for the services provided.
11. Any treatment plan, care plan, service plan, individual health plan, behavioral intervention plan, or individualized education program.
12. The provider's assessment, clinical impression, diagnosis, or narrative, including the complete date thereof and the identity of the person performing the assessment, clinical impression, diagnosis, or narrative.
13. Any additional documentation necessary to demonstrate the medical necessity of the service provided or otherwise required for Medicaid payment.

(3) Service documentation. The record for each service provided shall include information necessary to substantiate that the service was provided and shall include the following:

1. The specific procedures or treatments performed.
2. The complete date of the service, including the beginning and ending date if the service is rendered over more than one day.
3. The complete time of the service, including the beginning and ending time if the service is billed on a time-related basis. For those time-related services billed using Current Procedural Terminology (CPT) codes, the total time of the service shall be recorded, rather than the beginning and ending time.
4. The location where the service was provided if otherwise required on the billing form or in 441—paragraph 77.30(5)*"c"* or *"d,"* 441—paragraph 77.33(6)*"d,"* 441—paragraph 77.34(5)*"d,"* 441—paragraph 77.37(15)*"d,"* 441—paragraph 77.39(13)*"e,"* 441—paragraph 77.39(14)*"d,"* or 441—paragraph 77.46(5)*"i,"* or 441—subparagraph 78.9(10)*"a"*(1).
5. The name, dosage, and route of administration of any medication dispensed or administered as part of the service.
6. Any supplies dispensed as part of the service.
7. The first and last name and professional credentials, if any, of the person providing the service.
8. The signature of the person providing the service, or the initials of the person providing the service if a signature log indicates the person's identity.
9. For 24-hour care, documentation for every shift of the services provided, the member's response to the services provided, and the person who provided the services.

(4) Outcome of service. The medical record shall indicate the member's progress in response to the services rendered, including any changes in treatment, alteration of the plan of care, or revision of the diagnosis.

d. Basis for service requirements for specific services. The medical record for the following services must include, but is not limited to, the items specified below (unless the listed item is not routinely received or created in connection with the particular service or activity and is not required to document the reason for performing the service or activity, its medical necessity, or the level of care associated with it). These items will be specified on Form 470-4479, Documentation Checklist, when the Iowa Medicaid enterprise surveillance and utilization review services unit requests providers to submit records for review. (See paragraph 79.4(2)*"b."*)

(1) Physician (MD and DO) services:

1. Service or office notes or narratives.
2. Procedure, laboratory, or test orders and results.

(2) Pharmacy services:

1. Prescriptions.
2. Nursing facility physician order.
3. Telephone order.
4. Pharmacy notes.
5. Prior authorization documentation.

(3) Dentist services:

1. Treatment notes.
2. Anesthesia notes and records.
3. Prescriptions.

(4) Podiatrist services:
1. Service or office notes or narratives.
2. Certifying physician statement.
3. Prescription or order form.

(5) Certified registered nurse anesthetist services:
1. Service notes or narratives.
2. Preanesthesia physical examination report.
3. Operative report.
4. Anesthesia record.
5. Prescriptions.

(6) Other advanced registered nurse practitioner services:
1. Service or office notes or narratives.
2. Procedure, laboratory, or test orders and results.

(7) Optometrist and optician services:
1. Notes or narratives supporting eye examinations, medical services, and auxiliary procedures.
2. Original prescription or updated prescriptions for corrective lenses or contact lenses.
3. Prior authorization documentation.

(8) Psychologist services:
1. Service or office psychotherapy notes or narratives.
2. Psychological examination report and notes.

(9) Clinic services:
1. Service or office notes or narratives.
2. Procedure, laboratory, or test orders and results.
3. Nurses' notes.
4. Prescriptions.
5. Medication administration records.

(10) Services provided by rural health clinics or federally qualified health centers:
1. Service or office notes or narratives.
2. Form 470-2942, Prenatal Risk Assessment.
3. Procedure, laboratory, or test orders and results.
4. Immunization records.

(11) Services provided by community mental health centers:
1. Service referral documentation.
2. Initial evaluation.
3. Individual treatment plan.
4. Service or office notes or narratives.
5. Narratives related to the peer review process and peer review activities related to a member's treatment.
6. Written plan for accessing emergency services.

(12) Screening center services:
1. Service or office notes or narratives.
2. Immunization records.
3. Laboratory reports.
4. Results of health, vision, or hearing screenings.

(13) Family planning services:
1. Service or office notes or narratives.
2. Procedure, laboratory, or test orders and results.
3. Nurses' notes.
4. Immunization records.

5. Consent forms.
6. Prescriptions.
7. Medication administration records.

(14) Maternal health center services:
1. Service or office notes or narratives.
2. Procedure, laboratory, or test orders and results.
3. Form 470-2942, Prenatal Risk Assessment.

(15) Birthing center services:
1. Service or office notes or narratives.
2. Form 470-2942, Prenatal Risk Assessment.

(16) Ambulatory surgical center services:
1. Service notes or narratives (history and physical, consultation, operative report, discharge summary).
2. Physician orders.
3. Consent forms.
4. Anesthesia records.
5. Pathology reports.
6. Laboratory and X-ray reports.

(17) Hospital services:
1. Physician orders.
2. Service notes or narratives (history and physical, consultation, operative report, discharge summary).
3. Progress or status notes.
4. Diagnostic procedures, including laboratory and X-ray reports.
5. Pathology reports.
6. Anesthesia records.
7. Medication administration records.

(18) State mental hospital services:
1. Service referral documentation.
2. Resident assessment and initial evaluation.
3. Individual comprehensive treatment plan.
4. Service notes or narratives (history and physical, therapy records, discharge summary).
5. Form 470-0042, Case Activity Report.
6. Medication administration records.

(19) Services provided by skilled nursing facilities, nursing facilities, and nursing facilities for persons with mental illness:
1. Physician orders.
2. Progress or status notes.
3. Service notes or narratives.
4. Procedure, laboratory, or test orders and results.
5. Nurses' notes.
6. Physical therapy, occupational therapy, and speech therapy notes.
7. Medication administration records.
8. Form 470-0042, Case Activity Report.

(20) Services provided by intermediate care facilities for persons with mental retardation:
1. Physician orders.
2. Progress or status notes.
3. Preliminary evaluation.
4. Comprehensive functional assessment.
5. Individual program plan.
6. Form 470-0374, Resident Care Agreement.
7. Program documentation.

8. Medication administration records.
9. Nurses' notes.
10. Form 470-0042, Case Activity Report.

(21) Services provided by psychiatric medical institutions for children:
1. Physician orders or court orders.
2. Independent assessment.
3. Individual treatment plan.
4. Service notes or narratives (history and physical, therapy records, discharge summary).
5. Form 470-0042, Case Activity Report.
6. Medication administration records.

(22) Hospice services:
1. Physician certifications for hospice care.
2. Form 470-2618, Election of Medicaid Hospice Benefit.
3. Form 470-2619, Revocation of Medicaid Hospice Benefit.
4. Plan of care.
5. Physician orders.
6. Progress or status notes.
7. Service notes or narratives.
8. Medication administration records.
9. Prescriptions.

(23) Services provided by rehabilitation agencies:
1. Physician orders.
2. Initial certification, recertifications, and treatment plans.
3. Narratives from treatment sessions.
4. Treatment and daily progress or status notes and forms.

(24) Home- and community-based habilitation services:
1. Notice of decision for service authorization.
2. Service plan (initial and subsequent).
3. Service notes or narratives.

(25) Remedial services and rehabilitation services for adults with a chronic mental illness:
1. Order for services.
2. Comprehensive treatment or service plan (initial and subsequent).
3. Service notes or narratives.

(26) Services provided by area education agencies and local education agencies:
1. Service notes or narratives.
2. Individualized education program (IEP).
3. Individual health plan (IHP).
4. Behavioral intervention plan.

(27) Home health agency services:
1. Plan of care or plan of treatment.
2. Certifications and recertifications.
3. Service notes or narratives.
4. Physician orders or medical orders.

(28) Services provided by independent laboratories:
1. Laboratory reports.
2. Physician order for each laboratory test.

(29) Ambulance services:
1. Documentation on the claim or run report supporting medical necessity of the transport.
2. Documentation supporting mileage billed.

(30) Services of lead investigation agencies:
1. Service notes or narratives.
2. Child's lead level logs (including laboratory results).

3. Written investigation reports to family, owner of building, child's medical provider, and local childhood lead poisoning prevention program.

4. Health education notes, including follow-up notes.

(31) Medical supplies:

1. Prescriptions.

2. Certificate of medical necessity.

3. Prior authorization documentation.

4. Medical equipment invoice or receipt.

(32) Orthopedic shoe dealer services:

1. Service notes or narratives.

2. Prescriptions.

3. Certifying physician's statement.

(33) Case management services, including HCBS case management services:

1. Form 470-3956, MR/CMI/DD Case Management Service Authorization Request, for services authorized before May 1, 2007.

2. Notice of decision for service authorization.

3. Service notes or narratives.

4. Social history.

5. Comprehensive service plan.

6. Reassessment of member needs.

7. Incident reports in accordance with 441—subrule 24.4(5).

(34) Early access service coordinator services:

1. Individualized family service plan (IFSP).

2. Service notes or narratives.

(35) Home- and community-based waiver services, other than case management:

1. Notice of decision for service authorization.

2. Service plan.

3. Service logs, notes, or narratives.

4. Mileage and transportation logs.

5. Log of meal delivery.

6. Invoices or receipts.

7. Forms 470-3372, HCBS Consumer-Directed Attendant Care Agreement, and 470-4389, Consumer-Directed Attendant Care (CDAC) Service Record.

(36) Physical therapist services:

1. Physician order for physical therapy.

2. Initial physical therapy certification, recertifications, and treatment plans.

3. Treatment notes and forms.

4. Progress or status notes.

(37) Chiropractor services:

1. Service or office notes or narratives.

2. X-ray results.

(38) Hearing aid dealer and audiologist services:

1. Physician examinations and audiological testing (Form 470-0361, Sections A, B, and C).

2. Documentation of hearing aid evaluation and selection (Form 470-0828).

3. Waiver of informed consent.

4. Prior authorization documentation.

5. Service or office notes or narratives.

(39) Behavioral health services:

1. Assessment.

2. Individual treatment plan.

3. Service or office notes or narratives.

e. *Corrections.* A provider may correct the medical record before submitting a claim for reimbursement.

(1) Corrections must be made or authorized by the person who provided the service or by a person who has first-hand knowledge of the service.

(2) A correction to a medical record must not be written over or otherwise obliterate the original entry. A single line may be drawn through erroneous information, keeping the original entry legible. In the case of electronic records, the original information must be retained and retrievable.

(3) Any correction must indicate the person making the change and any other person authorizing the change, must be dated and signed by the person making the change, and must be clearly connected with the original entry in the record.

(4) If a correction made after a claim has been submitted affects the accuracy or validity of the claim, an amended claim must be submitted.

79.3(3) *Maintenance requirement.* The provider shall maintain records as required by this rule:

a. During the time the member is receiving services from the provider.

b. For a minimum of five years from the date when a claim for the service was submitted to the medical assistance program for payment.

c. As may be required by any licensing authority or accrediting body associated with determining the provider's qualifications.

79.3(4) *Availability.* Rescinded IAB 1/30/08, effective 4/1/08.

This rule is intended to implement Iowa Code section 249A.4.

[**ARC 7957B**, IAB 7/15/09, effective 7/1/09; **ARC 8262B**, IAB 11/4/09, effective 12/9/09]

441—79.4(249A) Reviews and audits.

79.4(1) *Definitions.*

"Authorized representative," within the context of this rule, means the person appointed to carry out audit or review procedures, including assigned auditors, reviewers or agents contracted for specific audits, reviews, or audit or review procedures.

"Claim" means each record received by the department or the Iowa Medicaid enterprise that states the amount of requested payment and the service rendered by a specific and particular Medicaid provider to an eligible member.

"Clinical record" means a legible electronic or hard-copy history that documents the criteria established for medical records as set forth in rule 441—79.3(249A). A claim form or billing statement does not constitute a clinical record.

"Confidence level" means the statistical reliability of the sampling parameters used to estimate the proportion of payment errors (overpayment and underpayment) in the universe under review.

"Customary and prevailing fee" means a fee that is both (1) the most consistent charge by a Medicaid provider for a given service and (2) within the range of usual charges for a given service billed by most providers with similar training and experience in the state of Iowa.

"Extrapolation" means that the total amount of overpayment or underpayment will be determined by using sample data meeting the confidence level requirement.

"Fiscal record" means a legible electronic or hard-copy history that documents the criteria established for fiscal records as set forth in rule 441—79.3(249A). A claim form or billing statement does not constitute a fiscal record.

"Overpayment" means any payment or portion of a payment made to a provider that is incorrect according to the laws and rules applicable to the Medicaid program and that results in a payment greater than that to which the provider is entitled.

"Procedure code" means the identifier that describes medical or remedial services performed or the supplies, drugs, or equipment provided.

"Random sample" means a statistically valid random sample for which the probability of selection for every item in the universe is known.

"Underpayment" means any payment or portion of a payment not made to a provider for services delivered to eligible members according to the laws and rules applicable to the Medicaid program and to which the provider is entitled.

"Universe" means all items or claims under review or audit during the period specified by the audit or review.

79.4(2) *Audit or review of clinical and fiscal records by the department.* Any Medicaid provider may be audited or reviewed at any time at the discretion of the department.

a. Authorized representatives of the department shall have the right, upon proper identification, to audit or review the clinical and fiscal records of the provider to determine whether:

(1) The department has correctly paid claims for goods or services.

(2) The provider has furnished the services to Medicaid members.

(3) The provider has retained clinical and fiscal records that substantiate claims submitted for payment.

(4) The goods or services provided were in accordance with Iowa Medicaid policy.

b. Requests for provider records by the Iowa Medicaid enterprise surveillance and utilization review services unit shall include Form 470-4479, Documentation Checklist, which is available at www.ime.state.ia.us/Providers/Forms.html, listing the specific records that must be provided for the audit or review pursuant to paragraph 79.3(2)*"d"* to document the basis for services or activities provided, in the following format:

Iowa Department of Human Services

Iowa Medicaid Enterprise Surveillance and Utilization Review Services

Documentation Checklist

Date of Request: _____

Reviewer Name & Phone Number: _____

Provider Name: _____

Provider Number: _____

Provider Type: _____

Please sign this form and return it with the information requested.

Follow the checklist to ensure that all documents requested for each patient have been copied and enclosed with this request. The documentation must support the validity of the claim that was paid by the Medicaid program.

Please send copies. Do not send original records.

If you have any questions about this request or checklist, please contact the reviewer listed above.

	[specific documentation required]
	[specific documentation required]
	[specific documentation required]
	[specific documentation required]
	[Note: number of specific documents required varies by provider type]
	Any additional documentation that demonstrates the medical necessity of the service provided or otherwise required for Medicaid payment. List additional documentation below if needed.

The person signing this form is certifying that all documentation that supports the Medicaid billed rates, units, and services is enclosed.

Signature	Title	Telephone Number

470-4479 (4/08)

c. Records generated and maintained by the department may be used by auditors or reviewers and in all proceedings of the department.

79.4(3) *Audit or review procedures.* The department will select the method of conducting an audit or review and will protect the confidential nature of the records being audited or reviewed. The provider may be required to furnish records to the department. Unless the department specifies otherwise, the provider may select the method of delivering any requested records to the department.

a. Upon a written request for records, the provider must submit all responsive records to the department or its authorized agent within 30 calendar days of the mailing date of the request, except as provided in paragraph *"b."*

b. Extension of time limit for submission.

(1) The department may grant an extension to the required submission date of up to 15 calendar days upon written request from the provider or the provider's designee. The request must:

1. Establish good cause for the delay in submitting the records; and
2. Be received by the department before the date the records are due to be submitted.

(2) Under exceptional circumstances, a provider may request one additional 15-calendar-day extension. The provider or the provider's designee shall submit a written request that:

1. Establishes exceptional circumstances for the delay in submitting records; and
2. Is received by the department before the expiration of the initial 15-day extension period.

(3) The department may grant a request for an extension of the time limit for submitting records at its discretion. The department shall issue a written notice of its decision.

(4) The provider may appeal the department's denial of a request to extend the time limit for submission of requested records according to the procedures in 441—Chapter 7.

c. The department may elect to conduct announced or unannounced on-site reviews or audits. Records must be provided upon request and before the end of the on-site review or audit.

(1) For an announced on-site review or audit, the department's employee or authorized agent may give as little as one day's advance notice of the review or audit and the records and supporting documentation to be reviewed.

(2) Notice is not required for unannounced on-site reviews and audits.

(3) In an on-site review or audit, the conclusion of that review or audit shall be considered the end of the period within which to produce records.

d. Audit or review procedures may include, but are not limited to, the following:

(1) Comparing clinical and fiscal records with each claim.

(2) Interviewing members who received goods or services and employees of providers.

(3) Examining third-party payment records.

(4) Comparing Medicaid charges with private-patient charges to determine that the charge to Medicaid is not more than the customary and prevailing fee.

(5) Examining all documents related to the services for which Medicaid was billed.

e. *Use of statistical sampling techniques.* The department's procedures for auditing or reviewing Medicaid providers may include the use of random sampling and extrapolation.

(1) A statistically valid random sample will be selected from the universe of records to be audited or reviewed. The sample size shall be selected using accepted sample size estimation methods. The confidence level of the sample size calculation shall not be less than 95 percent.

(2) Following the sample audit or review, the statistical margin of error of the sample will be computed, and a confidence interval will be determined. The estimated error rate will be extrapolated to the universe from which the sample was drawn within the computed margin of error of the sampling process.

(3) Commonly accepted statistical analysis programs may be used to estimate the sample size and calculate the confidence interval, consistent with the sampling parameters.

(4) The audit or review findings generated through statistical sampling procedures shall constitute prima facie evidence in all department proceedings regarding the number and amount of overpayments or underpayments received by the provider.

79.4(4) *Preliminary report of audit or review findings.* If the department concludes from an audit or review that an overpayment has occurred, the department will issue a preliminary finding of a tentative overpayment and inform the provider of the opportunity to request a reevaluation.

79.4(5) *Disagreement with audit or review findings.* If a provider disagrees with the preliminary finding of a tentative overpayment, the provider may request a reevaluation by the department and may present clarifying information and supplemental documentation.

a. Reevaluation request. A request for reevaluation must be submitted in writing within 15 calendar days of the date of the notice of the preliminary finding of a tentative overpayment. The request must specify the issues of disagreement.

(1) If the audit or review is being performed by the Iowa Medicaid enterprise surveillance and utilization review services unit, the request should be addressed to: IME SURS Unit, P.O. Box 36390, Des Moines, Iowa 50315.

(2) If the audit or review is being performed by any other departmental entity, the request should be addressed to: Iowa Department of Human Services, Attention: Fiscal Management Division, Hoover State Office Building, 1305 E. Walnut Street, Des Moines, Iowa 50319-0114.

b. Additional information. A provider that has made a reevaluation request pursuant to paragraph *"a"* of this subrule may submit clarifying information or supplemental documentation that was not previously provided. This information must be received at the applicable address within 30 calendar days of the mailing of the preliminary finding of a tentative overpayment to the provider, except as provided in paragraph *"c"* of this subrule.

c. Disagreement with sampling results. When the department's audit or review findings have been generated through sampling and extrapolation and the provider disagrees with the findings, the burden of proof of compliance rests with the provider. The provider may present evidence to show that the sample was invalid. The evidence may include a 100 percent audit or review of the universe of provider records used by the department in the drawing of the department's sample. Any such audit or review must:

(1) Be arranged and paid for by the provider.

(2) Be conducted by an individual or organization with expertise in coding, medical services, and Iowa Medicaid policy if the issues relate to clinical records.

(3) Be conducted by a certified public accountant if the issues relate to fiscal records.

(4) Demonstrate that bills and records that were not audited or reviewed in the department's sample are in compliance with program regulations.

(5) Be submitted to the department with all supporting documentation within 60 calendar days of the mailing of the preliminary finding of a tentative overpayment to the provider.

79.4(6) *Finding and order for repayment.* Upon completion of a requested reevaluation or upon expiration of the time to request reevaluation, the department shall issue a finding and order for repayment of any overpayment and may immediately begin withholding payments on other claims to recover any overpayment.

79.4(7) *Appeal by provider of care.* A provider may appeal the finding and order of repayment and withholding of payments pursuant to 441—Chapter 7. However, an appeal shall not stay the withholding of payments or other action to collect the overpayment.

This rule is intended to implement Iowa Code section 249A.4.

441—79.5(249A) Nondiscrimination on the basis of handicap. All providers of service shall comply with Section 504 of the Rehabilitation Act of 1973 and Federal regulations 45 CFR Part 84, as amended to December 19, 1990, which prohibit discrimination on the basis of handicap in all Department of Health and Human Services funded programs.

This rule is intended to implement Iowa Code subsection 249A.4(6).

441—79.6(249A) Provider participation agreement. Providers of medical and health care wishing to participate in the program shall execute an agreement with the department on Form 470-2965, Agreement Between Provider of Medical and Health Services and the Iowa Department of Human Services Regarding Participation in Medical Assistance Program.

EXCEPTION: Dental providers are required to complete Form 470-3174, Addendum to Dental Provider Agreement for Orthodontia, to receive reimbursement under the early and periodic screening, diagnosis, and treatment program.

In these agreements, the provider agrees to the following:

79.6(1) To maintain clinical and fiscal records as specified in rule 441—79.3(249A).

79.6(2) That the charges as determined in accordance with the department's policy shall be the full and complete charge for the services provided and no additional payment shall be claimed from the recipient or any other person for services provided under the program.

79.6(3) That it is understood that payment in satisfaction of the claim will be from federal and state funds and any false claims, statements, or documents, or concealment of a material fact may be prosecuted under applicable federal and state laws.

This rule is intended to implement Iowa Code section 249A.4.

441—79.7(249A) Medical assistance advisory council.

79.7(1) *Officers.* Officers shall be a chairperson and a vice-chairperson.

a. The director of public health shall serve as chairperson of the council. Elections for vice-chairperson will be held the first meeting after the beginning of the calendar year.

b. The vice-chairperson's term of office shall be two years. A vice-chairperson shall serve no more than two terms.

c. The vice-chairperson shall serve in the absence of the chairperson.

d. The chairperson and vice-chairperson shall have the right to vote on any issue before the council.

e. The chairperson shall appoint a committee of not less than three members to nominate vice-chairpersons and shall appoint other committees approved by the council.

79.7(2) *Membership.* The membership of the council and its executive committee shall be as prescribed at Iowa Code section 249A.4B, subsections 2 and 3.

79.7(3) *Expenses, staff support, and technical assistance.* Expenses of the council and executive committee, such as those for clerical services, mailing, telephone, and meeting place, shall be the responsibility of the department of human services. The department shall arrange for a meeting place, related services, and accommodations. The department shall provide staff support and independent technical assistance to the council and the executive committee.

79.7(4) *Meetings.* The council shall meet no more than quarterly. The executive committee shall meet on a monthly basis. Meetings may be called by the chairperson, upon written request of at least 50 percent of the members, or by the director of the department of human services.

a. Meetings shall be held in the Des Moines, Iowa, area, unless other notification is given.

b. Written notice of council meetings shall be mailed at least two weeks in advance of the meeting. Each notice shall include an agenda for the meeting.

79.7(5) *Procedures.*

a. A quorum shall consist of 50 percent of the voting members.

b. Where a quorum is present, a position is carried by two-thirds of the council members present.

c. Minutes of council meetings and other written materials developed by the council shall be distributed by the department to each member and to the executive office of each professional group or business entity represented.

d. Notice shall be given to a professional group or business entity represented on the council when the representative of that group or entity has been absent from three consecutive meetings.

e. In cases not covered by these rules, Robert's Rules of Order shall govern.

79.7(6) *Duties.*

a. *Executive committee.* Based upon the deliberations of the medical assistance advisory council and the executive committee, the executive committee shall make recommendations to the director regarding the budget, policy, and administration of the medical assistance program. Such recommendations may include:

(1) Recommendations on the reimbursement for medical services rendered by providers of services.

(2) Identification of unmet medical needs and maintenance needs which affect health.

(3) Recommendations for objectives of the program and for methods of program analysis and evaluation, including utilization review.

(4) Recommendations for ways in which needed medical supplies and services can be made available most effectively and economically to the program recipients.

(5) Advice on such administrative and fiscal matters as the director of the department of human services may request.

b. *Council.* The medical assistance advisory council shall:

(1) Advise the professional groups and business entities represented and act as liaison between them and the department.

(2) Report at least annually to the professional groups and business entities represented.

(3) Perform other functions as may be provided by state or federal law or regulation.

(4) Communicate information considered by the council to the professional groups and business entities represented.

79.7(7) *Responsibilities.*

a. Recommendations of the council shall be advisory and not binding upon the department of human services or the professional groups and business entities represented. The director of the department of human services shall consider the recommendations offered by the council and the executive committee in:

(1) The director's preparation of medical assistance budget recommendations to the council on human services, pursuant to Iowa Code section 217.3, and

(2) Implementation of medical assistance program policies.

b. The council may choose subjects for consideration and recommendation. It shall consider all matters referred to it by the department of human services.

c. Any matter referred by a member organization or body shall be considered upon an affirmative vote of the council.

d. The department shall provide the council with reports, data, and proposed and final amendments to rules, laws, and guidelines, for its information, review, and comment.

e. The department shall present the annual budget for the medical assistance program for review and comment.

f. The department shall permit staff members to appear before the council to review and discuss specific information and problems.

g. The department shall maintain a current list of members on the council and executive committee.

[**ARC 8263B**, IAB 11/4/09, effective 12/9/09]

441—79.8(249A) Requests for prior authorization. When the Iowa Medicaid enterprise has not reached a decision on a request for prior authorization after 60 days from the date of receipt, the request will be approved.

79.8(1) *Making the request.*

a. Providers may submit requests for prior authorization for any items or procedures by mail or by facsimile transmission (fax) using Form 470-0829, Request for Prior Authorization, or electronically using the Accredited Standards Committee (ASC) X12N 278 transaction, Health Care Services Request for Review and Response. Requests for prior authorization for drugs may also be made by telephone.

b. Providers shall send requests for prior authorization to the Iowa Medicaid enterprise. The request should address the relevant criteria applicable to the particular service, medication or equipment for which prior authorization is sought, according to rule 441—78.28(249A). Copies of history and examination results may be attached to rather than incorporated in the letter.

c. If a request for prior authorization submitted electronically requires attachments or supporting clinical documentation and a national electronic attachment has not been adopted, the provider shall:

(1) Use Form 470-3970, Prior Authorization Attachment Control, as the cover sheet for the paper attachments or supporting clinical documentation; and

(2) Reference on Form 470-3970 the attachment control number submitted on the ASC X12N 278 electronic transaction.

79.8(2) The policy applies to services or items specifically designated as requiring prior authorization.

79.8(3) The provider shall receive a notice of approval or denial for all requests.

a. In the case of prescription drugs, notices of approval or denial will be faxed to the prescriber and pharmacy.

b. Decisions regarding approval or denial will be made within 24 hours from the receipt of the prior authorization request. In cases where the request is received during nonworking hours, the time limit will be construed to start with the first hour of the normal working day following the receipt of the request.

79.8(4) Prior authorizations approved because a decision is not timely made shall not be considered a precedent for future similar requests.

79.8(5) Approved prior authorization applies to covered services and does not apply to the recipient's eligibility for medical assistance.

79.8(6) If a provider is unsure if an item or service is covered because it is rare or unusual, the provider may submit a request for prior approval in the same manner as other requests for prior approval in 79.8(1).

79.8(7) Requests for prior approval of services shall be reviewed according to rule 441—79.9(249A) and the conditions for payment as established by rule in 441—Chapter 78. Where ambiguity exists as to whether a particular item or service is covered, requests for prior approval shall be reviewed according to the following criteria in order of priority:

a. The conditions for payment outlined in the provider manual with reference to coverage and duration.

b. The determination made by the Medicare program unless specifically stated differently in state law or rule.

c. The recommendation to the department from the appropriate advisory committee.

d. Whether there are other less expensive procedures which are covered and which would be as effective.

e. The advice of an appropriate professional consultant.

79.8(8) The amount, duration and scope of the Medicaid program is outlined in 441—Chapters 78, 79, 81, 82 and 85. Additional clarification of the policies is available in the provider manual distributed and updated to all participating providers.

79.8(9) The Iowa Medicaid enterprise shall issue a notice of decision to the recipient upon a denial of request for prior approval pursuant to 441—Chapter 7. The Iowa Medicaid enterprise shall mail the notice of decision to the recipient within five working days of the date the prior approval form is returned to the provider.

79.8(10) If a request for prior approval is denied by the Iowa Medicaid enterprise, the request may be resubmitted for reconsideration with additional information justifying the request. The aggrieved party may file an appeal in accordance with 441—Chapter 7.

This rule is intended to implement Iowa Code section 249A.4.

441—79.9(249A) General provisions for Medicaid coverage applicable to all Medicaid providers and services.

79.9(1) Medicare definitions and policies shall apply to services provided unless specifically defined differently.

79.9(2) The services covered by Medicaid shall:

a. Be consistent with the diagnosis and treatment of the patient's condition.

b. Be in accordance with standards of good medical practice.

c. Be required to meet the medical need of the patient and be for reasons other than the convenience of the patient or the patient's practitioner or caregiver.

d. Be the least costly type of service which would reasonably meet the medical need of the patient.

e. Be eligible for federal financial participation unless specifically covered by state law or rule.

f. Be within the scope of the licensure of the provider.

g. Be provided with the full knowledge and consent of the recipient or someone acting in the recipient's behalf unless otherwise required by law or court order or in emergency situations.

h. Be supplied by a provider who is eligible to participate in the Medicaid program. The provider must use the billing procedures and documentation requirements described in 441—Chapters 78 and 80.

79.9(3) Providers shall supply all the same services to Medicaid eligibles served by the provider as are offered to other clients of the provider.

79.9(4) Recipients must be informed before the service is provided that the recipient will be responsible for the bill if a noncovered service is provided.

79.9(5) Coverage in public institutions. Medical services provided to a person while the person is an inmate of a public jail, prison, juvenile detention center, or other public penal institution of more than four beds are not covered by Medicaid.

This rule is intended to implement Iowa Code section 249A.4.

441—79.10(249A) Requests for preadmission review. The inpatient hospitalization of Medicaid recipients is subject to preadmission review by the Iowa Medicaid enterprise (IME) medical services unit as required in rule 441—78.3(249A).

79.10(1) The patient's admitting physician, the physician's designee, or the hospital will contact the IME medical services unit to request approval of Medicaid coverage for the hospitalization, according to instructions issued to providers by the IME medical services unit and instructions in the Medicaid provider manual.

79.10(2) Medicaid payment will not be made to the hospital if the IME medical services unit denies the procedure requested in the preadmission review.

79.10(3) The IME medical services unit shall issue a letter of denial to the patient, the physician, and the hospital when a request is denied. The patient, the physician, or the hospital may request a reconsideration of the decision by filing a written request with the IME medical services unit within 60 days of the date of the denial letter.

79.10(4) The aggrieved party may appeal a denial of a request for reconsideration by the IME medical services unit according to 441—Chapter 7.

79.10(5) The requirement to obtain preadmission review is waived when the patient is enrolled in the managed health care option known as patient management and proper authorization for the admission has been obtained from the patient manager as described in 441—Chapter 88.

This rule is intended to implement Iowa Code section 249A.4.

441—79.11(249A) Requests for preprocedure surgical review. The Iowa Medicaid enterprise (IME) medical services unit conducts a preprocedure review of certain frequently performed surgical procedures to determine the necessity of the procedures and if Medicaid payment will be approved according to requirements found in 441—subrules 78.1(19), 78.3(18), and 78.26(3).

79.11(1) The physician must request approval from the IME medical services unit when the physician expects to perform a surgical procedure appearing on the department's preprocedure surgical review list published in the Medicaid provider manual. All requests for preprocedure surgical review shall be made according to instructions issued to physicians, hospitals and ambulatory surgical centers appearing in the Medicaid provider manual and instructions issued to providers by the IME medical services unit.

79.11(2) The IME medical services unit shall issue the physician a validation number for each request and shall advise whether payment for the procedure will be approved or denied.

79.11(3) Medicaid payment will not be made to the physician and other medical personnel or the facility in which the procedure is performed, i.e., hospital or ambulatory surgical center, if the IME medical services unit does not give approval.

79.11(4) The IME medical services unit shall issue a denial letter to the patient, the physician, and the facility when the requested procedure is not approved. The patient, the physician, or the facility may

request a reconsideration of the decision by filing a written request with the IME medical services unit within 60 days of the date of the denial letter.

79.11(5) The aggrieved party may appeal a denial of a request for reconsideration by the IME medical services unit in accordance with 441—Chapter 7.

79.11(6) The requirement to obtain preprocedure surgical review is waived when the patient is enrolled in the managed health care option known as patient management and proper authorization for the procedure has been obtained from the patient manager as described in 441—Chapter 88.

This rule is intended to implement Iowa Code section 249A.4.

441—79.12(249A) Advance directives. "Advance directive" means a written instruction, such as a living will or durable power of attorney for health care, recognized under state law and related to the provision of health care when the person is incapacitated. All hospitals, home health agencies, home health providers of waiver services, hospice programs, and health maintenance organizations (HMOs) participating in Medicaid shall establish policies and procedures with respect to all adults receiving medical care through the provider or organization to comply with state law regarding advance directives as follows:

79.12(1) A hospital at the time of a person's admission as an inpatient, a home health care provider in advance of a person's coming under the care of the provider, a hospice provider at the time of initial receipt of hospice care by a person, and a health maintenance organization at the time of enrollment of the person with the organization shall provide written information to each adult which explains the person's rights under state law to make decisions concerning medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate advance directives, and the provider's policies regarding the implementation of these rights.

79.12(2) The provider or organization shall document in the person's medical record whether or not the person has executed an advance directive.

79.12(3) The provider or organization shall not condition the provision of care or otherwise discriminate against a person based on whether or not the person has executed an advance directive.

79.12(4) The provider or organization shall ensure compliance with requirements of state law regarding advance directives.

79.12(5) The provider or organization shall provide for education for staff and the community on issues concerning advance directives.

Nothing in this rule shall be construed to prohibit the application of a state law which allows for an objection on the basis of conscience for any provider or organization which as a matter of conscience cannot implement an advance directive.

This rule is intended to implement Iowa Code section 249A.4.

441—79.13(249A) Requirements for enrolled Medicaid providers supplying laboratory services. Medicaid enrolled entities providing laboratory services are subject to the provisions of the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, and implementing federal regulations published at 42 CFR Part 493 as amended to December 29, 2000. Medicaid payment shall not be afforded for services provided by an enrolled Medicaid provider supplying laboratory services that fails to meet these requirements. For the purposes of this rule, laboratory services are defined as services to examine human specimens for the diagnosis, prevention or treatment of any disease or impairment of, or assessment of, the health of human beings.

This rule is intended to implement Iowa Code section 249A.4.

441—79.14(249A) Provider enrollment.

79.14(1) Application request. A provider of medical or remedial services that wishes to enroll as an Iowa Medicaid provider shall begin the enrollment process by contacting the provider services unit at the Iowa Medicaid enterprise to request an application form.

a. A nursing facility shall also complete the process set forth in 441—subrule 81.13(1).

b. An intermediate care facility for persons with mental retardation shall also complete the process set forth in 441—subrule 82.3(1).

79.14(2) Submittal of application. The provider shall submit the appropriate application forms to the Iowa Medicaid enterprise provider services unit at P.O. Box 36450, Des Moines, Iowa 50315.

a. Providers of home- and community-based waiver services shall submit Form 470-2917, Medicaid HCBS Provider Application, at least 90 days before the planned service implementation date.

b. All other providers shall submit Form 470-0254, Iowa Medicaid Provider Enrollment Application.

c. The application shall include the provider's national provider identifier number or shall indicate that the provider is an atypical provider that is not issued a national provider identifier number.

79.14(3) Notification. Providers shall be notified of the decision on their application by the Iowa Medicaid enterprise provider services unit within 30 calendar days.

79.14(4) Providers not approved as the type of Medicaid provider requested shall have the right to appeal under 441—Chapter 7.

79.14(5) Effective date of approval. Applications shall be approved retroactive to the date requested by the provider or the date the provider meets the applicable participation criteria, whichever is later, not to exceed 12 months retroactive from the receipt of the application forms by the Iowa Medicaid enterprise provider services unit.

79.14(6) Providers approved for certification as a Medicaid provider shall complete a provider participation agreement as required by rule 441—79.6(249A).

79.14(7) No payment shall be made to a provider for care or services provided prior to the effective date of the department's approval of an application, unless the provider was enrolled and participating in the Iowa Medicaid program as of April 1, 1993.

79.14(8) Payment rates dependent on the nature of the provider or the nature of the care or services provided shall be based on information on the application form, together with information on claim forms, or on rates paid the provider prior to April 1, 1993.

79.14(9) Amendments to application forms shall be submitted to the Iowa Medicaid enterprise provider services unit and shall be approved or denied within 30 calendar days. Approval of an amendment shall be retroactive to the date requested by the provider or the date the provider meets all applicable criteria, whichever is later, not to exceed 30 days prior to the receipt of the amendment by the Iowa Medicaid enterprise provider services unit. Denial of an amendment may be appealed under 441—Chapter 7.

79.14(10) Providers who have not submitted claims in the last 24 months will be sent a notice asking if they wish to continue participation. Providers failing to reply to the notice within 30 calendar days of the date on the notice will be terminated as providers. Providers who do not submit any claims in 48 months will be terminated as providers without further notification.

79.14(11) Report of changes. The provider shall inform the Iowa Medicaid enterprise of all pertinent changes to enrollment information within 60 days of the change. Pertinent changes include, but are not limited to, changes to the business entity name, individual provider name, tax identification number, mailing address, and telephone number.

a. When a provider fails to provide current information within the 60-day period, the department may terminate the provider's Medicaid enrollment upon 30 days' notice. The termination may be appealed under 441—Chapter 7.

b. When the department incurs an informational tax-reporting fine because a provider submitted inaccurate information or failed to submit changes to the Iowa Medicaid enterprise in a timely manner, the fine shall be the responsibility of the individual provider to the extent that the fine relates to or arises out of the provider's failure to keep all provider information current.

(1) The provider shall remit the amount of the fine to the department within 30 days of notification by the department that the fine has been imposed.

(2) Payment of the fine may be appealed under 441—Chapter 7.

This rule is intended to implement Iowa Code section 249A.4.

441—79.15(249A) Education about false claims recovery. The provisions in this rule apply to any entity that has received medical assistance payments totaling at least $5 million during a federal fiscal year (ending on September 30). For entities whose payments reach this threshold, compliance with this rule is a condition of receiving payments under the medical assistance program during the following calendar year.

79.15(1) *Policy requirements.* Any entity whose medical assistance payments meet the threshold shall:

a. Establish written policies for all employees of the entity and for all employees of any contractor or agent of the entity, including management, which provide detailed information about:

(1) The False Claims Act established under Title 31, United States Code, Sections 3729 through 3733;

(2) Administrative remedies for false claims and statements established under Title 31, United States Code, Chapter 38;

(3) Any state laws pertaining to civil or criminal penalties for false claims and statements;

(4) Whistle blower protections under the laws described in subparagraphs (1) to (3) with respect to the role of these laws in preventing and detecting fraud, waste, and abuse in federal health care programs, as defined in Title 42, United States Code, Section 1320a-7b(f); and

(5) The entity's policies and procedures for detecting and preventing fraud, waste, and abuse.

b. Include in any employee handbook a specific discussion of:

(1) The laws described in paragraph 79.15(1)*"a"*;

(2) The rights of employees to be protected as whistle blowers; and

(3) The entity's policies and procedures for detecting and preventing fraud, waste, and abuse.

79.15(2) *Reporting requirements.*

a. Any entity whose medical assistance payments meet the specified threshold during a federal fiscal year shall provide the following information to the Iowa Medicaid enterprise by the following December 31:

(1) The name, address, and national provider identification numbers under which the entity receives payment;

(2) Copies of written or electronic policies that meet the requirements of subrule 79.15(1); and

(3) A written description of how the policies are made available and disseminated to all employees of the entity and to all employees of any contractor or agent of the entity.

b. The information may be provided by:

(1) Mailing the information to the IME Surveillance and Utilization Review Services Unit, P.O. Box 36390, Des Moines, Iowa 50315; or

(2) Faxing the information to (515)725-1354.

79.15(3) *Enforcement.* Any entity that fails to comply with the requirements of this rule shall be subject to sanction under rule 441—79.2(249A), including probation, suspension or withholding of payments, and suspension or termination from participation in the medical assistance program.

This rule is intended to implement Iowa Code section 249A.4 and Public Law 109-171, Section 6032.

441—79.16(249A) Payment reductions pursuant to executive order. The following payment provisions shall apply to services rendered during the period from December 1, 2009, to June 30, 2010, notwithstanding any contrary provision in this chapter.

79.16(1) Notwithstanding any provision of subrule 79.1(2), payment for covered services rendered by the following providers shall be reduced by 5 percent from the rates in effect November 30, 2009:

a. Ambulance services.

b. Ambulatory surgical centers.

c. Advanced registered nurse practitioners, including certified nurse-midwives.

d. Audiologists and hearing aid dealers.

e. Behavioral health providers.

f. Birth centers.

g. Chiropractors.

h. Clinics.

i. Durable medical equipment, medical supply, orthopedic shoe, and prosthetic device dealers.

j. Hospitals, not including services rendered by critical access hospitals or services billed under the IowaCare program, but including:

(1) Inpatient hospital care, including Medicaid-certified psychiatric and rehabilitation units.

(2) Outpatient hospital care.

(3) Indirect medical education payments.

(4) Direct medical education payments.

(5) Disproportionate-share payments (except for payments to the Iowa state-owned teaching hospital).

k. Independent laboratories and X-ray providers.

l. Independently practicing occupational therapists, physical therapists, and psychologists.

m. Lead inspection agencies.

n. Maternal health centers.

o. Optometrists and opticians.

p. Physicians, excluding services billed to the IowaCare program except for preventative examinations.

q. Podiatrists.

r. Rehabilitation agencies.

s. Screening centers.

79.16(2) Notwithstanding any provision of subrule 79.1(2), the basis of reimbursement for skilled nursing, physical therapy, occupational therapy, home health aide, and medical social services, and home health care for maternity patients and children provided by home health agencies shall be retrospective cost-related with cost settlement based on the lowest of the following:

a. The maximum Medicare rate in effect November 30, 2009,

b. The maximum Medicaid rate in effect November 30, 2009, less 5 percent, or

c. 100 percent of the reasonable and allowable Medicaid cost.

79.16(3) Notwithstanding any provision of subrule 79.1(2), the basis of reimbursement for private duty nursing and personal care for persons aged 20 or under provided by home health agencies shall be retrospective cost-related with cost settlement based on the lower of the following:

a. The maximum Medicaid rate in effect November 30, 2009, less 5 percent, or

b. 100 percent of the reasonable and allowable Medicaid cost.

79.16(4) Notwithstanding any provision of subrule 79.1(2) or 79.1(23), the basis of reimbursement for remedial services providers shall be consistent with the methodology described in subrule 79.1(23) except that the reasonable and proper cost of operation is equal to 100 percent of the actual and allowable cost subject to the established rate maximum less 5 percent.

79.16(5) Notwithstanding any provision of subrule 79.1(2) or rule 441—81.6(249A), the patient-day-weighted medians used in rate setting for nursing facilities shall be calculated and the rates adjusted to provide a 5 percent decrease in nursing facility rates (except for state-owned facilities).

79.16(6) Notwithstanding any provision of subrule 79.1(2) or rule 441—85.25(249A), the basis of reimbursement for non-state-owned psychiatric medical institutions for children shall be consistent with the methodology described in 441—subrule 85.25(1) except that the per diem rate shall be based on the facility's cost for the service, not to exceed the upper limit as provided in subrule 79.1(2) less 5 percent.

79.16(7) Notwithstanding any provision of subrule 79.1(2), payment for covered services rendered by dentists shall be reduced by 2.5 percent from the rates in effect November 30, 2009.

79.16(8) Notwithstanding any provision of subrule 79.1(2) or 79.1(25), the basis of reimbursement for community mental health centers shall be retrospective and cost-related with cost settlement limited to 97.5 percent of the provider's reasonable and allowable Medicaid cost.

79.16(9) Notwithstanding any provision of subrule 79.1(2), the basis of reimbursement for targeted case management services shall be as follows:

a. A provider-specific prospective cost-based interim rate shall be calculated based on the finalized state fiscal year 2009 cost report plus an inflation factor of 2.3 percent.

b. For a provider whose actual and allowable cost is less than the prospective cost-based interim rate calculated pursuant to paragraph *"a,"* the cost-settled amount paid to the provider shall be 100 percent of the provider's actual and allowable cost.

c. For a provider whose actual and allowable cost is greater than the prospective cost-based interim rate calculated pursuant to paragraph *"a,"* the cost-settled amount paid to the provider shall be the actual cost less 2.5 percent, not to be reduced below the prospective cost-based interim rate.

79.16(10) Notwithstanding any provision of subrule 79.1(2), payment for covered services rendered by home- and community-based waiver service providers shall be reduced by 2.5 percent from the rates in effect November 30, 2009.

a. Rates based on a submitted financial and statistical report shall be consistent with the methodology described in subparagraph 79.1(15)*"d"*(1) except that the inflation adjustment applied to actual, historical costs and the prior period base cost shall be reduced by 2.5 percent.

b. The retrospective adjustment of prospective rates shall be made based on revenues exceeding 100 percent of adjusted actual costs. Adjusted actual costs shall not exceed the upper limits as specified in subrule 79.1(2) less 2.5 percent.

This rule is intended to implement Executive Order Number 19 and Iowa Code chapter 249A.

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1 Effective date of 79.1(2) and 79.1(5)*"t"* delayed 70 days by the Administrative Rules Review Committee at its January 1988, meeting.

2 Effective date of 4/1/90 delayed 70 days by the Administrative Rules Review Committee at its March 12, 1990, meeting; delay lifted by this Committee, effective May 11, 1990.

3 Effective date of subrule 79.1(13) delayed until adjournment of the 1992 Sessions of the General Assembly by the Administrative Rules Review Committee at its meeting held July 12, 1991.

4 Effective date of 3/1/92 delayed until adjournment of the 1992 General Assembly by the Administrative Rules Review Committee at its meeting held February 3, 1992.

5 At a special meeting held January 24, 2002, the Administrative Rules Review Committee voted to delay until adjournment of the 2002 Session of the General Assembly the effective date of amendments published in the February 6, 2002, Iowa Administrative Bulletin as **ARC 1365B**.

6 Effective date of October 1, 2002, delayed 70 days by the Administrative Rules Review Committee at its meeting held September 10, 2002. At its meeting held November 19, 2002, the Committee voted to delay the effective date until adjournment of the 2003 Session of the General Assembly.

7 July 1, 2009, effective date of amendments to 79.1(1)*"d,"* 79.1(2), and 79.1(24)*"a"*(1) delayed 70 days by the Administrative Rules Review Committee at a special meeting held June 25, 2009.

CHAPTER 81
NURSING FACILITIES

[Prior to 7/1/83 Social Services[770] Ch 81]
[Prior to 2/11/87, Human Services[498]]

DIVISION I
GENERAL POLICIES

441—81.1(249A) Definitions.

"Abuse" means any of the following which occurs as a result of the willful or negligent acts or omissions of a nursing facility employee:

1. Physical injury to, or injury which is at a variance with the history given of the injury, or unreasonable confinement or unreasonable punishment or assault as defined in Iowa Code section 708.1 of a resident.

2. The commission of a sexual offense under Iowa Code chapter 709 or Iowa Code section 726.2 or 728.12, subsection 1, or sexual exploitation under Iowa Code chapter 235B, as a result of the acts or omissions of the facility employee responsible for the care of the resident with or against a resident.

3. Exploitation of a resident which means the act or process of taking unfair advantage of a resident or the resident's physical or financial resources for one's own personal or pecuniary profit without the informed consent of the resident, including theft, by the use of undue influence, harassment, duress, deception, false representation or false pretenses.

4. The deprivation of the minimum food, shelter, clothing, supervision, physical or mental health care, or other care necessary to maintain a resident's life or health.

"Advance directive" means a written instruction, such as a living will or durable power of attorney for health care, recognized under state law and related to the provision of health care when the resident is incapacitated.

"Allowable costs" means the price a prudent, cost-conscious buyer would pay a willing seller for goods or services in an arm's-length transaction, not to exceed the limitations set out in rules.

"Beginning eligibility date" means date of an individual's admission to the facility or date of eligibility for medical assistance, whichever is the later date.

"Case mix" means a measure of the intensity of care and services used by similar residents in a facility.

"Case-mix index" means a numeric score within a specific range that identifies the relative resources used by similar residents and represents the average resource consumption across a population or sample.

"Civil penalty" shall mean a civil money penalty not to exceed the amount authorized under Iowa Code section 135C.36 for health care facility violations.

"Clinical experience" means application or learned skills for direct resident care in a nursing facility.

"Complete replacement" means completed construction on a new nursing facility to replace an existing licensed and certified nursing facility. The replacement facility shall have no more licensed beds than the facility being replaced and shall be located either in the same county as the facility being replaced or within 30 miles from the facility being replaced.

"Cost normalization" refers to the process of removing cost variations associated with different levels of resident case mix. Normalized cost is determined by dividing a facility's per diem direct care component costs by the facility cost report period case-mix index.

"Denial of critical care" is a pattern of care in which the resident's basic needs are denied or ignored to such an extent that there is imminent or potential danger of the resident suffering injury or death, or is a denial of, or a failure to provide the mental health care necessary to adequately treat the resident's serious social maladjustment, or is a gross failure of the facility employee to meet the emotional needs of the resident necessary for normal functioning, or is a failure of the facility employee to provide for the proper supervision of the resident.

"Department" means the Iowa department of human services.

"Department's accounting firm" means the firm on contract with the department to calculate nursing facility rates and provide other accounting services as requested.

"Direct care component" means the portion of the Medicaid reimbursement rates that is attributable to the salaries and benefits of registered nurses, licensed practical nurses, certified nursing assistants, rehabilitation nurses, and contracted nursing services.

"Discharged resident" means a resident whose accounts and records have been closed out and whose personal effects have been taken from the facility. When a resident is discharged, the facility shall notify the department via Form 470-0042, Case Activity Report.

"Facility" means a licensed nursing facility certified in accordance with the provisions of 42 CFR Part 483, as amended to September 23, 1992, to provide health services and includes hospital-based nursing facilities that are Medicare-certified and provide only skilled level of care and swing-bed hospitals unless stated otherwise.

"Facility-based nurse aide training program" means a nurse aide training program that is offered by a nursing facility and taught by facility employees or under the control of the licensee.

"Facility cost report period case-mix index" is the average of quarterly facilitywide average case-mix indices, carried to four decimal places. The quarters used in this average will be the quarters that most closely coincide with the financial and statistical reporting period. For example, a 01/01/2000-12/31/2000 financial and statistical reporting period would use the facilitywide average case-mix indices for quarters ending 03/31/00, 06/30/00, 09/30/00 and 12/31/00.

"Facilitywide average case-mix index" is the simple average, carried to four decimal places, of all resident case-mix indices based on the last day of each calendar quarter.

"Informed consent" means a resident's agreement to allow something to happen that is based on a full disclosure of known facts and circumstances needed to make the decision intelligently, i.e., with knowledge of the risks involved or alternatives.

"Iowa Medicaid enterprise" means the entity comprised of department staff and contractors responsible for the management and reimbursement of Medicaid services.

"Laboratory experience" means practicing care-giving skills prior to contact in the clinical setting.

"Major renovations" means new construction or facility improvements to an existing licensed and certified nursing facility in which the total depreciable asset value of the new construction or facility improvements exceeds $1.5 million. The $1.5 million threshold shall be calculated based on the total depreciable asset value of new construction or facility improvements placed into service during a two-year period ending on the date the last asset was placed into service. When the property costs of an asset have been included in a facility's financial and statistical report that has already been used in a biennial rebasing, the costs of that asset shall not be considered in determining whether the facility meets the $1.5 million threshold.

"Medicaid average case-mix index" is the simple average, carried to four decimal places, of all resident case-mix indices where Medicaid is known to be the per diem payor source on the last day of the calendar quarter.

"Minimum data set" or *"MDS"* refers to a federally required resident assessment tool. Information from the MDS is used by the department to determine the facility's case-mix index for purposes of normalizing per diem allowable direct care costs as provided by paragraph 81.6(16)*"b,"* for determining the Medicaid average case-mix index to adjust the direct care component pursuant to paragraphs 81.6(16)*"c"* and *"e,"* the excess payment allowance pursuant to paragraph 81.6(16)*"d,"* and the limits on reimbursement components pursuant to paragraph 81.6(16)*"f."* MDS is described in subrule 81.13(9).

"Minimum food, shelter, clothing, supervision, physical or mental health care, or other care" means that food, shelter, clothing, supervision, physical or mental health care, or other care which, if not provided, would constitute denial of critical care.

"Mistreatment" means any intentional act, or threat of an act, coupled with the apparent ability to execute the act, which causes or puts another person in fear of mental anguish, humiliation, deprivation or physical contact which is or will be painful, insulting or offensive. Actions utilized in providing necessary treatment or care in accordance with accepted standards of practice are not considered mistreatment.

"New construction" means the construction of a new nursing facility that does not replace an existing licensed and certified facility and that requires the provider to obtain a certificate of need pursuant to Iowa Code chapter 135, division VI.

"Non-direct care component" means the portion of Medicaid reimbursement rates attributable to administrative, environmental, property, and support care costs reported on the financial and statistical report.

"Non-facility-based nurse aide training program" means a nurse aide training program that is offered by an organization that is not licensed to provide nursing facility services.

"Nurse aide" means any individual who is not a licensed health professional or volunteer providing nursing or nursing-related services to residents in a nursing facility.

"Nurse aide registry" means Nurse Aide Registry, Department of Inspections and Appeals, Third Floor, Lucas State Office Building, Des Moines, Iowa 50319.

"Nurse aide training and competency evaluation programs (NATCEP)" are educational programs approved by the department of inspections and appeals for nurse aide training as designated in subrule 81.16(3).

"Patient-day-weighted median cost" means the per diem cost of the nursing facility that is at the median per diem cost of all nursing facilities based on patient days provided when per diem allowable costs are ranked from low to high. A separate patient-day-weighted median cost amount shall be determined for the direct care and non-direct care components.

"Physical abuse" means any nonaccidental physical injury, or injury which is at variance with the history given of it, suffered by a resident as the result of the acts or omissions of a person responsible for the care of the resident.

"Physical injury" means damage to any bodily tissue to the extent that the tissue must undergo a healing process in order to be restored to a sound and healthy condition, or damage to any bodily tissue to the extent that the tissue cannot be restored to a sound and healthy condition, or damage to any bodily tissue which results in the death of the person who has sustained the damage.

"Poor performing facility (PPF)" is a facility designated by the department of inspections and appeals as a poor performing facility (PPF) based on surveys conducted by the department of inspections and appeals pursuant to subrule 81.13(1). A facility shall be designated a PPF if it has been cited for substandard quality of care on the current standard survey and it:

1. Has been cited for substandard quality of care or immediate jeopardy on at least one of the previous two standard surveys;
2. Has a history of substantiated complaints during the last two years;
3. Has a current deficiency for not having a quality assurance program; or
4. Does not have an effective quality assurance program as defined in paragraph 81.13(19)*"o."*

"Primary instructor" means a registered nurse responsible for teaching a state-approved nurse aide training course.

"Program coordinator" means a registered nurse responsible for administrative aspects of a state-approved nurse aide training course.

"Rate determination letter" means the letter that is distributed quarterly by the Iowa Medicaid enterprise to each nursing facility notifying the facility of the facility's Medicaid reimbursement rate calculated in accordance with this rule and of the effective date of the reimbursement rate.

"Skills performance record" means a record of major duties and skills taught which consists of, at a minimum:

1. A listing of the duties and skills expected to be learned in the program.
2. Space to record the date when the aide performs the duty or skill.
3. Space to note satisfactory or unsatisfactory performance.
4. The signature of the instructor supervising the performance.

"Special population nursing facility" refers to a nursing facility that serves the following populations:

1. One hundred percent of the residents served are aged 21 and under and require the skilled level of care.

2. Seventy percent of the residents served require the skilled level of care for neurological disorders.

"Terminated from the Medicare or Medicaid program" means a facility has lost the final appeal to which it is entitled.

"Testing entity" means a person, agency, institution, or facility approved by the department of inspections and appeals to take responsibility for obtaining, keeping secure and administering the competency test and reporting nurse aide scores to the nurse aide registry.

This rule is intended to implement Iowa Code sections 249A.2(6), 249A.3(2)*"a,"* and 249A.4.

[**ARC 8445B**, IAB 1/13/10, effective 12/11/09]

441—81.2 Rescinded, effective 11/21/79.

441—81.3(249A) Initial approval for nursing facility care.

81.3(1) *Need for nursing facility care.* Residents of nursing facilities must be in need of either nursing facility care or skilled nursing care. Payment will be made for nursing facility care residents only upon certification of the need for the level of care by a licensed physician of medicine or osteopathy and approval of the level of care by the department.

a. Decisions on level of care shall be made for the department by the Iowa Medicaid enterprise (IME) medical services unit within two working days of receipt of medical information. The IME medical services unit determines whether the level of care provided or to be provided should be approved based on medical necessity and the appropriateness of the level of care under 441—subrules 79.9(1) and 79.9(2).

b. Adverse decisions by the IME medical services unit may be appealed to the department pursuant to 441—Chapter 7.

81.3(2) *Skilled nursing care level of need.* Rescinded IAB 7/11/01, effective 7/1/01.

81.3(3) *Screening.* All persons, regardless of the source of payment, seeking admission to a nursing facility shall also be screened by the IME medical services unit to determine if mental illness, mental retardation, or a related condition is present. The Iowa Medicaid program will cover the cost of this screening through the managed mental health contractor.

a. Final approval for initial admissions and continued stay of persons with mental illness, mental retardation, or a related condition is determined by the department of human services, division of mental health and disability services.

b. Nursing facility payment under the Iowa Medicaid program will be made for persons with mental illness, mental retardation, or a related condition only if it is determined by the division of mental health and disability services that the person's treatment needs will be or are being met.

81.3(4) *Special care level of need.* Rescinded IAB 3/20/91, effective 3/1/91.

This rule is intended to implement Iowa Code sections 249A.2(6), 249A.3(2)*"a"* and 249A.4.

[**ARC 8445B**, IAB 1/13/10, effective 12/11/09]

441—81.4(249A) Arrangements with residents.

81.4(1) *Resident care agreement.* Rescinded IAB 12/6/95, effective 2/1/96.

81.4(2) *Financial participation by resident.* A resident's payment for care may include any voluntary payments made by family members toward cost of care of the resident. The resident's client participation and medical payments from a third party shall be paid toward the total cost of care for the month before any state payment is made. The state will pay the balance of the cost of care for the remainder of the month. The facility shall make arrangements directly with the resident for payment of client participation.

81.4(3) *Personal needs account.* When a facility manages the personal needs funds of a resident, it shall establish and maintain a system of accounting for expenditures from the resident's personal needs funds. (See subrule 81.13(5)*"c."*) The funds shall be deposited in a bank within the state of Iowa insured by FDIC. Expense for bank service charges for this account is an allowable expense under rule 441—81.6(249A) if the service cannot be obtained free of charge. The department shall charge back to the facility any maintenance item included in the computation of the audit cost that is charged

to the resident's personal needs when the charge constitutes double payment. Unverifiable expenditures charged to personal needs accounts may be charged back to the facility. The accounting system is subject to audit by representatives of the department and shall meet the following criteria:

a. Upon admittance, a ledger sheet shall be credited with the resident's total incidental money on hand. Thereafter, the ledger shall be kept current on a monthly basis. The facility may combine the accounting with the disbursement section showing the date, amount given the resident, and the resident's signature. A separate ledger shall be maintained for each resident.

b. When something is purchased for the resident and is not a direct cash disbursement, each expenditure item in the ledger shall be supported by a signed, dated receipt. The receipt shall indicate the article furnished for the resident's benefit.

c. Personal funds shall only be turned over to the resident, the resident's guardian, or other persons selected by the resident. With the consent of the resident, when the resident is able and willing to give consent the administrator may turn over personal funds to a close relative or friend of the resident to purchase a particular item. A signed, dated receipt shall be required to be deposited in the resident's files.

d. The ledger and receipts for each resident shall be made available for periodic audits by an accredited department representative. Audit certification shall be made by the department's representative at the bottom of the ledger sheet. Supporting receipts may then be destroyed.

e. Upon a patient's death, a receipt shall be obtained from the next of kin, the resident's guardian, or the representative handling the funeral before releasing the balance of the personal needs funds. In the event there is no next of kin or guardian available and there are no outstanding funeral expenses, any funds shall revert to the department. In the event that an estate is opened, the department shall turn the funds over to the estate.

81.4(4) *Safeguarding personal property.* The facility shall safeguard the resident's personal possessions. Safeguarding shall include, but is not limited to:

a. Providing a method of identification of the resident's suitcases, clothing, and other personal effects, and listing these on an appropriate form attached to the resident's record at the time of admission. These records shall be kept current. Any personal effects released to a relative of the resident shall be covered by a signed receipt.

b. Providing adequate storage facilities for the resident's personal effects.

c. Ensuring that all mail is delivered unopened to the resident to whom it is addressed, except in those cases where the resident is too confused, as documented in the person's permanent medical record, to receive it, in which case the mail is held unopened for the resident's conservator or relatives. Mail may be opened by the facility in cases where the resident or relatives or guardian have given permission in writing for mail to be opened and read to the resident.

This rule is intended to implement Iowa Code sections 249A.2, 249A.3(2)*"a,"* and 249A.4.

441—81.5(249A) Discharge and transfer. (See subrules 81.13(2)*"a"* and 81.13(6)*"c."*)

81.5(1) *Notice.* When a public assistance recipient requests transfer or discharge, or another person requests this for the recipient, the administrator shall promptly notify the local office of the department. This shall be done in sufficient time to permit a social service worker to assist in the planning for the transfer or discharge.

81.5(2) *Case activity report.* A Case Activity Report, Form 470-0042, shall be submitted to the department whenever a Medicaid applicant or recipient enters the facility, changes level of care, or is discharged from the facility.

81.5(3) *Plan.* The administrator and staff shall assist the resident in planning for transfer or discharge through development of a discharge plan.

81.5(4) *Transfer records.* When a resident is transferred to another facility, transfer information shall be summarized from the facility's records in a copy to accompany the resident. This information shall include:

a. A transfer form of diagnosis.

b. Aid to daily living information.

c. Transfer orders.
d. Nursing care plan.
e. Physician's orders for care.
f. The resident's personal records.
g. When applicable, the personal needs fund record.
h. Resident care review team assessment.

81.5(5) *Unused client participation.* When a resident leaves the facility during the month, any unused portion of the resident's client participation shall be refunded.

This rule is intended to implement Iowa Code sections 249A.2, 249A.3(2)*"a,"* and 249A.4.

441—81.6(249A) Financial and statistical report and determination of payment rate. With the exception of hospital-based nursing facilities that are Medicare-certified and provide only the skilled level of care, herein referred to as Medicare-certified hospital-based nursing facilities, all facilities in Iowa wishing to participate in the program shall submit a Financial and Statistical Report, Form 470-0030, to the department's accounting firm. All Medicare-certified hospital-based nursing facilities shall submit a copy of their Medicare cost report to the department's accounting firm. Costs for patient care services shall be reported, divided into the subcategories of "Direct Patient Care Costs" and "Support Care Costs." Costs associated with food and dietary wages shall be included in the "Support Care Costs" subcategory. The financial and statistical report shall be submitted in an electronic format approved by the department. These reports shall be based on the following rules.

81.6(1) *Failure to maintain records.* Failure to adequately maintain fiscal records, including census records, medical charts, ledgers, journals, tax returns, canceled checks, source documents, invoices, and audit reports by or for a facility may result in the penalties specified in subrule 81.14(1).

81.6(2) *Accounting procedures.* Financial information shall be based on that appearing in the audited financial statement. Adjustments to convert to the accrual basis of accounting shall be made when the records are maintained on other accounting bases. Facilities which are a part of a larger health facility extending short-term, intensive, or other health care not generally considered nursing care may submit a cost apportionment schedule prepared in accordance with recognized methods and procedures. A schedule shall be required when necessary for a fair presentation of expense attributable to nursing facility patients.

81.6(3) *Submission of reports.* All nursing facilities, except the Iowa Veterans Home, shall submit reports to the department's accounting firm no later than three months after the close of the facility's established fiscal year. The Iowa Veterans Home shall submit the report to the department's accounting firm no later than three months after the close of each six-month period of the facility's established fiscal year. Failure to submit a report that meets the requirements of this rule within this time shall reduce payment to 75 percent of the current rate. The reduced rate shall be paid for no longer than three months, after which time no further payments will be made.

A facility may change its fiscal year one time in any two-year period. If the facility changes its fiscal year, the facility shall notify the department's accounting firm 60 days prior to the first date of the change.

81.6(4) *Payment at new rate.*

a. Except for state-operated nursing facilities and special population nursing facilities, payment rates shall be updated July 1, 2001, and every second year thereafter with new cost report data, and adjusted quarterly to account for changes in the Medicaid average case-mix index. For nursing facilities receiving both an ICF and SNF Medicaid rate effective June 30, 2001, the June 30, 2001, Medicaid rate referenced in subparagraphs (1) and (2) below shall be the patient-day-weighted average of the ICF and SNF Medicaid rates effective June 30, 2001, excluding the case-mix transition add-on amount.

(1) The Medicaid payment rates for services rendered from July 1, 2001, through June 30, 2002, shall be 66.67 percent of the facility's Medicaid rate effective June 30, 2001, excluding the case-mix transition add-on amount, plus an inflation allowance of 6.21 percent, not to exceed $94, and 33.33 percent of the July 1, 2001, modified price-based rate pursuant to subrule 81.6(16). In no case shall the July 1, 2001, Medicaid rate be less than the Medicaid rate effective June 30, 2001, excluding the case-mix transition add-on amount, and increased by a 6.21 percent inflation allowance.

(2) Payment rates for services rendered from July 1, 2002, through June 30, 2003, shall be 33.33 percent of the facility's Medicaid rate effective June 30, 2001, excluding the case-mix transition add-on amount, plus an inflation allowance of 6.21 percent, and an additional inflation factor based on the CMS/SNF Total Market Basket Index. However, the current system rate to be used effective July 1, 2002, shall not exceed $94, times an inflation factor pursuant to subrule 81.6(18), and 66.67 percent of the July 1, 2002, modified price-based rate. In no case shall the July 1, 2002, Medicaid rate be less than the Medicaid rate effective June 30, 2002, plus an inflation factor pursuant to subrule 81.6(18) projected for the following 12 months.

(3) Payment rates for services rendered from July 1, 2003, and thereafter will be 100 percent of the modified price-based rate.

(4) Aggregate payments to a nursing facility that is owned or operated by state or non-state government shall not exceed the facility's actual medical assistance program costs. Aggregate payments shall include amounts received from the Medicaid program, as well as receipts from patient and other third-party payments up to the Medicaid-allowed amount.

b. The Medicaid payment rate for special population nursing facilities shall be updated annually without a quarterly adjustment.

c. The Medicaid payment rate for state-operated nursing facilities shall be updated annually without a quarterly adjustment.

81.6(5) *Accrual basis.* Facilities not using the accrual basis of accounting shall adjust recorded amounts to the accrual basis. Records of cash receipts and disbursements shall be adjusted to reflect accruals of income and expense.

81.6(6) *Census of public assistance recipients.* Census figures of public assistance recipients shall be obtained on the last day of the month ending the reporting period.

81.6(7) *Patient days.* In determining inpatient days, a patient day is that period of service rendered a patient between the census-taking hours on two successive days, the day of discharge being counted only when the patient was admitted that same day.

81.6(8) *Opinion of accountant.* The department may require that an opinion of a certified public accountant or public accountant accompany the report when adjustments made to prior reports indicate disregard of the certification and reporting instructions.

81.6(9) *Calculating patient days.* When calculating patient days, facilities shall use an accumulation method.

a. Census information shall be based on a patient's status at midnight at the end of each day.

b. When a recipient is on a reserve bed status and the department is paying on a per diem basis for the holding of a bed, or any day a bed is reserved for a public assistance or nonpublic assistance patient and a per diem rate for the bed is charged to any party, the reserved days shall be included in the total census figures for inpatient days.

81.6(10) *Revenues.* Revenues shall be reported as recorded in the general books and records. Expense recoveries credited to expense accounts shall not be reclassified in order to be reflected as revenues.

a. Routine daily services shall represent the established charge for daily care. Routine daily services are those services which include room, board, nursing services, and such services as supervision, feeding, incontinency, and similar services, for which the associated costs are in nursing service.

b. Revenue from ancillary services provided to patients shall be applied in reduction of the related expense.

c. Revenue from the sale of medical supplies, food or services to employees or nonresidents of the facility shall be applied in reduction of the related expense. Revenue from the sale to private pay residents of items or services which are included in the medical assistance per diem will not be offset.

d. Investment income adjustment is necessary only when interest expense is incurred, and only to the extent of the interest expense.

e. Laundry revenue shall be applied to laundry expense.

f. Accounts receivable charged off or provision for uncollectible accounts shall be reported as a deduction from gross revenue.

81.6(11) *Limitation of expenses.* Certain expenses that are not normally incurred in providing patient care shall be eliminated or limited according to the following rules.

a. Federal and state income taxes are not allowed as reimbursable costs.

b. Fees paid directors and nonworking officers' salaries are not allowed as reimbursable costs.

c. Bad debts are not an allowable expense.

d. Charity allowances and courtesy allowances are not an allowable expense.

e. Personal travel and entertainment are not allowable as reimbursable costs. Certain expenses such as rental or depreciation of a vehicle and expenses of travel which include both business and personal costs shall be prorated. Amounts which appear to be excessive may be limited after consideration of the specific circumstances. Records shall be maintained to substantiate the indicated charges.

(1) Commuter travel by the owner(s), owner-administrator(s), administrator, nursing director or any other employee is not an allowable cost (from private residence to facility and return to residence).

(2) The expense of one car or one van or both designated for use in transporting patients shall be an allowable cost. All expenses shall be documented by a sales slip, invoice or other document setting forth the designated vehicle as well as the charges incurred for the expenses to be allowable.

(3) Each facility which supplies transportation services as defined in Iowa Code section 601J.1, subsection 1, shall provide current documentation of compliance with or exemption from public transit coordination requirements as found in Iowa Code chapter 601J and 820—[09,A] chapter 2 of the department of transportation rules at the time of annual contract renewal. Failure to cooperate in obtaining or in providing the required documentation of compliance or exemption after receipt from the Iowa department of transportation, public transit division shall, result in disallowance of vehicle costs and other costs associated with transporting residents.

(4) Expenses related to association business meetings, limited to individual members of the association who are members of a national affiliate, and expenses associated with workshops, symposiums, and meetings which provide administrators or department heads with hourly credits required to comply with continuing education requirements for licensing, are allowable expenses.

(5) Travel of an emergency nature required for supplies, repairs of machinery or equipment, or building is an allowable expense.

(6) Travel for which a patient must pay is not an allowable expense.

(7) Allowable expenses in subparagraphs (2) through (5) above are limited to 6 percent of total administrative expense.

f. Entertainment provided by the facility for participation of all residents who are physically and mentally able to participate is an allowable expense except that entertainment for which the patient is required to pay is not an allowable expense.

g. Loan acquisition fees and standby fees are not considered part of the current expense of patient care, but should be amortized over the life of the related loan.

h. A reasonable allowance of compensation for services of owners or immediate relatives is an allowable cost, provided the services are actually performed in a necessary function. For this purpose, the following persons are considered immediate relatives: husband and wife; natural parent, child and sibling; adopted child and adoptive parent; stepparent, stepchild, stepbrother, and stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, and sister-in-law; grandparent and grandchild. Adequate time records shall be maintained. Adjustments may be necessary to provide compensation as an expense for nonsalaried working proprietors and partners. Members of religious orders serving under an agreement with their administrative office are allowed salaries paid persons performing comparable services. When maintenance is provided these persons by the facility, consideration shall be given to the value of these benefits and this amount shall be deducted from the amount otherwise allowed for a person not receiving maintenance.

(1) Compensation means the total benefit received by the owner or immediate relative for services rendered. It includes salary amounts paid for managerial, administrative, professional, and other services; amounts paid by the facility for the personal benefit of the proprietor or immediate relative;

the cost of assets and services which the proprietor or immediate relative receives from the facility; and deferred compensation.

(2) Reasonableness requires that the compensation allowance be the same amount as would ordinarily be paid for comparable services by comparable institutions, and depends upon the facts and circumstances of each case.

(3) Necessary requires that the function be such that had the owner or immediate relative not rendered the services, the facility would have had to employ another person to perform the service, and be pertinent to the operation and sound conduct of the institution.

(4) Effective July 1, 2001, the base maximum allowed compensation for an administrator who is involved in ownership of the facility or who is an immediate relative of an owner of the facility is $3,296 per month plus $35.16 per month per licensed bed capacity for each bed over 60, not to exceed $4,884 per month. An administrator is considered to be involved in ownership of a facility when the administrator has ownership interest of 5 percent or more.

On an annual basis, the maximum allowed compensation amounts for these administrators shall be increased or decreased by an annual inflation factor as specified by subrule 81.6(18).

(5) The maximum allowed compensation for an assistant administrator who is involved in ownership of the facility or who is an immediate relative of an owner of the facility in facilities having a licensed capacity of 151 or more beds is 60 percent of the amount allowed for the administrator. An assistant administrator is considered to be involved in ownership of a facility when the assistant administrator has ownership interest of 5 percent or more.

(6) The maximum allowed compensation for a director of nursing or any employee who is involved in ownership of the facility or who is an immediate relative of an owner of the facility is 60 percent of the amount allowed for the administrator. Persons involved in ownership or relatives providing professional services shall be limited to rates prevailing in the community not to exceed 60 percent of the allowable rate for the administrator on a semiannual basis. Records shall be maintained in the same manner for an employee involved in ownership or a relative as are maintained for any other employee of the facility. Ownership is defined as an interest of 5 percent or more.

i. Management fees shall be limited on the same basis as the owner administrator's salary, but shall have the amount paid the resident administrator deducted. When the parent company can separately identify accounting costs, the costs are allowed.

j. Depreciation based upon tax cost using only the straight-line method of computation, recognizing the estimated useful life of the asset as defined in the American Hospital Association Useful Life Guide, 1983 edition, may be included as a patient cost. When accelerated methods of computation have been elected for income tax purposes, an adjustment shall be made. For change of ownership, refer to subrule 81.6(12).

k. Necessary and proper interest on both current and capital indebtedness is an allowable cost.

(1) Interest is the cost incurred for the use of borrowed funds. Interest on current indebtedness is the cost incurred for funds borrowed for a relatively short term. Interest on capital indebtedness is the cost incurred for funds borrowed for capital purposes.

(2) "Necessary" requires that the interest be incurred on a loan made to satisfy a financial need of the provider, be incurred on a loan made for a purpose reasonably related to patient care, and be reduced by investment income except where the income is from gifts and grants whether restricted or unrestricted, and which are held separate and not commingled with other funds.

(3) "Proper" requires that interest be incurred at a rate not in excess of what a prudent borrower would have had to pay in the money market on the date the loan was made, and be paid to a lender not related through control or ownership to the borrowing organization.

(4) Interest on loans is allowable as cost at a rate not in excess of the amount an investor could receive on funds invested in the locality on the date the loan was made.

(5) Interest is an allowable cost when the general fund of a provider borrows from a donor-restricted fund, a funded depreciation account of the provider, or the provider's qualified pension fund, and pays interest to the fund, or when a provider operated by members of a religious order borrows from the order.

(6) When funded depreciation is used for purposes other than improvement, replacement or expansion of facilities or equipment related to patient care, allowable interest expense is reduced to adjust for offsets not made in prior years for earnings on funded depreciation. A similar treatment will be accorded deposits in the provider's qualified pension fund where the deposits are used for other than the purpose for which the fund was established.

l. Costs applicable to supplies furnished by a related party or organization are a reimbursable cost when included at the cost to the related party or organization. The cost shall not exceed the price of comparable supplies that could be purchased elsewhere.

(1) Related means that the facility, to a significant extent, is associated with or has control of or is controlled by the organization furnishing the services, facilities, or supplies.

(2) Common ownership exists when an individual or individuals possess significant ownership or equity in the facility and the institution or organization serving the provider.

(3) Control exists where an individual or an organization has power, directly or indirectly, to significantly influence or direct the actions or policies of an organization or institution.

(4) When the facility demonstrates by convincing evidence that the supplying organization is a bona fide separate organization; that a substantial part of its business activity of the type carried on with the facility is transacted with others and there is an open competitive market for the type of services, facilities, or supplies furnished by the organization; that the services, facilities, or supplies are those which commonly are obtained by similar institutions from other organizations and are not a basic element of patient care ordinarily furnished directly to patients by the institutions; and that the charge to the facility is in line with the charge for the services, facilities, or supplies in the open market and no more than the charge made under comparable circumstances to others by the organization for the services, facilities, or supplies, the charges by the supplier shall be allowable costs.

m. When the operator of a participating facility rents from a nonrelated party, the amount of rent expense allowable on the cost report shall be based on the cost of the facility as identified in subrule 81.6(12), paragraph *"a,"* plus the landlord's other expenses and a reasonable rate of return, not to exceed actual rent payments.

When the operator of a participating facility rents the building from a related party, the amount of rent expense allowable on the cost report shall be no more than the amortized cost of the facility as identified in subrule 81.6(12), paragraph *"a,"* plus the landlord's other expenses.

The landlord must be willing to provide documentation of these costs for rental arrangements.

n. Depreciation, interest and other capital costs attributable to construction of new facilities, expanding existing facilities, or the purchase of an existing facility, are allowable expenses only if prior approval has been gained through the health planning process specified in rules of the public health department, 641—Chapter 201.

o. Reasonable legal fees are an allowable cost when directly related to patient care. Legal fees related to defense against threatened state license revocation or Medicaid decertification are allowable costs only up to the date a final appeal decision is issued. However, in no case will legal fees related to Medicaid decertification be allowable costs following the decertification date.

p. The nursing facility quality assurance assessment paid pursuant to 441—Chapter 36, Division II, shall not be an allowable cost for cost reporting and audit purposes but shall be reimbursed pursuant to paragraph 81.6(21)*"a."*

81.6(12) *Termination or change of owner.*

a. A participating facility contemplating termination of participation or negotiating a change of ownership shall provide the department of human services with at least 60 days' prior notice. A transfer of ownership or operation terminates the participation agreement. A new owner or operator shall establish that the facility meets the conditions for participation and enter into a new agreement. The person responsible for transfer of ownership or for termination is responsible for submission of a final financial and statistical report through the date of the transfer. No payment to the new owner will be made until formal notification is received. The following situations are defined as a transfer of ownership:

(1) In the case of a partnership which is a party to an agreement to participate in the medical assistance program, the removal, addition, or substitution of an individual for a partner in the association in the absence of an express statement to the contrary, dissolves the old partnership and creates a new partnership which is not a party to the previously executed agreement and a transfer of ownership has occurred.

(2) When a participating nursing facility is a sole proprietorship, a transfer of title and property to another party constitutes a change of ownership.

(3) When the facility is a corporation, neither a transfer of corporate stock nor a merger of one or more corporations with the participating corporation surviving is a transfer of ownership. A consolidation of two or more corporations resulting in the creation of a new corporate entity constitutes a change of ownership.

(4) When a participating facility is leased, a transfer of ownership is considered to have taken place. When the entire facility is leased, the total agreement with the lessor terminates. When only part of the facility is leased, the agreement remains in effect with respect to the unleased portion, but terminates with respect to the leased portion.

b. No increase in the value of property shall be allowed in determining the Medicaid rate for the new owner with any change of ownership (including lease agreements). When filing the first cost report, the new owner shall either continue the schedule of depreciation and interest established by the previous owner, or the new owner may choose to claim the actual rate of interest expense. The results of the actual rate of interest expense shall not be higher than would be allowed under the Medicare principles of reimbursement and shall be applied to the allowed depreciable value established by the previous owner, less any down payment made by the new owner.

c. Other acquisition costs of the new owner such as legal fees, accounting and administrative costs, travel costs and the costs of feasibility studies attributable to the negotiation or settlement of the sale or purchase of the property shall not be allowed.

d. In general, the provisions of Section 1861(v)(1)(0) of the Social Security Act regarding payment allowed under Medicare principles of reimbursement at the time of a change of ownership shall be followed, except that no return on equity or recapture of depreciation provisions shall be employed.

e. A new owner or lessee wishing to claim a new rate of interest expense must submit documentation which verifies the amount of down payment made, the actual rate of interest, and the number of years required for repayment with the next annual cost report. In the absence of the necessary supportive documentation, interest and other property costs for all facilities that have changed or will change ownership shall continue at the rate allowed the previous owner.

81.6(13) *Facility-requested rate adjustment.* A facility may request a rate adjustment for a period of time no more than 18 months prior to the facility's rate effective date. The request for adjustment shall be made to the department's accounting firm.

81.6(14) *Payment to new facility.* The payment to a new facility shall be the sum of the patient-day-weighted median cost for the direct care and non-direct care components pursuant to paragraph 81.6(16)*"c."* After the first full calendar quarter of operation, the patient-day-weighted median cost for the direct care component shall be adjusted by the facility's average Medicaid case-mix index pursuant to subrule 81.6(19). A financial and statistical report shall be submitted from the beginning day of operation to the end of the fiscal year. Following the completion of the new facility's first fiscal year, rates will be established in accordance with subrule 81.6(16). Subsequent financial and statistical reports shall be submitted annually for a 12-month period ending with the facility's fiscal year.

81.6(15) *Payment to new owner.* An existing facility with a new owner shall continue to be reimbursed using the previous owner's per diem rate adjusted quarterly for changes in the Medicaid average case-mix index. The facility shall submit a financial and statistical report for the period from beginning of actual operation under new ownership to the end of the facility's fiscal year. Subsequent financial and statistical reports shall be submitted annually for a 12-month period ending with the facility's fiscal year. The facility shall notify the department's accounting firm of the date its fiscal year will end.

81.6(16) *Establishment of the direct care and non-direct care patient-day-weighted medians and modified price-based reimbursement rate.* This subrule provides for the establishment of the modified price-based reimbursement rate. The first step in the rate calculation (paragraph *"a"*) determines the per diem direct care and non-direct care component costs. The second step (paragraph *"b"*) normalizes the per diem direct care component costs to remove cost variations associated with different levels of resident case mix. The third step (paragraph *"c"*) calculates the patient-day-weighted medians for the direct care and non-direct care components that are used in subsequent steps to establish rate component limits and excess payment allowances, if any. The fourth step (paragraph *"d"*) calculates the potential excess payment allowance. The fifth step (paragraph *"e"*) calculates the reimbursement rate, including any applicable capital cost per diem instant relief add-on described in paragraph *"h,"* that is further subjected to the rate component limits, including any applicable enhanced non-direct care rate component limit described in paragraph *"h,"* in step six (paragraph *"f"*). The seventh step (paragraph *"g"*) calculates the additional reimbursement based on accountability measures available beginning July 1, 2002.

a. Calculation of per diem cost. For purposes of calculating the non-state-owned nursing facility Medicaid reimbursement rate and the Medicare-certified hospital-based nursing facility Medicaid reimbursement rate, the costs shall be divided into two components, the direct care component and non-direct care component as defined in rule 441—81.1(249A). Each nursing facility's per diem allowable direct care and non-direct care cost shall be established. Effective July 1, 2001, and every second year thereafter, the per diem allowable cost shall be arrived at by dividing total reported allowable costs by total inpatient days during the reporting period. On July 1, 2001, July 1, 2003, July 1, 2004, July 1, 2005, and every second year thereafter, total reported allowable costs shall be adjusted using the inflation factor specified in subrule 81.6(18) from the midpoint of the cost report period to the beginning of the state fiscal year rate period.

(1) Non-state-owned nursing facilities. Patient days for purposes of the computation of administrative, environmental, and property expenses for non-state-owned facilities shall be inpatient days as determined in subrule 81.6(7) or 90 percent of the licensed capacity of the facility, whichever is greater. Patient days for purposes of the computation of all other expenses shall be inpatient days as determined in subrule 81.6(7).

(2) Medicare-certified hospital-based nursing facilities. Patient days for purposes of the computation of all expenses shall be inpatient days as determined by subrule 81.6(7).

b. Cost normalization. The per diem allowable direct care costs are normalized by dividing a facility's per diem direct care costs by the facility's cost report period case-mix index as defined in rule 441—81.1(249A) and subrule 81.6(19).

c. Calculation of patient-day-weighted medians. For each of the rate components, a patient-day-weighted median shall be established for both the non-state-owned nursing facilities and the Medicare-certified hospital-based nursing facilities, hereinafter referred to as the non-state-owned nursing facility patient-day-weighted medians and the Medicare-certified hospital-based nursing facility patient-day-weighted medians.

The per diem normalized direct care cost for each facility is arrayed from low to high to determine the direct care component patient-day-weighted median cost based on the number of patient days provided by facilities. The per diem non-direct care cost for each facility is also arrayed from low to high to determine the non-direct care component patient-day-weighted median cost based on the number of patient days provided by facilities. An array and patient-day-weighted median for each cost component is determined separately for both non-state-owned nursing facilities and the Medicare-certified hospital-based nursing facilities.

(1) For the fiscal period beginning July 1, 2001, and ending June 30, 2003, the non-state-owned nursing facility direct care and non-direct care patient-day-weighted medians and the Medicare-certified hospital-based nursing facility direct care and non-direct care patient-day-weighted medians shall be calculated using the latest financial and statistical report with a fiscal year end of December 31, 2000, or earlier, inflated from the midpoint of the cost report period to July 1, 2001, using the inflation factor specified in subrule 81.6(18).

(2) Effective July 1, 2003, and each second year thereafter, the patient-day-weighted medians used in rate setting shall be recalculated. The non-state-owned nursing facility direct care and non-direct care patient-day-weighted medians and the Medicare-certified hospital-based nursing facility direct care and non-direct care patient-day-weighted medians shall be calculated using the latest completed cost report with a fiscal year end of the preceding December 31 or earlier. When patient-day-weighted medians are recalculated, inflation is applied from the midpoint of the cost report period to the first day of the state fiscal year rate period using the inflation factor specified in subrule 81.6(18).

(3) For the fiscal period beginning July 1, 2004, and ending June 30, 2005, the non-state-owned and Medicare-certified hospital-based nursing facility direct care and the non-direct care patient-day-weighted medians calculated July 1, 2003, shall be inflated to July 1, 2004, using the inflation factor specified in subrule 81.6(18).

d. Excess payment allowance.

(1) For non-state-operated nursing facilities not located in a Metropolitan Statistical Area as defined by the Centers for Medicare and Medicaid Services (not including Medicare-certified hospital-based nursing facilities), the excess payment allowance is calculated as follows:

1. For the direct care component, subject to the limit provided below, the excess payment allowance is equal to the percentage specified in 441—subrule 79.1(2) times the difference (if greater than zero) of the following: the direct care non-state-operated nursing facility patient-day-weighted median times the percentage specified in 441—subrule 79.1(2) times the Medicaid average case-mix index pursuant to subrule 81.6(19), minus a provider's allowable normalized per patient day direct care costs pursuant to 81.6(16)*"b"* times the Medicaid average case-mix index pursuant to subrule 81.6(19). In no case shall the excess payment allowance exceed the percentage specified in 441—subrule 79.1(2) times the direct care non-state-operated nursing facility patient-day-weighted median.

2. For the non-direct care component, subject to the limit provided below, the excess payment allowance is equal to the percentage specified in 441—subrule 79.1(2) times the difference (if greater than zero) of the following: the non-direct care non-state-operated nursing facility patient-day-weighted median times the percentage specified in 441—subrule 79.1(2), minus a provider's allowable per patient day non-direct care cost pursuant to paragraph 81.6(16)*"a."* In no case shall the excess payment allowance exceed the percentage specified in 441—subrule 79.1(2) times the non-direct care non-state-operated nursing facility patient-day-weighted median.

(2) For non-state-operated nursing facilities located in a Metropolitan Statistical Area as defined by the Centers for Medicare and Medicaid Services (not including Medicare-certified hospital-based nursing facilities), the excess payment allowance is calculated as follows:

1. For the direct care component, subject to the limit provided below, the excess payment allowance is equal to the percentage specified in 441—subrule 79.1(2) times the difference (if greater than zero) of the following: the direct care non-state-operated nursing facility patient-day-weighted median times the percentage specified in 441—subrule 79.1(2) times the wage index factor specified below times the Medicaid average case-mix index pursuant to subrule 81.6(19), minus a provider's allowable normalized per patient day direct care costs pursuant to paragraph 81.6(16)*"b"* times the Medicaid average case-mix index pursuant to subrule 81.6(19). In no case shall the excess payment allowance exceed the percentage specified in 441—subrule 79.1(2) times the direct care non-state-operated nursing facility patient-day-weighted median.

The wage index factor applied July 1, 2001, through June 30, 2002, shall be 11.46 percent. Beginning July 1, 2002, and thereafter, the wage index factor shall be determined annually by calculating the average difference between the Iowa hospital-based rural wage index and all Iowa hospital-based Metropolitan Statistical Area wage indices as published by the Centers for Medicare and Medicaid Services (CMS) each July. The geographic wage index adjustment shall not exceed $8 per patient day.

A nursing facility may request an exception to application of the geographic wage index based upon a reasonable demonstration of wages, locations, and total cost. The nursing facility shall request the exception within 30 days of receipt of notification to the nursing facility of the new reimbursement rate using the department's procedures for requesting exceptions at rule 441—1.8(17A,217).

2. For the non-direct care component, subject to the limit provided below, the excess payment allowance is equal to the percentage specified in 441—subrule 79.1(2) times the difference (if greater than zero) of the following: the non-direct care non-state-operated nursing facility patient-day-weighted median times the percentage specified in 441—subrule 79.1(2), minus a provider's allowable per patient day non-direct care cost pursuant to paragraph 81.6(16)*"a."* In no case shall the excess payment allowance exceed the percentage specified in 441—subrule 79.1(2) times the non-direct care non-state-operated nursing facility patient-day-weighted median.

(3) For Medicare-certified hospital-based nursing facilities, the excess payment allowance is calculated as follows:

1. For the direct care component, subject to the limit provided below, the excess payment allowance is equal to the percentage specified in 441—subrule 79.1(2) times the difference (if greater than zero) of the following: the direct care Medicare-certified hospital-based nursing facility patient-day-weighted median times the percentage specified in 441—subrule 79.1(2) times the Medicaid average case-mix index pursuant to subrule 81.6(19), minus a provider's normalized allowable per patient day direct care costs pursuant to paragraph 81.6(16)*"b"* times the Medicaid average case-mix index pursuant to subrule 81.6(19). In no case shall the excess payment allowance exceed the percentage specified in 441—subrule 79.1(2) times the direct care Medicare-certified hospital-based nursing facility patient-day-weighted median.

2. For the non-direct care component, subject to the limit provided below, the excess payment allowance is equal to the percentage specified in 441—subrule 79.1(2) times the difference (if greater than zero) of the following: the non-direct care Medicare-certified hospital-based nursing facility patient-day-weighted median times the percentage specified in 441—subrule 79.1(2), minus a provider's allowable per patient day non-direct care cost pursuant to paragraph 81.6(16)*"a."* In no case shall the excess payment allowance exceed the percentage specified in 441—subrule 79.1(2) times the non-direct care Medicare-certified hospital-based nursing facility patient-day-weighted median.

e. Reimbursement rate. The Medicaid reimbursement rate is based on allowable costs, updated July 1, 2001, and every second year thereafter, as specified in subparagraphs (1) and (2) below, plus a potential excess payment allowance determined by the methodology in paragraph *"d,"* not to exceed the rate component limits determined by the methodology in paragraph *"f."*

(1) For non-state-owned nursing facilities and Medicare-certified hospital-based nursing facilities, direct care and non-direct care rate components are calculated as follows:

1. The direct care component is equal to the provider's normalized allowable per patient day costs times the Medicaid average case-mix index pursuant to subrule 81.6(19), plus the allowed excess payment allowance as determined by the methodology in paragraph *"d."*

2. The non-direct care component is equal to the provider's allowable per patient day costs, plus the allowed excess payment allowance as determined by the methodology in paragraph *"d"* and the allowable capital cost per diem instant relief add-on as determined by the methodology in paragraph *"h."*

(2) The reimbursement rate for state-operated nursing facilities and special population nursing facilities shall be the facility's average allowable per diem costs, adjusted for inflation pursuant to subrule 81.6(18), based on the most current financial and statistical report.

f. Notwithstanding paragraphs *"d"* and *"e,"* in no instance shall a rate component exceed the rate component limit defined as follows:

(1) For non-state-operated nursing facilities not located in a Metropolitan Statistical Area (not including Medicare-certified hospital-based nursing facilities), the direct care and non-direct care rate component limits are calculated as follows:

1. The direct care rate component limit is the direct care non-state-operated nursing facility patient-day-weighted median times the percentage of the median specified in 441—subrule 79.1(2) times the Medicaid average case-mix index pursuant to subrule 81.6(19).

2. The non-direct care rate component limit is the non-direct care non-state-operated nursing facility patient-day-weighted median multiplied by the percentage of the median specified in

441—subrule 79.1(2) or is 120 percent of the median if the facility qualifies for the enhanced non-direct care rate component limit pursuant to paragraph *"h."*

(2) For non-state-operated nursing facilities located in a Metropolitan Statistical Area (not including Medicare-certified hospital-based nursing facilities), the direct care and non-direct care rate component limits are calculated as follows:

1. The direct care rate component limit is the direct care non-state-operated nursing facility patient-day-weighted median times the percentage of the median specified in 441—subrule 79.1(2) times the wage factor specified in paragraph *"d"* times the Medicaid average case-mix index pursuant to subrule 81.6(19).

2. The non-direct care rate component limit is the non-direct care non-state-operated nursing facility patient-day-weighted median multiplied by the percentage of the median specified in 441—subrule 79.1(2) or is 120 percent of the median if the facility qualifies for the enhanced non-direct care rate component limit pursuant to paragraph *"h."*

(3) For Medicare-certified hospital-based nursing facilities, the direct care and non-direct care rate component limits are calculated as follows:

1. The direct care rate component limit is the direct care Medicare-certified hospital-based nursing facility patient-day-weighted median times the percentage of the median specified in 441—subrule 79.1(2) times the Medicaid average case-mix index pursuant to subrule 81.6(19).

2. The non-direct care rate component limit is the non-direct care Medicare-certified hospital-based nursing facility patient-day-weighted median multiplied by the percentage of the median specified in 441—subrule 79.1(2) or is 120 percent of the median if the facility qualifies for the enhanced non-direct care rate component limit pursuant to paragraph *"h."*

(4) For special population nursing facilities enrolled on or after June 1, 1993, the upper limit on their rate is equal to the sum of the following:

1. The direct care Medicare-certified hospital-based nursing facility patient-day-weighted median times the percentage of the median specified in 441—subrule 79.1(2).

2. The non-direct care Medicare-certified hospital-based nursing facility patient-day-weighted median multiplied by the percentage of the median specified in 441—subrule 79.1(2) or 120 percent of the median if the facility qualifies for the enhanced non-direct care rate component limit pursuant to paragraph *"h."*

g. Pay-for-performance program. Additional reimbursement based on the nursing facility pay-for-performance program is available for non-state-owned facilities effective July 1, 2009, as provided in this paragraph. The pay-for-performance program provides additional reimbursement based upon a nursing facility's achievement of multiple favorable outcomes as determined by established benchmarks. The reimbursement is issued as an add-on payment after the end of the state fiscal year (which is referred to in this paragraph as the "payment period").

(1) Scope. Additional reimbursement for the nursing facility pay-for-performance program is not available to Medicare-certified hospital-based nursing facilities, state-operated nursing facilities, or special population nursing facilities. Therefore, data from these facility types shall not be used when determining eligibility for or the amount of additional reimbursement based on the nursing facility pay-for-performance program.

(2) Benchmarks. The pay-for-performance benchmarks include characteristics in four domains: quality of life, quality of care, access, and efficiency. These characteristics are objective and measurable and when considered in combination with each other are deemed to have a correlation to a resident's quality of life and care. While any single measure does not ensure the delivery of quality care, a nursing facility's achievement of multiple measures suggests that quality is an essential element in the facility's delivery of resident care.

(3) Definition of direct care. For the purposes of the nursing facility pay-for-performance program, "direct care staff" is defined to include registered nurses (RNs), licensed practical nurses (LPNs), certified nurse assistants (CNAs), rehabilitation nursing, and other contracted nursing services. "Direct care staff" does not include the director of nursing (DON) or minimum data set (MDS) coordinator.

(4) Qualifying for additional reimbursement. The Iowa Medicaid enterprise shall annually award points based on the measures achieved in each of the four domains, as described in subparagraphs (5) through (8). The maximum available points are 100. To qualify for additional Medicaid reimbursement under the nursing facility pay-for-performance program, a facility must achieve a minimum score of 51 points. The relationship of the score achieved to additional payments is described in subparagraph (10). Payments are subject to reduction or forfeiture as described in subparagraphs (12) and (13).

(5) Domain 1: Quality of life.

Standard	Measurement Period	Value	Source
Subcategory: Person-Directed Care			
Enhanced Dining A: The facility makes available menu options and alternative selections for all meals.	For SFY 2010, 10/1/09 to 6/30/10; thereafter, payment period	1 point	Self-certification
Enhanced Dining B: The facility provides residents with access to food and beverages 24 hours per day and 7 days per week and empowers staff to honor resident choices.	For SFY 2010, 10/1/09 to 6/30/10; thereafter, payment period	1 point	Self-certification
Enhanced Dining C: The facility offers at least one meal per day for an extended period to give residents the choice of what time to eat.	For SFY 2010, 10/1/09 to 6/30/10; thereafter, payment period	2 points	Self-certification
Resident Activities A: The facility employs a certified activity coordinator for at least 38 minutes per week per licensed bed.	For SFY 2010, 10/1/09 to 6/30/10; thereafter, payment period	1 point	Self-certification
Resident Activities B: The facility either has activity staff that exceed the required minimum set by law or has direct care staff who are trained to plan and conduct activities and carry out both planned and spontaneous activities on a daily basis.	For SFY 2010, 10/1/09 to 6/30/10; thereafter, payment period	1 point	Self-certification
Resident Activities C: The facility's residents report that activities meet their social, emotional and spiritual needs.	For SFY 2010, 10/1/09 to 3/31/10; thereafter, July through March of payment period	2 points	Self-certification
Resident Choice A: The facility allows residents to set their own schedules, including what time to get up and what time to go to bed.	For SFY 2010, 10/1/09 to 6/30/10; thereafter, payment period	1 point	Self-certification

Standard	Measurement Period	Value	Source
Resident Choice B: The facility allows residents to have a choice of whether to take a bath or shower and on which days and at what time the bath or shower will be taken.	For SFY 2010, 10/1/09 to 6/30/10; thereafter, payment period	1 point	Self-certification
Consistent Staffing: The facility has all direct care staff members caring for the same residents at least 70% of their shifts.	For SFY 2010, 10/1/09 to 6/30/10; thereafter, payment period	3 points	Self-certification
National Accreditation: The facility has CARF or another nationally recognized accreditation for the provision of person-directed care.	For SFY 2010, 10/1/09 to 6/30/10; thereafter, payment period	13 points NOTE: A facility that receives points for this measure does not receive points for any other measures in this subcategory.	Self-certification
Subcategory: Resident Satisfaction			
Resident/Family Satisfaction Survey: The facility administers an anonymous resident/family satisfaction survey annually. The survey tool must be developed, recognized, and standardized by an entity external to the facility. Results must be tabulated by an entity external to the facility. To qualify for the measure, the facility must have a response rate of at least 35%. A summary report of the aggregate results and point scale must be made publicly available and be posted prominently along with the facility's state survey results until the next satisfaction survey is completed.	For SFY 2010, survey completed between 9/1/08 and 3/31/10; thereafter, survey completed between October 1 and March 31 of the payment period	5 points	Form 470-3891, Nursing Facility Opinion Survey Transmittal, submitted by independent entity that compiled results
Long-Term Care Ombudsman: The facility has resolved 70% or more of complaints received and investigated by the local or state ombudsman.	Calendar year ending December 31 of the payment period	5 points if resolution 70% to 74% 7 points if resolution 75% or greater	LTC ombudsman's list of facilities meeting the standard

(6) Domain 2: Quality of care.

Standard	Measurement Period	Value	Source
Subcategory: Survey			
Deficiency-Free Survey: The facility is deficiency-free on the latest annual state and federal licensing and certification survey and any subsequent surveys, complaint investigations, or revisit investigations. If a facility's only scope and severity deficiencies are an A level pursuant to 42 CFR Part 483, Subparts B and C, as amended to July 30, 1999, the facility shall be deemed to have a deficiency-free survey for purposes of this measure. Surveys are considered complete when all appeal rights have been exhausted.	Calendar year ending December 31 of the payment period, including any subsequent surveys, revisit, or complaint investigations	10 points	DIA list of facilities meeting the standard
Regulatory Compliance with Survey: No on-site revisit to the facility is required for recertification surveys or for any substantiated complaint investigations during the measurement period.	Calendar year ending December 31 of the payment period, including any subsequent surveys, revisits, or complaint investigations	5 points NOTE: A facility that receives points for a deficiency-free survey does not receive points for this measure.	DIA list of facilities meeting the standard
Subcategory: Staffing			
Nursing Hours Provided: The facility's per-resident-day nursing hours are at or above one-half standard deviation above the mean of per-resident-day nursing hours for all facilities. Nursing hours include those of RNs, LPNs, CNAs, rehabilitation nurses, and other contracted nursing services. Nursing hours shall be normalized to remove variations in staff hours associated with different levels of resident case mix.	Facility fiscal year ending on or before December 31 of the payment period	5 points if case-mix adjusted nursing hours are above mean plus one-half standard deviation 10 points if case-mix adjusted nursing hours are greater than mean plus one standard deviation	Form 470-0030, Financial and Statistical Report, as analyzed by IME provider cost audit and rate setting unit. The facility cost report period case-mix index shall be used to normalize nursing hours.
Employee Turnover: The facility has overall employee turnover of 50% or less and CNA turnover of 55% or less.	Facility fiscal year ending on or before December 31 of the payment period	5 points if overall turnover is between 40% and 50% and CNA turnover is between 45% and 55% 10 points if overall turnover is less than or equal to 40% and CNA turnover is less than or equal to 45%	Form 470-0030, Financial and Statistical Report, as analyzed by IME provider cost audit and rate setting unit

Standard	Measurement Period	Value	Source
Staff Education, Training and Development: The facility provides staff education, training, and development at 25% above the basic requirements for each position that requires continuing education. The number of hours for these programs must apply to at least 75% of all staff of the facility, based upon administrator or officer certification.	Calendar year ending December 31 of the payment period	5 points	Self-certification
Staff Satisfaction Survey: The facility annually administers an anonymous staff satisfaction survey. The survey tool must be developed, recognized, and standardized by an entity external to the facility and must identify worker job classification. Results must be tabulated by an entity external to the facility. To qualify for this measure, the facility must have a response rate of at least 35%. A summary report of the aggregate results and point scale must be made publicly available and be posted prominently along with the facility's state survey results until the next satisfaction survey is completed.	For SFY 2010, survey completed between 9/1/08 and 3/31/10; thereafter, survey completed between October 1 and March 31 of the payment period	5 points	Form 470-3891, Nursing Facility Opinion Survey Transmittal, submitted by independent entity that compiled results
Subcategory: Nationally Reported Quality Measures			
High-Risk Pressure Ulcer: The facility has occurrences of high-risk pressure ulcers at rates one-half standard deviation or more below the mean percentage of occurrences for all facilities, based on MDS data as applied to the nationally reported quality measures.	12-month period ending September 30 of the payment period	3 points if one-half to one standard deviation below the mean percentage of occurrences 5 points if one standard deviation or more below the mean percentage of occurrences	IME medical services unit report based on MDS data as reported by CMS
Physical Restraints: The facility has a physical restraint rate of 0% based on MDS data as applied to the nationally reported quality measures.	12-month period ending September 30 of the payment period	5 points	IME medical services unit report based on MDS data as reported by CMS

Standard	Measurement Period	Value	Source
Chronic Care Pain: The facility has occurrences of chronic care pain at rates one-half standard deviation or more below the mean rate of occurrences for all facilities based on MDS data as applied to the nationally reported quality measures.	12-month period ending September 30 of the payment period	3 points if one-half to one standard deviation below the mean rate of occurrences 5 points if one standard deviation or more below the mean rate of occurrences	IME medical services unit report based on MDS data as reported by CMS
High Achievement of Nationally Reported Quality Measures: The facility received at least 9 points from a combination of the measures listed in this subcategory.	12-month period ending September 30 of the payment period	2 points if the facility receives 9 to 12 points in the subcategory of nationally reported quality measures 4 points if the facility receives 13 to 15 points in this subcategory	IME medical services unit report based on MDS data as reported by CMS

(7) Domain 3: Access.

Standard	Measurement Period	Value	Source
Special Licensure Classification: The facility has a unit licensed for the care of residents with chronic confusion or a dementing illness (CCDI unit).	Status on December 31 of the payment period	4 points	DIA list of facilities meeting the standard
High Medicaid Utilization: The facility has Medicaid utilization at or above the statewide median plus 10%. Medicaid utilization is determined by dividing total nursing facility Medicaid days by total nursing facility patient days.	Facility fiscal year ending on or before December 31 of the payment period	3 points if Medicaid utilization is more than the median plus 10% 4 points if Medicaid utilization is more than the median plus 20%	Form 470-0030, Financial and Statistical Report, as analyzed by IME provider cost audit and rate setting unit

(8) Domain 4: Efficiency.

Standard	Measurement Period	Value	Source
High Occupancy Rate: The facility has an occupancy rate at or above 95%. "Occupancy rate" is defined as the percentage derived when dividing total patient days based on census logs by total bed days available based on the number of authorized licensed beds within the facility.	Facility fiscal year ending on or before December 31 of the payment period	4 points	Form 470-0030, Financial and Statistical Report, as analyzed by IME provider cost audit and rate setting unit
Low Administrative Costs: The facility's percentage of administrative costs to total allowable costs is one-half standard deviation or more below the mean percentage of administrative costs for all Iowa facilities.	Facility fiscal year ending on or before December 31 of the payment period	3 points if administrative costs percentage is less than the mean less one-half standard deviation 4 points if administrative costs percentage is less than the mean less one standard deviation	Form 470-0030, Financial and Statistical Report, as analyzed by IME provider cost audit and rate setting unit

(9) Source of measurements. Source reports are due to the department by May 1 of each year. For those measures whose source is self-certification, the data shall be drawn from Form 470-4828, Nursing Facility Medicaid Pay-for-Performance Self-Certification Report, submitted by the facility to IME. The independent party that collects and compiles the results of the resident/family survey shall communicate the results to IME on Form 470-3891, Nursing Facility Opinion Survey Transmittal. The department shall request required source reports from the long-term care ombudsman and the department of inspections and appeals (DIA).

(10) Calculation of potential add-on payment. The number of points awarded shall be determined annually. A determination is made on whether a facility qualifies for an add-on payment at the end of the payment period. Based upon the number of points awarded, a retroactive add-on payment is made effective beginning the first day of the payment period as follows, subject to subparagraph (11):

Score	Amount of Add-on Payment
0-50 points	No additional reimbursement
51-60 points	1 percent of the direct care plus nondirect care cost component patient-day-weighted medians, subject to reduction as provided in subparagraph (13)
61-70 points	2 percent of the direct care plus nondirect care cost component patient-day-weighted medians, subject to reduction as provided in subparagraph (13)
71-80 points	3 percent of the direct care plus nondirect care cost component patient-day-weighted medians, subject to reduction as provided in subparagraph (13)
81-90 points	4 percent of the direct care plus nondirect care cost component patient-day-weighted medians, subject to reduction as provided in subparagraph (13)

91-100 points	5 percent of the direct care plus nondirect care cost component patient-day-weighted medians, subject to reduction as provided in subparagraph (13)

(11) Monitoring for reduction or forfeiture of reimbursement. The department shall request the department of inspections and appeals to furnish by September 1, December 1, March 1, and August 1 of each year a list of nursing facilities subject to a reduction or forfeiture of the additional reimbursement pursuant to the criteria in subparagraph (12) or (13).

(12) Forfeiture of additional reimbursement. A nursing facility shall not be eligible for any additional reimbursement under this program if during the payment period the nursing facility is cited for a deficiency resulting in actual harm or immediate jeopardy pursuant to the federal certification guidelines at a scope and severity level of H or higher, regardless of the amount of fines assessed.

(13) Reduction of additional reimbursement. The additional reimbursement for the nursing facility pay-for-performance program calculated according to subparagraph (10) shall be subject to reduction based on survey compliance as follows:

1. The add-on payment shall be suspended for any month in which the nursing facility has received denial of payment for new admission status that was enforced by CMS.

2. A facility's add-on payment shall be reduced by 25 percent for each citation received during the year for a deficiency resulting in actual harm at a scope and severity level of G pursuant to the federal certification guidelines.

3. If the facility fails to cure a cited level G deficiency within the time allowed by the department of inspections and appeals, the add-on payment shall be forfeited, and the facility shall not receive any nursing facility pay-for-performance program payment for the payment period.

(14) Application of additional payments. The additional reimbursement for the nursing facility pay-for-performance program shall be paid to qualifying facilities at the end of the state fiscal year. At the end of each state fiscal year, the Iowa Medicaid enterprise shall:

1. Retroactively adjust each qualifying facility's quarterly rates from the first day of the state fiscal year to include the amount of additional reimbursement for the nursing facility pay-for-performance program calculated according to paragraph 81.6(16)*"g"*; and

2. Reprice all facility claims with dates of service during the period in which an additional reimbursement for the nursing facility pay-for-performance program is effective to reflect the adjusted reimbursement rate.

(15) Use of additional payments. As a condition of eligibility for such payments, any additional payments received by a nursing facility for the pay-for-performance program must be:

1. Used to support direct care staff through increased wages, enhanced benefits, and expanded training opportunities; and

2. Used in a manner that improves and enhances quality of care for residents.

(16) Monitoring facility compliance on the use of payments. Each nursing facility shall complete Form 470-4829, Nursing Facility Medicaid Enhanced Payment Report, to report the use of any additional payments received for the nursing facility pay-for-performance program. Form 470-4829 is due to the department each year by May 1, beginning May 1, 2011. Failure to submit the report by the due date shall result in disqualification for add-on payment for the next pay-for-performance payment period.

(17) Reporting results of the program. The department shall publish the results of the nursing facility pay-for-performance program annually.

h. Capital cost per diem instant relief add-on and enhanced non-direct care rate component limit. Contingent upon approval from the Centers for Medicare and Medicaid Services (CMS) and to the extent that funding is appropriated by the Iowa general assembly, additional reimbursement is available for nursing facilities that have completed a complete replacement, new construction, or major renovations. Additional reimbursement under this paragraph is available for services rendered beginning on October 1, 2007, or beginning on the effective date of CMS approval if CMS approval is effective on a later date.

(1) Types of additional reimbursement. Two types of additional reimbursement are available:

1. The capital cost per diem instant relief add-on is an amount per patient day to be added to the non-direct care component of the reimbursement rate and is subject to the non-direct care rate component limit as determined in paragraph *"f."*

2. The enhanced non-direct care rate component limit provides an increase in the percentage of the median that is applied when calculating the non-direct care rate component limit as defined in paragraph *"f."* The percentage of the median is increased to 120 percent when the enhanced non-direct care rate component limit is granted.

(2) Eligible projects. To qualify for either the capital cost per diem instant relief add-on or the enhanced non-direct care rate component limit, a facility must have undertaken a complete replacement, new construction, or major renovations for the purpose of:

1. Rectification of a violation of Life Safety Code requirements; or

2. Development of home- and community-based waiver program services.

(3) Additional requirements for all requests. To qualify for additional reimbursement, a facility with an eligible project must also meet the following requirements:

1. The facility has Medicaid utilization at or above 40 percent for the two-month period before the request for additional reimbursement is submitted. Medicaid utilization for this purpose is calculated as total nursing facility Medicaid patient days divided by total licensed bed capacity as reported on the facility's most current financial and statistical report.

2. The facility meets the accountability measure criteria set forth in paragraph *"g,"* subparagraph (1), deficiency-free survey, or subparagraph (2), regulatory compliance with survey, based on the most current information available when the request for additional reimbursement is submitted.

3. The facility has documented active participation in a quality of care program.

4. The facility has documented plans to facilitate person-directed care, dementia units, or specialty post-acute services.

(4) Additional requirements for waiver services. To qualify for additional reimbursement for the development of home- and community-based waiver services, the facility shall also meet the following requirements:

1. Services shall be provided in an underserved area, which may include a rural area.

2. Services shall be provided on the direct site of the facility but not as a nursing facility service.

3. Services shall meet all federal and state requirements for Medicaid reimbursement.

4. Services shall include one or more of the following: adult day care as defined by 441—subrule 78.37(1), consumer-directed attendant care as defined by 441—subrule 78.37(15) provided in an assisted living setting, day habilitation as defined by 441—subrule 78.41(14), home-delivered meals as defined by 441—subrule 78.37(8), emergency response system as defined by 441—subrule 78.37(2), and respite care as defined by 441—subrule 78.37(6).

(5) Submission of request. A facility shall submit a written request for the capital cost per diem instant relief add-on, the enhanced non-direct care rate component limit, or a preliminary evaluation of whether a project may qualify for additional reimbursement to the Iowa Medicaid Enterprise, Provider Cost Audit and Rate Setting Unit, 100 Army Post Road, Des Moines, Iowa 50315. A qualifying facility may request one or both types of additional reimbursement.

1. A request for the capital cost per diem instant relief add-on may be submitted no earlier than 30 days before the complete replacement, new construction, or major renovations are placed in service.

2. A request for the enhanced non-direct care rate component limit may be submitted with a request for a capital cost per diem instant relief add-on or within 60 days after the release of a rate determination letter reflecting a change in the non-direct care rate component limit.

3. A request for a preliminary evaluation may be submitted when a facility is preparing a feasibility projection for a construction or renovation project. A preliminary evaluation does not guarantee approval of the capital cost per diem instant relief add-on or enhanced non-direct care rate component limit upon submission of a formal request.

(6) Content of request for add-on. A facility's request for the capital cost per diem instant relief add-on shall include:

1. A description of the project for which the add-on is requested, including a list of goals for the project and a time line of the project that spans the life of the project.

2. Documentation that the facility meets the qualifications in subparagraphs (2) and (3) and, if applicable, in subparagraph (4).

3. The period during which the add-on is requested (no more than two years).

4. Whether the facility is also requesting the enhanced non-direct care rate component limit. (See subparagraph (7) for requirements.)

5. A copy of the facility's most current depreciation schedule which clearly identifies the cost of the project for which the add-on is requested if assets placed in service by that project are included on the schedule. Any removal of assets shall be clearly identifiable either on the depreciation schedule or on a separate detailed schedule, and that schedule shall include the amount of depreciation expense for removed assets that is included in the current reimbursement rate.

6. If the cost of the project is not reported on the submitted depreciation schedule, a detailed schedule of the assets to be placed in service by the project, including:

- The estimated date the assets will be placed into service;
- The total estimated depreciable value of the assets;
- The estimated useful life of the assets based upon existing Medicaid and Medicare provisions; and
- The estimated annual depreciation expense of the assets using the straight-line method in accordance with generally accepted accounting principles.

7. The facility's estimated annual licensed bed capacity and estimated annual total patient days. If this information is not provided, estimated annual total patient days shall be determined using the most current submitted financial and statistical report.

8. If interest expense has been or will be incurred and is related to the project for which the add-on is requested, a copy of the general terms of the debt service and the estimated annual amount of interest expense shall be submitted.

9. If any debt service has been retired, a copy of the general terms of the debt service and the amount of interest expense for debt service retired that is included in the current reimbursement rate.

(7) Content of request for enhanced limit. A facility's request for the enhanced non-direct care rate component limit shall include:

1. A description of the project for which the enhanced non-direct care rate component limit is requested, including a list of goals for the project and a time line of the project that spans the life of the project.

2. Documentation that the facility meets the qualifications in subparagraphs (2) and (3) and, if applicable, in subparagraph (4).

3. Identification of any period in which the capital cost per diem instant relief add-on was previously granted and the number of times the capital cost per diem instant relief add-on and the enhanced non-direct care rate component limit have previously been granted.

(8) Content of request for preliminary evaluation. A facility's request for a preliminary evaluation of a proposed project shall include:

1. The estimated completion date of the project.

2. The estimated date when a formal request for an add-on or enhanced limit will be submitted.

3. For a preliminary evaluation for a capital cost per diem instant relief add-on, all information required in subparagraph (6).

4. For a preliminary evaluation for the enhanced non-direct care rate component limit, all information required in subparagraph (7).

(9) Calculation of capital cost per diem instant relief add-on. The capital cost per diem instant relief add-on is calculated by dividing the annual estimated property costs for the complete replacement, new construction, or major renovation project for which the add-on is granted by the facility's estimated annual total patient days.

1. Total patient days shall be determined using the most current submitted financial and statistical report or using the estimated total patient days as reported in the request for the add-on. For purposes of

calculating the add-on, total patient days shall be the greater of the estimated annual total patient days or 90 percent of the facility's estimated licensed capacity.

2. The annual estimated property costs for the project are calculated as the estimated annual depreciation expense for the cost of the project, plus estimated annual interest expense for the cost of the project, less the amount of depreciation expense for assets removed that is included in the current reimbursement rate and the amount of interest expense for debt service retired that is included in the current reimbursement rate.

3. A reconciliation between the estimated amounts and actual amounts shall be completed as described in subparagraph (12).

(10) Effective date of capital cost per diem instant relief add-on. Subject to available funding and previously approved requests for capital cost per diem instant relief add-ons and enhanced non-direct care rate component limits, a capital cost per diem instant relief add-on shall be effective the first day of the calendar quarter following the placement in service of the assets associated with the add-on and receipt of all required information. The capital cost per diem instant relief add-on shall be added to the non-direct care component of the reimbursement rate, not to exceed the non-direct care rate component limit as determined in paragraph *"f."*

(11) Term of capital cost per diem instant relief add-on. The period for which a facility may be granted the capital cost per diem instant relief add-on shall not exceed two years. The capital cost per diem instant relief add-on shall terminate at the time of the subsequent biennial rebasing. If the facility's submitted annual financial and statistical report used in the subsequent biennial rebasing does not include 12 months of property costs for the assets with which the capital cost per diem instant relief add-on is associated, including interest expense, if applicable, the facility may submit a new request for the capital cost per diem instant relief add-on.

(12) Reconciliation of capital cost per diem instant relief add-on. During the period in which the capital cost per diem instant relief add-on is granted, the Iowa Medicaid enterprise shall recalculate the amount of the add-on based on actual allowable costs and patient days reported on the facility's submitted annual financial and statistical report. A separate reconciliation shall be performed for each cost report period in which the capital cost per diem instant relief add-on was paid. The facility shall submit with the annual financial and statistical report a separate schedule reporting total patient days per calendar quarter and a current depreciation schedule identifying the assets related to the add-on.

1. For purposes of recalculating the capital cost per diem instant relief add-on, total patient days shall be based on the greater of the number of actual patient days during the period in which the add-on was paid or 90 percent of the facility's actual licensed bed capacity during the period in which the add-on was paid.

2. The recalculated capital cost per diem instant relief add-on shall be added to the non-direct care component of the reimbursement rate for the relevant period, not to exceed the non-direct care rate component limit as determined in paragraph *"f."* The facility's quarterly rates for the relevant period shall be retroactively adjusted to reflect the recalculated non-direct care component of the reimbursement rate. All claims with dates of service during the period the capital cost per diem instant relief add-on is paid shall be repriced to reflect the recalculated capital cost per diem instant relief add-on.

(13) Effective date of enhanced non-direct care rate component limit. Subject to available funding and previously approved requests for capital cost per diem instant relief add-ons and enhanced non-direct care rate component limits, an enhanced non-direct care rate component limit shall be effective:

1. With a capital cost per diem instant relief add-on (if requested at the same time); or

2. Retroactive to the first day of the quarter in which the revised non-direct care rate component limit amount is effective. All claims with dates of service from the effective date shall be repriced.

(14) Term of enhanced non-direct care rate component limit. The period for which a facility may be granted an enhanced non-direct care rate component limit without reapplication shall not exceed two years. The total period for which a facility may be granted enhanced non-direct care rate component limits shall not exceed ten years. If the amount of the non-direct care rate component limit is revised during the period for which a facility is granted the enhanced limit, the approval shall be terminated

effective the first day of the quarter in which the revised non-direct care rate component limit is effective. The facility may submit a new request for the enhanced non-direct care rate component limit.

(15) Ongoing conditions. Any capital cost per diem instant relief add-on or enhanced non-direct care rate component limit granted by the Iowa Medicaid enterprise is temporary. Additional reimbursement shall be immediately terminated if:

1. The facility does not continue to meet all of the initial qualifications for additional reimbursement; or

2. The facility does not make reasonable progress on any plans required for initial qualification; or

3. The facility's medical assistance program or Medicare certification is revoked. A facility whose certification is revoked is not eligible to submit a subsequent request for a capital cost per diem instant relief add-on or the enhanced non-direct care rate component limit.

(16) Change of ownership. Following a change in nursing facility ownership, any capital cost per diem instant relief add-on or enhanced non-direct care rate component limit that was granted before the change in ownership shall continue under the new owner. Future reimbursement rates shall be determined pursuant to subrules 81.6(15) and 81.6(16).

81.6(17) *Cost report documentation.* All nursing facilities, except the Iowa Veterans Home, shall submit an annual cost report based on the closing date of the facility's fiscal year that incorporates documentation as set forth below. The Iowa Veterans Home shall submit semiannual cost reports based on the closing date of the facility's fiscal year and the midpoint of the facility's fiscal year that incorporate documentation as set forth below. The documentation incorporated in all cost reports shall include all of the following information:

a. Information on staffing costs, including the number of hours of the following provided per resident per day by all the following: nursing services provided by registered nurses, licensed practical nurses, certified nurse aides, restorative aides, certified medication aides, and contracted nursing services; other care services; administrative functions; housekeeping and maintenance; and dietary services.

b. The starting and average hourly wage for each class of employees for the period of the report.

c. An itemization of expenses attributable to the home or principal office or headquarters of the nursing facility included in the administrative cost line item.

81.6(18) *Inflation factor.* The department shall consider an inflation factor in determining the reimbursement rate. The inflation factor shall be based on the CMS Total Skilled Nursing Facility (CMS/SNF) Market Basket Index published by Data Resources, Inc. The CMS/SNF index listed in the latest available quarterly publication prior to the July 1 rate setting shall be used to determine the inflation factor.

81.6(19) *Case-mix index calculation.*

a. The Resource Utilization Groups-III (RUG-III) Version 5.12b, 34 group, index maximizer model shall be used as the resident classification system to determine all case-mix indices, using data from the minimum data set (MDS) submitted by each facility pursuant to subrule 81.13(9). Standard Version 5.12b case-mix indices developed by CMS shall be the basis for calculating the average case-mix index and shall be used to adjust the direct care costs in the determination of the direct care patient-day-weighted median and the reimbursement rate pursuant to subrule 81.6(16).

b. Each resident in the facility on the last day of each calendar quarter with a completed and submitted assessment shall be assigned a RUG-III 34 group calculated on the resident's most current assessment available on the last day of each calendar quarter. This RUG-III group shall be translated to the appropriate case-mix index referenced in paragraph *"a."* From the individual resident case-mix indices, two average case-mix indices for each Medicaid nursing facility shall be determined four times per year based on the last day of each calendar quarter.

The facilitywide average case-mix index is the simple average, carried to four decimal places, of all resident case-mix indices. The Medicaid average case-mix index is the simple average, carried to four decimal places, of all indices for residents where Medicaid is known to be the per diem payor source on the last day of the calendar quarter. Assessments that cannot be classified to a RUG-III group due to errors shall be excluded from both average case-mix index calculations.

81.6(20) *Medicare crossover claims for nursing facility services.*

a. Definitions. For purposes of this subrule:

"Crossover claim" means a claim for Medicaid payment for Medicare-covered nursing facility services rendered to a Medicare beneficiary who is also eligible for Medicaid. Crossover claims include claims for services rendered to beneficiaries who are eligible for Medicaid in any category including, but not limited to, qualified Medicare beneficiaries and beneficiaries who are eligible for full Medicaid coverage.

"Medicaid-allowed amount" means the Medicaid reimbursement rate for the services rendered (including any portion to be paid by the Medicaid beneficiary as client participation) multiplied by the number of Medicaid units of service included in a crossover claim, as determined under state and federal law and policies.

"Medicaid reimbursement" includes any amount to be paid by the Medicaid beneficiary as Medicaid client participation and any amount to be paid by the department after application of any applicable Medicaid client participation.

"Medicare payment amount" means the Medicare reimbursement rate for the services rendered multiplied by the number of Medicare units of service included in a crossover claim, excluding any Medicare coinsurance or deductible amounts to be paid by the Medicare beneficiary.

b. Crossover claims. Crossover claims for services covered under Medicare Part A and under Medicaid are reimbursed as set out in this paragraph.

(1) If the Medicare payment amount for a crossover claim exceeds or equals the Medicaid-allowed amount for that claim, Medicaid reimbursement for the crossover claim will be zero.

(2) If the Medicaid-allowed amount for a crossover claim exceeds the Medicare payment amount for that claim, Medicaid reimbursement for the crossover claim is the lesser of:

1. The Medicaid-allowed amount minus the Medicare payment amount; or
2. The Medicare coinsurance and deductible amounts applicable to the claim.

c. Additional Medicaid payment for crossover claims uncollectible from Medicare. Medicaid shall reimburse nursing facilities for the portion of crossover claims not covered by Medicaid reimbursement pursuant to paragraph *"b"* and not reimbursable by Medicare as an allowable bad debt pursuant to 42 CFR 413.80, as amended June 13, 2001, up to a limit of 30 percent of the amount not paid by Medicaid pursuant to paragraph *"b."* The department shall calculate these amounts for each provider on a calendar-year basis and make payment for these amounts by March 31 of each year for the preceding calendar year or by a mutually acceptable schedule consistent with Medicare interim payment schedules.

d. Application of savings. Effective May 1, 2003, savings in Medicaid reimbursements attributable to the limits on nursing facility crossover claims established by this subrule shall be used to pay costs associated with development and implementation of this subrule before reversion to Medicaid.

81.6(21) *Nursing facility quality assurance payments.*

a. Quality assurance assessment pass-through. Effective with the implementation of the quality assurance assessment paid pursuant to 441—Chapter 36, Division II, a quality assurance assessment pass-through shall be added to the Medicaid per diem reimbursement rate as otherwise calculated pursuant to this rule. The quality assurance assessment pass-through shall equal the per-patient-day assessment determined pursuant to 441—subrule 36.6(2).

b. Quality assurance assessment rate add-on. Effective with the implementation of the quality assurance assessment paid pursuant to 441—Chapter 36, Division II, a quality assurance add-on of $10 per patient day shall be added to the Medicaid per diem reimbursement rate as otherwise calculated pursuant to this rule.

c. Use of the pass-through and add-on. As a condition for receipt of the pass-through and add-on, each nursing facility shall submit information to the department on Form 470-4829, Nursing Facility Medicaid Enhanced Payment Report, demonstrating compliance by the nursing facility with the requirements for use of the pass-through and add-on. If the sum of the quality assurance assessment pass-through and the quality assurance assessment rate add-on is greater than the total cost incurred by a nursing facility in payment of the quality assurance assessment:

(1) No less than 35 percent of the difference shall be used to increase compensation and costs of employment for direct care workers determined pursuant to 2009 Iowa Acts, Senate File 476.

(2) No less than 60 percent of the difference shall be used to increase compensation and costs of employment for all nursing facility staff, with increases in compensation and costs of employment determined pursuant to 2009 Iowa Acts, Senate File 476.

d. *Effective date.* Until federal financial participation to match money collected from the quality assurance assessment pursuant to 441—Chapter 36, Division II, has been approved by the federal Centers for Medicare and Medicaid Services, none of the nursing facility rate-setting methodologies of this subrule shall become effective.

e. *End date.* If the federal Centers for Medicare and Medicaid Services determines that federal financial participation to match money collected from the quality assurance assessment pursuant to 441—Chapter 36, Division II, is unavailable for any period, or if the department no longer has the authority to collect the assessment, then beginning on the effective date that such federal financial participation is not available or authority to collect the assessment is rescinded, none of the nursing facility rate-setting methodologies of this subrule shall be effective. If the period for which federal match money is unavailable or the authority to collect the assessment is rescinded includes a retroactive period, the department shall:

(1) Recalculate Medicaid rates in effect during that period without the rate-setting methodologies of this subrule;

(2) Recompute Medicaid payments due based on the recalculated Medicaid rates;

(3) Recoup any previous overpayments; and

(4) Determine for each nursing facility the amount of quality assurance assessment collected during that period and refund that amount to the facility.

This rule is intended to implement Iowa Code sections 249A.2(7), 249A.3(2)*"c,"* 249A.4, and 249A.16, chapter 249K, and 2009 Iowa Acts, Senate File 476.

[**ARC 8258B**, IAB 11/4/09, effective 1/1/10; **ARC 8344B**, IAB 12/2/09, effective 12/1/09; **ARC 8445B**, IAB 1/13/10, effective 12/11/09; **ARC 8643B**, IAB 4/7/10, effective 3/11/10]

441—81.7(249A) Continued review. The IME medical services unit shall review Medicaid members' need of continued care in nursing facilities, pursuant to the standards and subject to the appeals process in subrule 81.3(1).

This rule is intended to implement Iowa Code sections 249A.2(6) and 249A.3(2)*"a."*

[**ARC 8445B**, IAB 1/13/10, effective 12/11/09]

441—81.8(249A) Quality of care review. Rescinded IAB 8/8/90, effective 10/1/90.

441—81.9(249A) Records.

81.9(1) *Content.* The facility shall as a minimum maintain the following records:

a. All records required by the department of public health and the department of inspections and appeals.

b. Records of all treatments, drugs, and services for which vendors' payments have been made or are to be made under the medical assistance program, including the authority for and the date of administration of the treatment, drugs, or services.

c. Documentation in each resident's records which will enable the department to verify that each charge is due and proper prior to payment.

d. Financial records maintained in the standard, specified form including the facility's most recent audited cost report.

e. All other records as may be found necessary by the department in determining compliance with any federal or state law or rule or regulation promulgated by the United States Department of Health and Human Services or by the department.

f. Census records to include the date, number of residents at the beginning of each day, names of residents admitted, and names of residents discharged.

(1) Census information shall be provided for all residents of the facility.

(2) Census figures for each type of care shall be totaled monthly to indicate the number admitted, the number discharged, and the number of patient days.

(3) Failure to maintain acceptable census records shall result in the per diem rate being computed on the basis of 100 percent occupancy and a request for refunds covering indicated recipients of nursing care which have not been properly accounted for.

g. Resident accounts.

h. In-service education program records.

i. Inspection reports pertaining to conformity with federal, state and local laws.

j. Residents' personal records.

k. Residents' medical records.

l. Disaster preparedness reports.

81.9(2) *Retention.* Records identified in subrule 81.9(1) shall be retained in the facility for a minimum of five years or until an audit is performed on those records, whichever is longer.

81.9(3) *Change of owner.* All records shall be retained within the facility upon change of ownership.

This rule is intended to implement Iowa Code sections 249A.2(6) and 249A.3(2)*"a."*

441—81.10(249A) Payment procedures.

81.10(1) *Method of payment.* Except for Medicaid accountability measures payment established in paragraph 81.6(16)*"g,"* facilities shall be reimbursed under a modified price-based vendor payment program. A per diem rate shall be established based on information submitted according to rule 441—81.6(249A). Effective July 1, 2002, the per diem rate shall include an amount for Medicaid accountability measures.

81.10(2) *Authorization of payment.* The department shall authorize payment for care in a facility. The authorization shall be obtained prior to admission of the resident, whenever possible. For a nursing facility to be eligible for Medicaid payment for a resident, the facility must, when applicable, exhaust all Medicare benefits.

81.10(3) Rescinded IAB 8/9/89, effective 10/1/89.

81.10(4) *Periods authorized for payment.*

a. Payment shall be made on a per diem basis for the portion of the month the resident is in the facility.

b. Payment will be authorized as long as the resident is certified as needing care in a nursing facility.

c. Payment will be approved for the day of admission but not the day of discharge or death.

d. Payment will be approved for periods the resident is absent overnight for purpose of visitation or vacation. The facility will be paid to hold the bed for a period not to exceed 18 days in any calendar year. Additional days shall be based upon a recommendation by the resident's physician in the plan of care that additional days would be rehabilitative.

e. Payment will be approved for a period not to exceed 10 days in any calendar month when the resident is absent due to hospitalization. Medicaid payment to the facility may not be initiated while a resident is on reserve bed days unless the person was residing in the facility as a private pay resident prior to the hospitalization and returns to the facility as a resident.

f. Payment for periods when residents are absent for a visit shall be made at 42 percent of the nursing facility's rate. Payment for periods when residents are absent for hospitalization shall:

(1) Be made at 25 percent of the nursing facility's rate if the facility occupancy percentage is 95 percent or greater.

(2) Not be made if a facility's occupancy percentage is less than 95 percent.

(3) Be made at 42 percent of the nursing facility's rate for special population facilities.

g. Payment for residents determined by utilization review to require the residential level of care shall be made at the maximum state supplementary assistance rate. This rate is effective as of the date of final notice by utilization review that the lower level of care is required.

h. In-state nursing facilities serving Medicaid eligible patients who require a ventilator at least six hours every day, are inappropriate for home care, and have medical needs that require skilled care as

determined by the peer review organization shall receive reimbursement for the care of these patients equal to the sum of the Medicare-certified hospital-based nursing facility direct care rate component limit plus the Medicare-certified hospital-based nursing facility non-direct care rate component limit factor pursuant to subparagraph 81.6(16)*"f"*(3). Facilities may continue to receive reimbursement at this rate for 30 days for any person weaned from a respirator who continues to reside in the facility and continues to meet skilled care criteria for those 30 days.

81.10(5) *Supplementation.* Only the amount of client participation may be billed to the resident for the cost of care and the facility must accept the combination of client participation and payment made through the Iowa Medicaid program as payment in full for the care of a resident. No additional charges shall be made to residents or family members for any supplies or services required in the facility-developed plan of care for the resident.

Residents may choose to spend their personal funds on items of personal care such as professional beauty or barber services but the facility shall not require this expenditure and shall not routinely obligate residents to any use of their personal funds.

a. Supplies or services which the facility shall provide:

(1) Nursing services, social work services, activity programs, individual and group therapy, rehabilitation or habilitation programs provided by facility staff in order to carry out the plan of care for the resident.

(2) Services related to the nutrition, comfort, cleanliness and grooming of a resident as required under state licensure and Medicaid survey regulations.

(3) Medical equipment and supplies including wheelchairs, medical supplies except for those listed in 441—paragraph 78.10(4)*"b,"* oxygen except under circumstances specified in 441—paragraph 78.10(2)*"a,"* and other items required in the facility-developed plan of care.

(4) Nonprescription drugs ordered by the physician except for those specified in 441—78.1(2)*"f."*

(5) Fees charged by medical professionals for services requested by the facility which do not meet criteria for direct Medicaid payment.

b. The facility shall arrange for transportation to receive necessary medical services outside the facility. If a family member, friend, or volunteer is not available to provide the transportation at no charge, the facility shall arrange and pay for the medically necessary transportation.

c. The Medicaid program will provide direct payment to relieve the facility of payment responsibility for certain medical equipment and services which meet the Medicare definition of medical necessity and are provided by vendors enrolled in the Medicaid programs including:

(1) Physician services.

(2) Ambulance services.

(3) Hospital services.

(4) Hearing aids, braces and prosthetic devices.

(5) Therapy services.

d. Other supplies or services for which direct Medicaid payment may be available include:

(1) Drugs covered pursuant to 441—78.1(2).

(2) Dental services.

(3) Optician and optometrist services.

(4) Repair of medical equipment and appliances which belong to the resident.

(5) Transportation to receive medical services outside the community subject to limitations specified in rule 441—78.13(249A).

(6) Other medical services specified in 441—Chapter 78.

e. The following supplementation is permitted:

(1) The resident, the resident's family, or friends may pay to hold the resident's bed in cases where a resident who is not discharged from the facility spends over 18 days per year on visits (or longer under 81.10(4)*"d"*) or spends over 10 days per calendar month on a hospital stay. These supplementation payments shall not exceed the amount the department would pay to hold the bed under paragraph 81.10(4)*"f."*

When the resident is discharged, the facility may handle the holding of the bed in the same manner as for a private paying resident.

(2) Payments made by the resident's family toward cost of care of the resident shall not be considered as supplementation so long as the payments are included in client participation and are not over and above the payment made by the state for care of the resident.

(3) If a physician does not order a nonprescription drug by brand name, the facility may offer a generic. If a resident or family member requests a brand name, the resident or family member may pay for the brand-name nonprescription drug.

81.10(6) *Payment for out-of-state care.* Rescinded IAB 9/5/90, effective 11/1/90.

81.10(7) *Comparative charges between private pay and Medicaid residents.* Rescinded IAB 2/6/02, effective 4/1/02.

[**ARC 8344B**, IAB 12/2/09, effective 12/1/09; **ARC 8643B**, IAB 4/7/10, effective 3/11/10]

441—81.11(249A) Billing procedures.

81.11(1) *Claims.* Claims for service must be sent to the Iowa Medicaid enterprise after the month of service and within 365 days of the date of service. Claims may be submitted electronically on software provided by the Iowa Medicaid enterprise or in writing on Form 470-0039.

a. When payment is made, the facility will receive a copy of Form 470-0039, Iowa Medicaid Long-Term Care Claim. The white copy of the form shall be signed and returned to the Iowa Medicaid enterprise as a claim for the next month. If the claim is submitted electronically, the facility will receive remittance advice of the claims paid.

b. When there has been a new admission or a discharge, the facility shall submit Form 470-0039 with the changes noted. When a change is necessary to adjust a previously paid claim, the facility shall submit Form 470-0040, Credit/Adjustment Request. Adjustments to electronically submitted claims may be made electronically as provided for by the Iowa Medicaid enterprise. A request for an adjustment to a paid claim must be received by the Iowa Medicaid enterprise within one year from the date the claim was paid in accordance with rule 441—80.4(249A).

81.11(2) Reserved.

This rule is intended to implement Iowa Code sections 249A.2(6) and 249A.3(2)*"a."*

441—81.12(249A) Closing of facility. When a facility is planning on closing, the department shall be notified at least 60 days in advance of the closing. Plans for the transfer of residents receiving medical assistance shall be approved by the local office of the department.

This rule is intended to implement Iowa Code sections 249A.2(6) and 249A.3(2)*"a."*

441—81.13(249A) Conditions of participation for nursing facilities. All nursing facilities shall enter into a contractual agreement with the department which sets forth the terms under which they will participate in the program.

81.13(1) *Procedures for establishing health care facilities as Medicaid facilities.* All survey procedures and certification process shall be in accordance with Department of Health and Human Services publication "State Operations Manual."

a. The facility shall obtain the applicable license from the department of inspections and appeals and must be recommended for certification by the department of inspections and appeals.

b. The facility shall request an application, Form 470-0254, Iowa Medicaid Provider Enrollment Application, from the Iowa Medicaid enterprise provider services unit.

c. The Iowa Medicaid enterprise provider services unit shall transmit an application form and a copy of the nursing facility provider manual to the facility.

d. The facility shall complete its portion of the application form and submit it to the Iowa Medicaid enterprise provider services unit.

e. The Iowa Medicaid enterprise provider services unit shall review the application form and verify with the department of inspections and appeals that the facility is licensed and has been recommended for certification.

f. Prior to requesting enrollment, the facility shall contact the department of inspections and appeals to schedule a survey. The department of inspections and appeals shall schedule and complete a survey of the facility.

g. The department of inspections and appeals shall notify the facility of any deficiencies and ask for a plan for the correction of the deficiencies.

h. The facility shall submit a plan of correction within ten days after receipt of written deficiencies from the health facilities division department of inspections and appeals. This plan must be approved before the facility can be certified.

i. The department of inspections and appeals shall evaluate the survey findings and plan of correction and either recommend the facility for certification or recommend denial of certification. The date of certification will be the date of approval of the plan of corrections.

j. When certification is recommended, the department of inspections and appeals shall notify the department recommending a provider agreement.

k. Rescinded IAB 12/6/95, effective 2/1/96.

81.13(2) *Medicaid provider agreements.* The health care facility shall be recommended for certification by the department of inspections and appeals for participation as a nursing facility before a provider agreement may be issued. All survey procedures and certification process shall be in accordance with Department of Health and Human Services publication "Providers Certification State Operations Manual." The effective date of a provider agreement may not be earlier than the date of certification.

a. Rescinded IAB 2/3/93, effective 4/1/93.

b. Rescinded IAB 2/3/93, effective 4/1/93.

c. Rescinded IAB 2/3/93, effective 4/1/93.

d. Rescinded IAB 2/3/93, effective 4/1/93.

e. When it becomes necessary for the department to cancel or refuse to renew a Title XIX provider agreement, federal financial participation may continue for 30 days beyond the date of cancellation, if the extension is necessary to ensure the orderly transfer of residents.

f. Rescinded IAB 2/3/93, effective 4/1/93.

81.13(3) *Distinct part requirement.* All facilities which provide nursing facility care and also provide other types of care shall set aside a distinct or identifiable part for the provision of the nursing facility care.

a. The distinct part shall meet the following conditions:

(1) The distinct part shall meet all requirements for a nursing facility.

(2) The distinct part shall be identifiable as a unit such as a designated group of rooms, an entire ward or contiguous wards, wings, floor, or building. It shall consist of all beds and related facilities in the unit for whom payment is being made for nursing facility services. It shall be clearly identified and licensed by the department of inspections and appeals.

(3) The appropriate personnel shall be assigned to the identifiable unit and shall work regularly therein. Immediate supervision of staff shall be provided in the unit at all times by qualified personnel as required for licensure.

(4) The distinct part may share such central services and facilities as management services, dietary services, building maintenance and laundry with other units.

(5) When members of the staff share time between units of the facility, written records shall be maintained of the time assigned to each unit.

b. Hospitals participating as nursing facilities shall meet all of the same conditions applicable to freestanding nursing facilities.

c. Nothing herein shall be construed as requiring transfer of a resident within or between facilities when in the opinion of the attending physician the transfer might be harmful to the physical or mental health of the resident. The opinion of the physician shall be recorded on the resident's medical chart and stands as a continuing order unless the circumstances requiring the exception change.

81.13(4) *Civil rights.* The nursing facility shall comply with Title VI of the Civil Rights Act of 1964 in all areas of administration including admissions, records, services and physical facilities,

room assignments and transfers, attending physicians' privileges and referrals. Written statements of compliance shall be available to residents, employees, attending physicians and other members of the public.

81.13(5) *Resident rights.* The resident has a right to a dignified existence, self-determination and communication with and access to persons and services inside and outside the facility. A facility shall protect and promote the rights of each resident, including each of the following rights:

a. Exercise of rights.

(1) The resident has the right to exercise rights as a resident of the facility and as a citizen of the United States.

(2) The resident has the right to be free of interference, coercion, discrimination, or reprisal from the facility in exercising those rights.

(3) In the case of a resident adjudged incompetent under the laws of a state, by a court of competent jurisdiction, the rights of the resident are exercised by the person appointed under state law to act on the resident's behalf.

(4) In the case of a resident who has not been adjudged incompetent by the state court, any legal-surrogate designated in accordance with state law may exercise the resident's rights to the extent provided by state law.

b. Notice of rights and services.

(1) The facility shall inform the resident, both orally and in writing in a language that the resident understands, of the resident's rights and all rules and regulations governing resident conduct and responsibilities during the stay in the facility. The facility shall also provide the resident with the pamphlet "Medicaid for People in Nursing Homes and Other Care Facilities," Comm. 52. This notification shall be made prior to or upon admission and during the resident's stay. Receipt of this information, and any amendments to it, must be acknowledged in writing.

(2) The resident or the resident's legal representative has the right, upon an oral or written request, to access all records pertaining to the resident including clinical records within 24 hours (excluding weekends and holidays); and after receipt of the records for inspection, to purchase at a cost not to exceed the community standard photocopies of the records or any portions of them upon request and two working days' advance notice to the facility.

(3) The resident has the right to be fully informed in language that the resident can understand of the resident's total health status, including, but not limited to, medical condition.

(4) The resident has the right to refuse treatment and to refuse to participate in experimental research.

(5) The facility shall:

1. Inform each resident who is entitled to Medicaid benefits, in writing, at the time of admission to the nursing facility or when the resident becomes eligible for Medicaid, of the items and services that are included in nursing facility services under the state plan and for which the resident may not be charged and of those other items and services that the facility offers and for which the resident may be charged, and the amount of charges for those services.

2. Inform each resident when changes are made to the items and services specified in number "1" of this subparagraph.

(6) The facility shall inform each resident before, or at the time of admission, and periodically during the resident's stay, of services available in the facility and of charges for those services, including any charges for services not covered under Medicare or by the facility's per diem rate.

(7) The facility shall furnish a written description of legal rights which includes:

1. A description of the manner of protecting personal funds.

2. A description of the requirements and procedures for establishing eligibility for Medicaid, including the right to request an assessment which determines the extent of a couple's nonexempt resources at the time of institutionalization and attributes to the community spouse an equitable share of resources which cannot be considered available for payment toward the cost of the institutionalized spouse's medical care in the resident's process of spending down to Medicaid eligibility levels.

3. A posting of names, addresses, and telephone numbers of all pertinent state client advocacy groups such as the state survey and certification agency, the state licensure office, the state ombudsman program, the protection and advocacy network, and the Medicaid fraud control unit.

4. A statement that the resident may file a complaint with the state survey and certification agency concerning resident abuse, neglect and misappropriation of resident property in the facility.

(8) The facility shall inform each resident of the name, specialty and way of contacting the physician responsible for the resident's care.

(9) The facility shall prominently display in the facility written information and provide to residents and applicants for admission oral and written information about how to apply for and use Medicare and Medicaid benefits, and how to receive refunds for previous payments covered by these benefits.

(10) Notification of changes.

1. A facility shall immediately inform the resident, consult with the resident's physician, and, if known, notify the resident's legal representative or an interested family member when there is an accident involving the resident which results in injury and has the potential for requiring physician intervention; a significant change in the resident's physical, mental, or psychosocial status (i.e., a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications); a need to alter treatment significantly (i.e., a need to discontinue an existing form of treatment due to adverse consequences, or to commence a new form of treatment); or a decision to transfer or discharge the resident from the facility.

2. The facility shall also promptly notify the resident and, if known, the resident's legal representative or interested family member when there is a change in room or roommate assignment or a change in resident rights under federal or state law or regulations.

3. The facility shall record and periodically update the address and telephone number of the resident's legal representative or interested family member.

c. Protection of resident funds.

(1) The resident has the right to manage the resident's financial affairs and the facility may not require residents to deposit their personal funds with the facility.

(2) Management of personal funds. Upon written authorization of a resident, the facility shall hold, safeguard, manage and account for the personal funds of the resident deposited with the facility, as specified in subparagraphs (3) to (8) of this paragraph.

(3) Deposit of funds. The facility shall deposit any residents' personal funds in excess of $50 in an interest-bearing account that is separate from any of the facility's operating accounts, and that credits all interest earned on the resident's funds to that account. In pooled accounts, there must be a separate accounting for each resident's share.

The facility shall maintain a resident's personal funds that do not exceed $50 in a non-interest-bearing account, an interest-bearing account, or petty cash fund.

(4) Accounting and records. The facility shall establish and maintain a system that ensures a full and complete and separate accounting, according to generally accepted accounting principles, of each resident's personal funds entrusted to the facility on the resident's behalf.

1. The system shall preclude any commingling of resident funds with facility funds or with the funds of any person other than another resident.

2. The individual financial record shall be available through quarterly statements and on request to the resident or the resident's legal representative.

(5) Notice of certain balances. The facility shall notify each resident that receives Medicaid benefits:

1. When the amount in the resident's account reaches $200 less than the SSI resource limit for one person.

2. That, if the amount in the account, in addition to the value of the resident's other nonexempt resources, reaches the SSI resource limit for one person, the resident may lose eligibility for Medicaid or SSI.

(6) Conveyance upon death. Upon the death of a resident with a personal fund deposited with the facility, the facility shall convey within 30 days the resident's funds, and a final accounting of those funds, to the individual or probate jurisdiction administering the resident's estate.

(7) Assurance of financial security. The facility shall purchase a surety bond, or otherwise provide assurance satisfactory to the department of inspections and appeals and the department of human services, to ensure the security of all personal funds of residents deposited with the facility.

(8) Limitation on charges to personal funds. The facility may not impose a charge against the personal funds of a resident for any item or service for which payment is made under Medicaid or Medicare.

d. *Free choice.* The resident has the right to:

(1) Choose a personal attending physician.

(2) Be fully informed in advance about care and treatment and of any changes in that care or treatment that may affect the resident's well-being.

(3) Unless adjudged incompetent or otherwise found to be incapacitated under the laws of the state, participate in planning care and treatment or changes in care and treatment.

e. *Privacy and confidentiality.* The resident has the right to personal privacy and confidentiality of personal and clinical records.

(1) Personal privacy includes accommodations, medical treatment, written and telephone communications, personal care, visits, and meetings of family and resident groups, but this does not require the facility to provide a private room.

(2) Except as provided in subparagraph (3) below, the resident may approve or refuse the release of personal and clinical records to any person outside the facility.

(3) The resident's right to refuse release of personal and clinical records does not apply when the resident is transferred to another health care institution or record release is required by law.

f. *Grievances.* A resident has the right to:

(1) Voice grievances without discrimination or reprisal for voicing the grievances. The grievances include those with respect to treatment which has been furnished as well as that which has not been furnished.

(2) Prompt efforts by the facility to resolve grievances the resident may have, including those with respect to the behavior of other residents.

g. *Examination of survey results.* A resident has the right to:

(1) Examine the results of the most recent survey of the facility conducted by federal or state surveyors and any plan of correction in effect with respect to the facility. The facility must make the results available for examination in a place readily accessible to residents, and must post a notice of their availability.

(2) Receive information from agencies acting as client advocates, and be afforded the opportunity to contact these agencies.

h. *Work.* The resident has the right to:

(1) Refuse to perform services for the facility.

(2) Perform services for the facility if the resident chooses, when:

1. The facility has documented the need or desire for work in the plan of care.

2. The plan specifies the nature of the services performed and whether the services are voluntary or paid.

3. Compensation for paid services is at or above prevailing rates.

4. The resident agrees to the work arrangement described in the plan of care.

5. Rescinded IAB 3/4/92, effective 4/8/92.

i. *Mail.* The resident has the right to privacy in written communications, including the right to send and receive mail promptly that is unopened and to have access to stationery, postage and writing implements at the resident's own expense.

j. *Access and visitation rights.*

(1) The resident has the right and the facility shall provide immediate access to any resident by the following:

1. Any representative of the secretary of the Department of Health and Human Services.
2. Any representative of the state.
3. The resident's individual physician.
4. The state long-term care ombudsman.
5. The agency responsible for the protection and advocacy system for developmentally disabled individuals.
6. The agency responsible for the protection and advocacy system for mentally ill individuals.
7. Immediate family or other relatives of the resident subject to the resident's right to deny or withdraw consent at any time.
8. Others who are visiting with the consent of the resident subject to reasonable restrictions and to the resident's right to deny or withdraw consent at any time.

(2) The facility shall provide reasonable access to any resident by any entity or individual that provides health, social, legal, or other services to the resident, subject to the resident's right to deny or withdraw consent at any time.

(3) The facility shall allow representatives of the state ombudsman to examine a resident's clinical records with the permission of the resident or the resident's legal representative, and consistent with state law.

k. *Telephone.* The resident has the right to have reasonable access to the use of a telephone where calls can be made without being overheard.

l. *Personal property.* The resident has the right to retain and use personal possessions, including some furnishings, and appropriate clothing, as space permits, unless to do so would infringe upon the rights or health and safety of other residents.

m. *Married couples.* The resident has the right to share a room with the resident's spouse when married residents live in the same facility and both spouses consent to the arrangement.

n. *Self-administration of drugs.* An individual resident has the right to self-administer drugs if the interdisciplinary team has determined that this practice is safe.

o. *Refusal of certain transfers.*

(1) A person has the right to refuse a transfer to another room within the institution, if the purpose of the transfer is to relocate a resident of a skilled nursing facility from the distinct part of the institution that is a skilled nursing facility to a part of the institution that is not a skilled nursing facility or, if a resident of a nursing facility, from the distinct part of the institution that is a nursing facility to a distinct part of the institution that is a skilled nursing facility.

(2) A resident's exercise of the right to refuse transfer under subparagraph (1) does not affect the resident's eligibility or entitlement to Medicare or Medicaid benefits.

p. *Advance directives.*

(1) The nursing facility, at the time of admission, shall provide written information to each resident which explains the resident's rights under state law to make decisions concerning medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate advance directives and the nursing facility's policies regarding the implementation of these rights.

(2) The nursing facility shall document in the resident's medical record whether or not the resident has executed an advance directive.

(3) The nursing facility shall not condition the provision of care or otherwise discriminate against a resident based on whether or not the resident has executed an advance directive.

(4) The nursing facility shall ensure compliance with requirements of state law regarding advance directives.

(5) The nursing facility shall provide for education for staff and the community on issues concerning advance directives.

Nothing in this paragraph shall be construed to prohibit the application of a state law which allows for an objection on the basis of conscience for any nursing facility which as a matter of conscience cannot implement an advance directive.

81.13(6) *Admission, transfer and discharge rights.*

a. *Transfer and discharge.*

(1) Definition: Transfer and discharge includes movement of a resident to a bed outside of the certified facility whether that bed is in the same physical plant or not. Transfer and discharge does not refer to movement of a resident to a bed within the same certified facility.

(2) Transfer or discharge requirements. The facility shall permit each resident to remain in the facility, and not transfer or discharge the resident from the facility unless:

1. The transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met in the facility.

2. The transfer or discharge is appropriate because the resident's health has improved sufficiently so the resident no longer needs the services provided by the facility.

3. The safety of persons in the facility is endangered.

4. The health of persons in the facility would otherwise be endangered.

5. The resident has failed, after reasonable and appropriate notice, to pay for (or to have paid under Medicare or Medicaid) a stay at the facility. For a resident who becomes eligible for Medicaid after admission to a facility, the facility may charge a resident only allowable charges under Medicaid.

6. The facility ceases to operate.

(3) Documentation. When the facility transfers or discharges a resident under any of the circumstances specified in subparagraph (2), numbers 1 through 5 above, the resident's clinical record shall be documented. The documentation shall be made by:

1. The resident's physician when transfer or discharge is necessary under subparagraph (2), number 1 or 2.

2. A physician when transfer or discharge is necessary under subparagraph (2), number 4.

(4) Notice before transfer. Before a facility transfers or discharges a resident, the facility shall:

1. Notify the resident and, if known, a family member or legal representative of the resident of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand.

2. Record the reasons in the resident's clinical record.

3. Include in the notice the items in subparagraph (6) below.

(5) Timing of the notice. The notice of transfer or discharge shall be made by the facility at least 30 days before the resident is transferred or discharged except that notice shall be made as soon as practicable before transfer or discharge when:

1. The safety of persons in the facility would be endangered.

2. The health of persons in the facility would be endangered.

3. The resident's health improves sufficiently to allow a more immediate transfer or discharge.

4. An immediate transfer or discharge is required by the resident's urgent medical needs.

5. A resident has not resided in the facility for 30 days.

(6) Contents of the notice. The written notice shall including the following:

1. The reason for transfer or discharge.

2. The effective date of transfer or discharge.

3. The location to which the resident is transferred or discharged.

4. A statement that the resident has the right to appeal the action to the department.

5. The name, address, and telephone number of the state long-term care ombudsman.

6. The mailing address and telephone number of the agency responsible for the protection and advocacy of developmentally disabled individuals for residents with developmental disabilities.

7. The mailing address and telephone number of the agency responsible for the protection and advocacy of mentally ill individuals for residents who are mentally ill.

(7) Orientation for transfer or discharge. A facility shall provide sufficient preparation and orientation to residents to ensure safe and orderly transfer or discharge from the facility.

b. Notice of bed-hold policy and readmission.

(1) Notice before transfer. Before a facility transfers a resident to a hospital or allows a resident to go on therapeutic leave, the facility shall provide written information to the resident and a family member or legal representative that specifies:

1. The duration of the bed-hold policy under the state plan during which the resident is permitted to return and resume residence in the facility.

2. The facility's policies regarding bed-hold periods, which shall be consistent with subparagraph (3) below, permitting a resident to return.

(2) Notice upon transfer. At the time of transfer of a resident to a hospital or for therapeutic leave, a nursing facility shall provide written notice to the resident and a family member or legal representative, which specifies the duration of the bed-hold policy described in subparagraph (1) above.

(3) Permitting resident to return to facility. A nursing facility shall establish and follow a written policy under which a resident, whose hospitalization or therapeutic leave exceeds the bed-hold period under the state plan, is readmitted to the facility immediately upon the first availability of a bed in a semiprivate room if the resident requires the services provided by the facility and is eligible for Medicaid nursing facility services.

c. Equal access to quality care.

(1) A facility shall establish and maintain identical policies and practices regarding transfer, discharge, and the provision of services under the state plan for all persons regardless of source of payment.

(2) The facility may charge any amount for services furnished to non-Medicaid residents consistent with the notice requirement in 81.13(1)*"a"*(5).

(3) The state is not required to offer additional services on behalf of a resident other than services provided in the state plan.

d. Admissions policy.

(1) The facility shall not require residents or potential residents to:

1. Waive their rights to Medicare or Medicaid; or

2. Give oral or written assurance that they are not eligible for, or will not apply for, Medicare or Medicaid benefits. However, a continuing care retirement community or a life care community that is licensed, registered, certified, or the equivalent by the state, including a nursing facility that is part of such a community, may require in its contract for admission that before a resident applies for medical assistance, the resources that the resident declared for the purposes of admission must be spent on the resident's care, subject to 441—subrule 75.5(3), 441—paragraph 75.5(4)*"a,"* and 441—subrule 75.16(2).

(2) The facility shall not require a third-party guarantee of payment to the facility as a condition of admission or expedited admission, or continued stay in the facility. However, the facility may require a person who has legal access to a resident's income or resources available to pay for facility care to sign a contract, without incurring personal financial liability, to provide facility payment from the resident's income or resources.

(3) In the case of a person eligible for Medicaid, a nursing facility must not charge, solicit, accept, or receive, in addition to any amount otherwise required to be paid under the state plan, any gift, money, donation, or other consideration as a precondition of admission, expedited admission or continued stay in the facility. However:

1. A nursing facility may charge a resident who is eligible for Medicaid for items and services the resident has requested and received, and that are not specified in the state plan as included in the term "nursing facility services" so long as the facility gives proper notice of the availability and cost of these services to residents and does not condition the resident's admission or continued stay on the request for and receipt of these additional services.

2. A nursing facility may solicit, accept, or receive a charitable, religious, or philanthropic contribution from an organization or from a person unrelated to a Medicaid-eligible resident or potential resident, but only to the extent that the contribution is not a condition of admission, expedited admission, or continued stay in the facility for a Medicaid-eligible resident.

(4) States or political subdivisions may apply stricter admission standards under state or local laws than are specified in these rules, to prohibit discrimination against persons entitled to Medicaid.

81.13(7) *Resident behavior and facility practices.*

a. Restraints. The resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience and not required to treat the resident's medical symptoms.

b. Abuse. The resident has the right to be free from verbal, sexual, physical, or mental abuse, corporal punishment, and involuntary seclusion.

c. Staff treatment of residents. The facility shall develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property.

*(1) Facility staff shall not use verbal, mental, sexual, or physical abuse, including corporal punishment, or involuntary seclusion of residents. The facility shall not employ persons who have been found guilty by a court of law of abusing, neglecting or mistreating residents or who have had a finding entered into the state nurse aide registry concerning abuse, neglect, mistreatment of residents or misappropriation of their property.

The facility shall report any knowledge it has of actions by a court of law against an employee, which would indicate unfitness for service as a nurse aide or other facility staff to the state nurse aide registry or licensing authorities.

*See Objection filed 8/25/92 published herein at end of 441—Chapter 81.

(2) The facility shall ensure that all alleged violations involving mistreatment, neglect or abuse including injuries of unknown source and misappropriation of resident property, are reported immediately to the administrator of the facility or to other officials (including the department of inspections and appeals) in accordance with state law through established procedures.

(3) The facility shall have evidence that all alleged violations are thoroughly investigated and shall prevent further potential abuse while the investigation is in progress.

(4) The results of all investigations conducted by facility staff shall be reported to the administrator or the administrator's designated representative or to other officials (including the department of inspections and appeals) in accordance with state law within five working days of the incident and if the alleged violation is verified, take appropriate corrective action.

81.13(8) *Quality of life.* A facility shall care for its residents in a manner and in an environment that promotes maintenance or enhancement of each resident's quality of life.

a. Dignity. The facility shall promote care for residents in a manner and in an environment that maintains or enhances each resident's dignity and respect in full recognition of the resident's individuality.

b. Self-determination and participation. The resident has the right to:

(1) Choose activities, schedules, and health care consistent with the resident's interests, assessments and plans of care.

(2) Interact with members of the community both inside and outside the facility.

(3) Make choices about aspects of life in the facility that are significant to the resident.

c. Participation in resident and family groups.

(1) A resident has the right to organize and participate in resident groups in the facility.

(2) A resident's family has the right to meet in the facility with the families of other residents in the facility.

(3) The facility shall provide a resident or family group, if one exists, with private space.

(4) Staff or visitors may attend meetings at the group's invitation.

(5) The facility shall provide a designated staff person responsible for providing assistance and responding to written requests that result from group meetings.

(6) When a resident or family group exists, the facility shall listen to the views and act upon the grievances and recommendations of residents and families concerning proposed policy and operational decisions affecting resident care and life in the facility.

d. Participation in other activities. A resident has the right to participate in social, religious, and community activities that do not interfere with the rights of other residents in the facility.

e. Accommodation of needs. A resident has the right to:

(1) Reside and receive services in the facility with reasonable accommodation of individual needs and preferences, except when the health or safety of the individual or other residents would be endangered.

(2) Receive notice before the resident's room or roommate in the facility is changed.

f. *Activities.*

(1) The facility shall provide for an ongoing program of activities designed to meet, in accordance with the comprehensive assessment, the interests and the physical, mental, and psychosocial well-being of each resident.

(2) The activities program shall be directed by a qualified professional who meets one of the following criteria:

1. Is a qualified therapeutic recreation specialist or an activities professional who is eligible for certification as a therapeutic recreation specialist or as an activities professional by a recognized accrediting body on or after October 1, 1990.

2. Has two years of experience in a social or recreational program within the last five years, one of which was full-time in a patient activities program in a health care setting.

3. Is a qualified occupational therapist or occupational therapy assistant.

4. Has completed a training course approved by the state.

g. *Social services.*

(1) The facility shall provide medically related social services to attain or maintain the highest practicable physical, mental, or psychosocial well-being of each resident.

(2) A facility with more than 120 beds shall employ a qualified social worker on a full-time basis.

(3) Qualifications of social worker. A qualified social worker is a person who meets both of the following criteria:

1. A bachelor's degree in social work or a bachelor's degree in a human services field including, but not limited to, sociology, special education, rehabilitation, counseling and psychology.

2. One year of supervised social work experience in a health care setting working directly with individuals.

h. *Environment.* The facility shall provide:

(1) A safe, clean, comfortable and homelike environment, allowing the resident to use personal belongings to the extent possible.

(2) Housekeeping and maintenance services necessary to maintain a sanitary, orderly and comfortable interior.

(3) Clean bed and bath linens that are in good condition.

(4) Private closet space in each resident room.

(5) Adequate and comfortable lighting levels in all areas.

(6) Comfortable and safe temperature levels. Facilities initially certified after October 1, 1990, shall maintain a temperature range of 71 to 81 degrees Fahrenheit.

(7) For the maintenance of comfortable sound levels.

81.13(9) *Resident assessment.* The facility shall conduct initially and periodically a comprehensive, accurate, standardized, reproducible assessment of each resident's functional ability.

a. *Admission orders.* At the time each resident is admitted, the facility shall have physician orders for the resident's immediate care.

b. *Comprehensive assessments.*

(1) The facility shall make a comprehensive assessment of a resident's needs which is based on the minimum data set (MDS) specified by the department of inspections and appeals, which describes the resident's capability to perform daily life functions and significant impairments in functional capacity.

(2) The assessment process shall include direct observation and communication with the resident, as well as communication with licensed and nonlicensed direct care staff members on all shifts. The comprehensive assessment shall include at least the following information:

1. Identification and demographic information.

2. Customary routine.

3. Cognitive patterns.

4. Communication.
5. Vision.
6. Mood and behavior patterns.
7. Psychosocial well-being.
8. Physical functioning and structural problems.
9. Continence.
10. Disease diagnoses and health conditions.
11. Dental and nutritional status.
12. Skin condition.
13. Activity pursuit.
14. Medications.
15. Special treatments and procedures.
16. Discharge potential.
17. Documentation of summary information regarding the additional assessment performed through the resident assessment protocols.
18. Documentation of participation in assessment.
19. Additional specification relating to resident status as required in Section S of the MDS.

(3) Frequency. Assessments shall be conducted:

1. Within 14 calendar days after admission or readmission, excluding readmissions in which there is no significant change in the resident's physical or mental condition. "Readmission" means a return to the facility following a temporary absence for hospitalization or for therapeutic leave.

2. Within 14 calendar days after the facility determines, or should have determined, that there has been a significant change in the resident's physical or mental condition. A "significant change" means a major decline or improvement in the resident's status that will not normally resolve itself without further intervention by staff or by implementing standard disease-related clinical interventions, that has an impact on more than one area of the resident's health status, and that requires either interdisciplinary review, revision of the care plan, or both.

3. In no case less often than once every 12 months.

(4) Review of assessments. The facility shall examine each resident no less than once every three months, and as appropriate, revise the resident's assessment to ensure the continued accuracy of the assessment.

(5) Maintenance and use. A facility shall maintain all resident assessments completed within the previous 15 months in the resident's active record and use the results to develop, review and revise the resident's comprehensive plan of care.

(6) Coordination. The facility shall coordinate assessments with any state-required preadmission screening program to the maximum extent practicable to avoid duplicative testing and effort.

(7) Automated data processing requirement.

1. Entering data. Within seven days after a facility completes a resident's assessment, a facility shall enter the following information for the resident into a computerized format that meets the specifications defined in numbered paragraphs "2" and "4" below.

- Admission assessment.
- Annual assessment updates.
- Significant change in status assessments.
- Quarterly review assessments.
- A subset of items upon a resident's transfer, reentry, discharge, and death.
- Background (face sheet) information, if there is no admission assessment.

2. Transmitting data. Within seven days after a facility completes a resident's assessment, a facility shall be capable of transmitting to the state each resident's assessment information contained in the MDS in a format that conforms to standard record layouts and data dictionaries and that passes edits that ensure accurate and consistent coding of the MDS data as defined by the Centers for Medicare and Medicaid Services (CMS) and the department of human services or the department of inspections and appeals.

3. Monthly transmittal requirements. On at least a monthly basis, a facility shall input and electronically transmit accurate and complete MDS data for all assessments conducted during the previous month, including the following:

- Admission assessment.
- Annual assessment.
- Significant correction of prior full assessment.
- Significant correction of prior quarterly assessment.
- Quarterly review.
- A subset of items upon a resident's transfer, reentry, discharge, and death.
- Background (face sheet) information, for an initial transmission of MDS data on a resident who does not have an admission assessment.

4. The facility must transmit MDS data in the ASCII format specified by CMS.

(8) Resident-identifiable information. A facility shall not release information that is resident-identifiable to the public. The facility may release information that is resident-identifiable to an agent only in accordance with a contract under which the agent agrees not to use or disclose the information except to the extent the facility itself is permitted to do so.

c. Accuracy of assessments. The assessment shall accurately reflect the resident's status.

(1) Coordination. Each assessment shall be conducted or coordinated with the appropriate participation of health professionals. Each assessment shall be conducted or coordinated by a registered nurse.

(2) Certification. Each person who completes a portion of the assessment shall sign and certify the accuracy of that portion of the assessment. A registered nurse shall sign and certify that the assessment is completed.

(3) Penalty for falsification. An individual who willfully and knowingly certifies a material and false statement in a resident assessment is subject to a civil money penalty of not more than $1,000 for each assessment. An individual who willfully and knowingly causes another individual to certify a material and false statement in a resident assessment is subject to a civil money penalty of not more than $5,000 for each assessment.

Clinical disagreement does not constitute a material and false statement.

(4) Use of independent assessors. If the department of human services or the department of inspections and appeals determines, under a survey or otherwise, that there has been a knowing and willful certification of false statements under subparagraph (3) above, the department of human services or the department of inspections and appeals may require that resident assessments under this paragraph be conducted and certified by individuals who are independent of the facility and who are approved by the department of human services or the department of inspections and appeals for a period specified by the agency.

d. Comprehensive care plans.

(1) The facility shall develop a comprehensive care plan for each resident that includes measurable objectives and timetables to meet a resident's medical, nursing, and mental and psychosocial needs that are identified in the comprehensive assessment.

The care plan shall describe the following:

1. The services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being as required under subrule 81.13(10).

2. Any services that would otherwise be required under subrule 81.13(10), but are not provided due to the resident's exercise of rights under subrule 81.13(5), including the right to refuse treatment under subrule 81.13(5), paragraph *"b,"* subparagraph (4).

(2) A comprehensive care plan shall be developed within seven days after completion of the comprehensive assessment by an interdisciplinary team and with the participation of the resident, the resident's family or legal representative to the extent practicable, and shall be periodically reviewed and revised by a team of qualified persons after each assessment.

The interdisciplinary team shall include the attending physician, a registered nurse with responsibility for the resident, and other appropriate staff in disciplines as determined by the resident's needs.

(3) The services provided or arranged by the facility shall meet professional standards of quality and be provided by qualified persons in accordance with each resident's written plan of care.

e. Discharge summary. When the facility anticipates discharges, a resident shall have a discharge summary that includes:

(1) A recapitulation of the resident's stay.

(2) A final summary of the resident's status to include items in paragraph *"b,"* subparagraph (2) above, at the time of the discharge that is available for release to authorized persons and agencies, with the consent of the resident or legal representative.

(3) A postdischarge plan of care developed with the participation of the resident and resident's family which will assist the resident to adjust to a new living environment.

f. Preadmission screening for mentally ill individuals and individuals with mental retardation.

(1) A nursing facility shall not admit a new resident with mental illness or mental retardation unless the division of mental health and disability services has approved the admission, based on an independent physical and mental health evaluation. This evaluation shall be reviewed by the IME medical services unit before admission to determine whether the individual requires the level of services provided by the facility because of the physical and mental condition of the individual. If the individual requires nursing facility level of services, the individual shall receive specialized services for mental illness or mental retardation.

(2) Definition. For purposes of this rule:

1. An individual is considered to have "mental illness" if the individual has a primary or secondary diagnosis of mental disorder (as defined in the Diagnostic and Statistical Manual of Mental Disorders, 3rd edition) and does not have a primary diagnosis of dementia (including Alzheimer's disease or a related disorder).

2. An individual is considered to be "mentally retarded" if the individual is mentally retarded or a person with a related condition as described in 42 CFR 435.1009.

g. Preadmission resident assessment. The facility shall conduct prior to admission a resident assessment of all persons seeking nursing facility placement. The assessment information gathered shall be similar to the data in the minimum data set (MDS) resident assessment tool.

81.13(10) *Quality of care.* Each resident shall receive and the facility shall provide the necessary care and services to attain or maintain the highest practicable physical, mental and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

a. Activities of daily living. Based on the comprehensive assessment of a resident, the facility shall ensure that:

(1) A resident's abilities in activities of daily living do not diminish unless circumstances of the individual's clinical condition demonstrate that diminution was unavoidable. This includes the resident's ability to bathe, dress and groom; transfer and ambulate; toilet; eat, and to use speech, language or other functional communication systems.

(2) A resident is given the appropriate treatment and services to maintain or improve the resident's abilities specified in subparagraph (1) above.

(3) A resident who is unable to carry out activities of daily living receives the necessary services to maintain good nutrition, grooming, and personal and oral hygiene.

b. Vision and hearing. To ensure that residents receive proper treatment and assistive devices to maintain vision and hearing abilities, the facility shall, if necessary, assist the resident:

(1) In making appointments.

(2) By arranging for transportation to and from the office of a medical practitioner specializing in the treatment of vision or hearing impairment or the office of a professional specializing in the provision of vision or hearing assistive devices.

c. Pressure sores. Based on the comprehensive assessment of a resident, the facility shall ensure that:

(1) A resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable.

(2) A resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing.

d. *Urinary incontinence.* Based on the resident's comprehensive assessment, the facility shall ensure that:

(1) A resident who enters the facility without an indwelling catheter is not catheterized unless the resident's clinical condition demonstrates that catheterization was necessary.

(2) A resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infections and to restore as much normal bladder function as possible.

e. *Range of motion.* Based on the comprehensive assessment of a resident, the facility shall ensure that:

(1) A resident who enters the facility without a limited range of motion does not experience reduction in range of motion unless the resident's clinical condition demonstrates that a reduction in range of motion is unavoidable.

(2) A resident with a limited range of motion receives appropriate treatment and services to increase range of motion to prevent further decrease in range of motion.

f. *Mental and psychosocial functioning.* Based on the comprehensive assessment of a resident, the facility shall ensure that:

(1) A resident who displays mental or psychosocial adjustment difficulty receives appropriate treatment and services to correct the assessed problem.

(2) A resident whose assessment did not reveal a mental or psychosocial adjustment difficulty does not display a pattern of decreased social interaction or increased withdrawn, angry or depressive behaviors, unless the resident's clinical condition demonstrates that such a pattern was unavoidable.

g. *Naso-gastric tubes.* Based on the comprehensive assessment of a resident, the facility shall ensure that:

(1) A resident who has been able to eat enough alone or with assistance is not fed by naso-gastric tube unless the resident's clinical condition demonstrates that use of a naso-gastric tube was unavoidable.

(2) A resident who is fed by a naso-gastric or gastrostomy tube receives the appropriate treatment and services to prevent aspiration pneumonia, diarrhea, vomiting, dehydration, metabolic abnormalities, and nasalpharyngeal ulcers and to restore, if possible, normal eating skills.

h. *Accidents.* The facility shall ensure that:

(1) The resident environment remains as free of accident hazards as is possible.

(2) Each resident receives adequate supervision and assistive devices to prevent accidents.

i. *Nutrition.* Based on a resident's comprehensive assessment, the facility shall ensure that a resident:

(1) Maintains acceptable parameters of nutritional status, such as body weight and protein levels, unless the resident's clinical condition demonstrates that this is not possible.

(2) Receives a therapeutic diet when there is a nutritional problem.

j. *Hydration.* The facility shall provide each resident with sufficient fluid intake to maintain proper hydration and health.

k. *Special needs.* The facility shall ensure that residents receive proper treatment and care for the following special services:

(1) Injections.

(2) Parenteral and enteral fluids.

(3) Colostomy, ureterostomy or ileostomy care.

(4) Tracheostomy care.

(5) Tracheal suctioning.

(6) Respiratory care.

(7) Foot care.

(8) Prostheses.

l. *Unnecessary drugs.*

(1) General. Each resident's drug regimen shall be free from unnecessary drugs. An unnecessary drug is any drug when used:

1. In excessive dose including duplicate drug therapy; or
2. For excessive duration; or
3. Without adequate monitoring; or
4. Without adequate indications for its use; or
5. In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or
6. Any combinations of the reasons above.

(2) Antipsychotic drugs. Based on a comprehensive assessment of a resident, the facility shall ensure that:

1. Residents who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record.
2. Residents who use antipsychotic drugs receive gradual dose reductions and behavioral programming, unless clinically contraindicated in an effort to discontinue these drugs.

m. Medication errors. The facility shall ensure that:

(1) It is free of significant medication error rates of 5 percent or greater.

(2) Residents are free of any significant medication errors.

81.13(11) *Nursing services.* The facility shall have sufficient nursing staff to provide nursing and related services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care.

a. Sufficient staff.

(1) The facility shall provide services by sufficient numbers of each of the following types of personnel on a 24-hour basis to provide nursing care to all residents in accordance with resident care plans:

1. Except when waived under paragraph *"c,"* licensed nurses.
2. Other nursing personnel.

(2) Except when waived under paragraph *"c,"* the facility shall designate a licensed nurse to serve as a charge nurse on each tour of duty.

b. Registered nurse.

(1) Except when waived under paragraph *"c,"* the facility shall use the services of a registered nurse for at least eight consecutive hours a day, seven days a week.

(2) Except when waived under paragraph *"c,"* the facility shall designate a registered nurse to serve as the director of nursing on a full-time basis.

(3) The director of nursing may serve as a charge nurse only when the facility has an average daily occupancy of 60 or fewer residents.

c. Nursing facilities. Waiver of requirement to provide licensed nurses on a 24-hour basis. A facility may request a waiver from either the requirement that a nursing facility provide a registered nurse for at least eight consecutive hours a day, seven days a week, as specified in paragraph *"b,"* or the requirement that a nursing facility provide licensed nurses on a 24-hour basis, including a charge nurse as specified in paragraph *"a,"* if the following conditions are met:

(1) The facility demonstrates to the satisfaction of the state that the facility has been unable, despite diligent efforts (including offering wages at the community prevailing rate for nursing facilities), to recruit appropriate personnel.

(2) The department of inspections and appeals determines that a waiver of the requirement will not endanger the health or safety of individuals staying in the facility.

(3) The department of inspections and appeals finds that, for any periods in which licensed nursing services are not available, a registered nurse or a physician is obligated to respond immediately to telephone calls from the facility.

(4) A waiver granted under the conditions listed in paragraph *"c"* is subject to annual department of inspections and appeals review.

(5) In granting or renewing a waiver, a facility may be required by the department of inspections and appeals to use other qualified, licensed personnel.

(6) The department of inspections and appeals shall provide notice of a waiver granted under this paragraph to the state long-term care ombudsman established under Section 307(a)(12) of the Older Americans Act of 1965 and the protection and advocacy system in the state for the mentally ill and mentally retarded.

(7) The nursing facility that is granted a waiver under this paragraph shall notify residents of the facility or, where appropriate, the guardians or legal representatives of the residents and members of their immediate families of the waiver.

81.13(12) *Dietary services.* The facility shall provide each resident with a nourishing, palatable, well-balanced diet that meets the daily nutritional and special dietary needs of each resident.

a. Staffing. The facility shall employ a qualified dietitian either full-time, part-time or on a consultant basis.

(1) If a qualified dietitian is not employed full-time, the facility shall designate a person to serve as the director of food services who receives frequently scheduled consultation from a qualified dietitian.

(2) A qualified dietitian is one who is licensed by the state according to Iowa Code chapter 152A.

b. Sufficient staff. The facility shall employ sufficient support personnel competent to carry out the functions of the dietary service.

c. Menus and nutritional adequacy. Menus shall:

(1) Meet the nutritional needs of residents in accordance with the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences.

(2) Be prepared in advance.

(3) Be followed.

d. Food. Each resident receives and the facility provides:

(1) Food prepared by methods that conserve nutritive value, flavor and appearances.

(2) Food that is palatable, attractive and at the proper temperature.

(3) Food prepared in a form designed to meet individual needs.

(4) Substitutes offered of similar nutritive value to residents who refuse food served.

e. Therapeutic diets. Therapeutic diets shall be prescribed by the attending physician.

f. Frequency of meals.

(1) Each resident receives and the facility provides at least three meals daily, at regular times comparable to normal mealtimes in the community.

(2) There shall be no more than 14 hours between a substantial evening meal and breakfast the following day, except as provided in subparagraph (4) below.

(3) The facility shall offer snacks at bedtime daily.

(4) When a nourishing snack is provided at bedtime, up to 16 hours may elapse between a substantial evening meal and breakfast the following day if a resident group agrees to this meal span.

g. Assistive devices. The facility shall provide special eating equipment and utensils for residents who need them.

h. Sanitary conditions. The facility shall:

(1) Procure food from sources approved or considered satisfactory by federal, state or local authorities.

(2) Store, prepare, distribute and serve food under sanitary conditions.

(3) Dispose of garbage and refuse properly.

81.13(13) *Physician services.* A physician shall personally approve in writing a recommendation that an individual be admitted to a facility. Each resident shall remain under the care of a physician.

a. Physician supervision. The facility shall ensure that:

(1) The medical care of each resident is supervised by a physician.

(2) Another physician supervises the medical care of residents when their attending physician is unavailable.

b. Physician visits. The physician shall:

(1) Review the resident's total program of care, including medications and treatments, at each visit required by paragraph *"c"* below.

(2) Write, sign and date progress notes at each visit.

(3) Sign and date all orders.

c. *Frequency of physician visits.*

(1) The resident shall be seen by a physician at least once every 30 days for the first 90 days after admission, and at least once every 60 days thereafter.

(2) A physician visit is considered timely if it occurs not later than ten days after the date the visit was required.

(3) Except as provided in paragraph *"e,"* all required physician visits shall be made by the physician personally.

d. *Availability of physicians for emergency care.* The facility shall provide or arrange for the provision of physician services 24 hours a day, in case of an emergency.

e. *Performance of physician tasks in nursing facilities.* Any required physician task in a nursing facility (including tasks which the rules specify must be performed personally by the physician) may also be satisfied when performed by a nurse practitioner, clinical nurse specialist, or physician assistant who is not an employee of the facility, but who is working in collaboration with a physician except where prohibited by state law.

81.13(14) *Specialized rehabilitative services.*

a. *Provision of services.* If specialized rehabilitative services such as, but not limited to, physical therapy, speech-language pathology, occupational therapy, and mental health rehabilitative services for mental illness and mental retardation, are required in the resident's comprehensive plan of care, the facility shall:

(1) Provide the required services; or

(2) Obtain the required services from an outside provider of specialized rehabilitative services.

b. *Qualifications.* Specialized rehabilitative services shall be provided under the written order of a physician by qualified personnel.

81.13(15) *Dental services.* The facility shall assist residents in obtaining routine and 24-hour emergency dental care. The facility shall:

a. Provide or obtain from an outside resource the following dental services to meet the needs of each resident:

(1) Routine dental services to the extent covered under the state plan.

(2) Emergency dental services.

b. If necessary, assist the resident in making appointments; and by arranging for transportation to and from the dentist's office.

c. Promptly refer residents with lost or damaged dentures to a dentist.

81.13(16) *Pharmacy services.* The facility shall provide routine and emergency drugs and biologicals to its residents or obtain them under an agreement. The nursing facility may permit a certified medication aide to administer drugs, but only under the general supervision of a licensed nurse.

a. *Procedures.* A facility shall provide pharmaceutical services (including procedures that ensure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident.

b. *Service consultation.* The facility shall employ or obtain the services of a licensed pharmacist who:

(1) Provides consultation on all aspects of the provision of pharmacy services in the facility.

(2) Establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation.

(3) Determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.

c. *Drug regimen review.*

(1) The drug regimen of each resident shall be reviewed at least once a month by a licensed pharmacist.

(2) The pharmacist shall report any irregularities to the attending physician and the director of nursing, and these reports shall be acted upon.

d. Labeling of drugs and biologicals. Drugs and biologicals used in the facility shall be labeled in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, and the expiration date when applicable.

e. Storage of drugs and biologicals.

(1) In accordance with state and federal laws, the facility shall store all drugs and biologicals in locked compartments under proper temperature controls and permit only authorized personnel to have access to the keys.

(2) The facility shall provide separately locked, permanently affixed compartments for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse, except when the facility uses single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.

f. Consultant pharmacists. When the facility does not employ a licensed pharmacist, it shall have formal arrangements with a licensed pharmacist to provide consultation on methods and procedures for ordering, storage, administration and disposal and record keeping of drugs and biologicals. The formal arrangements with the licensed pharmacist shall include separate written contracts for pharmaceutical vendor services and consultant pharmacist services. The consultant's visits are scheduled to be of sufficient duration and at a time convenient to work with nursing staff on the resident care plan, consult with the administrator and others on developing and implementing policies and procedures, and planning in-service training and staff development for employees. The consultant shall provide monthly drug regimen review reports. The facility shall provide reimbursement for consultant pharmacists based on fair market value. Documentation of consultation shall be available for review in the facility.

81.13(17) *Infection control.* The facility shall establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment in which residents reside and to help prevent the development and transmission of disease and infection.

a. Infection control program. The facility shall establish an infection control program under which it:

(1) Investigates, controls and prevents infections in the facility.

(2) Decides what procedures, such as isolation, should be applied to an individual resident.

(3) Maintains a record of incidents and corrective actions related to infections.

b. Preventing spread of infection.

(1) When the infection control program determines that a resident needs isolation to prevent the spread of infection, the facility shall isolate the resident.

(2) The facility shall prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease.

(3) The facility shall require staff to wash their hands after each direct resident contact for which handwashing is indicated by accepted professional practice.

c. Linens. Personnel shall handle, store, process, and transport linens so as to prevent the spread of infection.

81.13(18) *Physical environment.* The facility shall be designed, constructed, equipped and maintained to protect the health and safety of residents, personnel and the public.

a. Life safety from fire. Except as provided in subparagraph (1) or (3) below, the facility shall meet the applicable provisions of the 1985 edition of the Life Safety Code of the National Fire Protection Association.

(1) A facility is considered to be in compliance with this requirement as long as the facility:

1. On November 26, 1982, complied with or without waivers with the requirements of the 1967 or 1973 editions of the Life Safety Code and continues to remain in compliance with those editions of the code; or

2. On May 9, 1988, complied, with or without waivers, with the 1981 edition of the Life Safety Code and continues to remain in compliance with that edition of the Code.

(2) When Medicaid nursing facilities and Medicaid distinct part nursing facility providers request a waiver of Life Safety Code requirements in accordance with Subsection 1919(d)(2)(B)(i) of the Social Security Act, the department of inspections and appeals shall forward the requests to the Centers for Medicare and Medicaid Services Regional Office for review and approval.

(3) The provisions of the Life Safety Code do not apply in a state where the Centers for Medicare and Medicaid Services finds that a fire and safety code imposed by state law adequately protects patients, residents and personnel in long-term care facilities.

b. Emergency power.

(1) An emergency electrical power system shall supply power adequate at least for lighting all entrances and exits, equipment to maintain the fire detection, alarm and extinguishing systems, and life support systems in the event the normal electrical supply is interrupted.

(2) When life support systems are used that have no nonelectrical backup, the facility shall provide emergency electrical power with an emergency generator, as defined in NFPA 99, Health Care Facilities, that is located on the premises.

c. Space and equipment. The facility shall:

(1) Provide sufficient space and equipment in dining, health services, recreation, and program areas to enable staff to provide residents with needed services as required by these standards and as identified in each resident's plan of care.

(2) Maintain all essential mechanical, electrical, and patient care equipment in safe operating condition.

d. Resident rooms. Resident rooms shall be designed and equipped for adequate nursing care, comfort and privacy of residents.

(1) Bedrooms shall:

1. Accommodate no more than four residents.
2. Measure at least 80 square feet per resident in multiple resident bedrooms, and at least 100 square feet in single resident rooms.
3. Have direct access to an exit corridor.
4. Be designed or equipped to ensure full visual privacy for each resident.
5. In facilities initially certified after March 31, 1992, except in private rooms, each bed shall have ceiling-suspended curtains, which extend around the bed to provide total visual privacy, in combination with adjacent walls and curtains.
6. Have at least one window to the outside.
7. Have a floor at or above grade level.

(2) The facility shall provide each resident with:

1. A separate bed of proper size and height for the convenience of the resident.
2. A clean, comfortable mattress.
3. Bedding appropriate to the weather and climate.
4. Functional furniture appropriate to the resident's needs and individual closet space in the resident's bedroom with clothes racks and shelves accessible to the resident.

(3) The department of inspections and appeals may permit variations in requirements specified in paragraph *"d,"* subparagraph (1), numbers 1 and 2 above relating to rooms in individual cases when the facility demonstrates in writing that the variations are required by the special needs of the residents and will not adversely affect residents' health and safety.

e. Toilet facilities. Each resident room shall be equipped with or located adjacent to toilet facilities unless a waiver is granted by the department of inspections and appeals. Additionally, each resident room shall be equipped with or located adjacent to bathing facilities.

f. Resident call system. The nurse's station shall be equipped to receive resident calls through a communication system from:

(1) Resident rooms.

(2) Toilet and bathing facilities.

g. Dining and resident activities. The facility shall provide one or more rooms designated for resident dining and activities. These rooms shall:

(1) Be well lighted.

(2) Be well ventilated, with nonsmoking areas identified.

(3) Be adequately furnished.

(4) Have sufficient space to accommodate all activities.

h. Other environmental conditions. The facility shall provide a safe, functional, sanitary and comfortable environment for residents, staff and the public. The facility shall:

(1) Establish procedures to ensure that water is available to essential areas when there is a loss of normal water supply.

(2) Have adequate outside ventilation by means of windows or mechanical ventilation or a combination of the two.

(3) Equip corridors with firmly secured handrails on each side.

(4) Maintain an effective pest control program so that the facility is free of pests and rodents.

81.13(19) *Administration.* A facility shall be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident.

a. Licensure. A facility shall be licensed under applicable state and federal law.

b. Compliance with federal, state and local laws and professional standards. The facility shall operate and provide services in compliance with all applicable federal, state, and local laws, regulations and codes, and with accepted professional standards and principles that apply to professionals providing services in such a facility.

c. Relationship to other Department of Health and Human Services (HHS) regulations. In addition to compliance with these rules, facilities shall meet the applicable provisions of other HHS regulations, including, but not limited to, those pertaining to nondiscrimination on the basis of race, color, or national origin, nondiscrimination on the basis of handicap, nondiscrimination on the basis of age, protection of human subjects of research, and fraud and abuse. Although these regulations are not in themselves considered requirements under these rules, their violation may result in the termination or suspension of, or the refusal to grant or continue payment with federal funds.

d. Governing body.

(1) The facility shall have a governing body, or designated persons functioning as a governing body, that is legally responsible for establishing and implementing policies regarding the management and operation of the facility.

(2) The governing body appoints the administrator who is:

1. Licensed by the state.

2. Responsible for management of the facility.

e. Required training of nurse aides.

(1) Definitions.

"Licensed health professional" means a physician; physician assistant; nurse practitioner; physical, speech or occupational therapist; registered professional nurse; licensed practical nurse; or licensed or certified social worker.

"Nurse aide" means any person providing nursing or nursing-related services to residents in a facility who is not a licensed health professional, a registered dietitian, or someone who volunteers to provide these services without pay.

(2) General rule. A facility shall not use any person working in the facility as a nurse aide for more than four months, on a permanent basis, unless:

1. That person is competent to provide nursing and nursing-related services.

2. That person has completed a training and competency evaluation program or a competency evaluation program approved by the department of inspections and appeals; or that person has been deemed or determined competent by the department of inspections and appeals.

(3) Nonpermanent employees. A facility shall not use on a temporary, per diem, leased, or any basis other than a permanent employee any person who does not meet the requirements in subparagraph (2).

(4) Competency. A facility shall not use any person who has worked less than four months as a nurse aide in that facility unless the person:

1. Is a permanent employee and is in a nurse aide training and competency evaluation program approved by the department of inspections and appeals;

2. Has demonstrated competence through satisfactory participation in a nurse aide training and competency evaluation program or competency evaluation program approved by the department of inspections and appeals; or

3. Has been deemed or determined competent by the department of inspections and appeals.

(5) Registry verification. Before allowing a person to serve as a nurse aide, a facility shall receive registry verification that the person has met competency evaluation requirements unless:

1. The person is a permanent employee and is in a training and competency evaluation program approved by the department of inspections and appeals; or

2. The person can prove that the person has recently successfully completed a training and competency evaluation program or competency evaluation program approved by the department of inspections and appeals and has not yet been included in the registry. Facilities shall follow up to ensure that such a person actually becomes registered.

(6) Multistate registry verification. Before allowing a person to serve as a nurse aide, a facility shall seek information from every state registry the facility believes will include information on the person.

(7) Required retraining. If since October 1, 1990, there has been a continuous period of 24 consecutive months during none of which the person provided nursing or nursing-related services for monetary compensation, the person shall complete a new training and competency evaluation program or a new competency evaluation program.

(8) Regular in-service education. The facility shall complete a performance review of every nurse aide at least once every 12 months and shall provide regular in-service education based on the outcome of these reviews. The in-service training shall:

1. Be sufficient to ensure the continuing competencies of nurse aides, but shall be no less than 12 hours per year.

2. Address areas of weakness as determined in nurse aides' performance reviews and may address the special needs of residents as determined by the facility staff.

3. For nurse aides providing services to persons with cognitive impairments, also address the care of the cognitively impaired.

f. *Proficiency of nurse aides.* The facility shall ensure that nurse aides are able to demonstrate competency in skills and technique necessary to care for residents' needs, as identified through resident assessments, and described in the plan of care.

g. *Staff qualifications.*

(1) The facility shall employ on a full-time, part-time, or consultant basis those professionals necessary to carry out the provisions of these conditions of participation.

(2) Professional staff shall be licensed, certified or registered in accordance with applicable state laws.

h. *Use of outside resources.*

(1) If the facility does not employ a qualified professional person to furnish a specific service to be provided by the facility, the facility shall have that service furnished to residents by a person or agency outside the facility under an arrangement described in Section 1861(w) of the Omnibus Budget Reconciliation Act of 1987 or an agreement described in subparagraph (2) below.

(2) Arrangements or agreements pertaining to services furnished by outside resources shall specify in writing that the facility assumes responsibility for obtaining services that meet professional standards and principles that apply to professionals providing services in such a facility and for the timeliness of the services.

i. *Medical director.*

(1) The facility shall designate a physician to serve as medical director.

(2) The medical director is responsible for implementation of resident care policies and the coordination of medical care in the facility.

j. Laboratory services.

(1) The facility shall provide or obtain clinical laboratory services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.

1. If the facility provides its own laboratory services, the services shall meet the applicable conditions for coverage of the services furnished by laboratories specified in 42 CFR Part 493 as amended to October 1, 1990.

2. If the facility provides blood bank and transfusion services, it shall meet the requirements for laboratories specified in 42 CFR Part 493 as amended to October 1, 1990.

3. If the laboratory chooses to refer specimens for testing to another laboratory, the referral laboratory shall be approved or licensed to test specimens in the appropriate specialties or subspecialties of service in accordance with 42 CFR Part 493 as amended to October 1, 1990.

4. If the facility does not provide laboratory services on site, it shall have an agreement to obtain these services only from a laboratory that meets the requirements of 42 CFR Part 493 as amended to October 1, 1990, or from a physician's office.

(2) The facility shall:

1. Provide or obtain laboratory services only when ordered by the attending physician.

2. Promptly notify the attending physician of the findings.

3. Assist the resident in making transportation arrangements to and from the source of service, if the resident needs assistance.

4. File in the resident's clinical record signed and dated reports of clinical laboratory services.

k. Radiology and other diagnostic services.

(1) The facility shall provide or obtain radiology and other diagnostic services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.

1. If the facility provides its own diagnostic services, the services shall meet the applicable conditions of participation for hospitals.

2. If the facility does not provide its own diagnostic services, it shall have an agreement to obtain these services from a provider or supplier that is approved to provide these services under Medicare.

(2) The facility shall:

1. Provide or obtain radiology and other diagnostic services only when ordered by the attending physician.

2. Promptly notify the attending physician of the findings.

3. Assist the resident in making transportation arrangements to and from the source of service, if the resident needs assistance.

4. File in the resident's clinical record signed and dated reports of X-ray and other diagnostic services.

l. Clinical records.

(1) The facility shall maintain clinical records on each resident in accordance with accepted professional standards and practices that are complete, accurately documented, readily accessible, and systematically organized.

(2) Clinical records shall be retained for:

1. The period of time required by state law.

2. Five years from the date of discharge when there is no requirement in state law.

3. For a minor, three years after a resident reaches legal age under state law.

(3) The facility shall safeguard clinical record information against loss, destruction, or unauthorized use.

(4) The facility shall keep confidential all information contained in the resident's records, regardless of the form or storage method of the records, except when release is required by:

1. Transfer to another health care institution.

2. Law.

3. Third-party payment contract.

4. The resident.

(5) The clinical record shall contain:

1. Sufficient information to identify the resident.
2. A record of the resident's assessments.
3. The plan of care and services provided.
4. The results of any preadmission screening conducted by the state.
5. Progress notes.

m. Disaster and emergency preparedness.

(1) The facility shall have detailed written plans and procedures to meet all potential emergencies and disasters, such as fire, severe weather, and missing residents.

(2) The facility shall train all employees in emergency procedures when they begin to work in the facility, periodically review the procedures with existing staff, and carry out staff drills using those procedures.

n. Transfer agreement.

(1) The facility shall have in effect a written transfer agreement with one or more hospitals approved for participation under the Medicare and Medicaid programs that reasonably ensures that:

1. Residents will be transferred from the facility to the hospital and ensured of timely admission to the hospital when transfer is medically appropriate as determined by the attending physician.
2. Medical and other information needed for care and treatment of residents, and, when the transferring facility deems it appropriate, for determining whether the residents can be adequately cared for in a less expensive setting than either the facility or the hospital, will be exchanged between the institutions.

(2) The facility is considered to have a transfer agreement in effect if the facility has attempted in good faith to enter into an agreement with a hospital sufficiently close to the facility to make transfer feasible.

o. Quality assessment and assurance.

(1) A facility shall maintain a quality assessment and assurance committee consisting of the director of nursing services, a physician designated by the facility, and at least three other members of the facility's staff.

(2) The quality assessment and assurance committee:

1. Meets at least quarterly to identify issues with respect to which quality assessment and assurance activities are necessary.
2. Develops and implements appropriate plans of action to correct identified quality deficiencies.

(3) The state or the Secretary of the Department of Health and Human Services may not require disclosure of the records of the committee except insofar as the disclosure is related to the compliance of the committee with the requirements of this paragraph.

(4) Good faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions.

p. Disclosure of ownership.

(1) The facility shall comply with the disclosure requirements of 42 CFR 420.206 and 455.104.

(2) The facility shall provide written notice to the department of inspections and appeals at the time of change, if a change occurs in:

1. Persons with an ownership or control interest.
2. The officers, directors, agents, or managing employees.
3. The corporation, association, or other company responsible for the management of the facility.
4. The facility's administrator or director of nursing.

(3) The notice specified in subparagraph (2) above shall include the identity of each new individual or company.

This rule is intended to implement Iowa Code sections 249A.2, 249A.3(2)*"a,"* and 249A.4.

[**ARC 8445B**, IAB 1/13/10, effective 12/11/09]

441—81.14(249A) Audits.

81.14(1) *Audit of financial and statistical report.* Authorized representatives of the department or the Department of Health and Human Services shall have the right, upon proper identification, to audit,

using generally accepted auditing procedures, the general financial records of a facility to determine if expenses reported on the Financial and Statistical Report, Form 470-0030, are reasonable and proper according to the rules set forth in 441—81.6(249A). The aforementioned audits may be done either on the basis of an on-site visit to the facility, their central accounting office, or office(s) of their agent(s).

a. When a proper per diem rate cannot be determined, through generally accepted and customary auditing procedures, the auditor shall examine and adjust the report to arrive at what appears to be an acceptable rate and shall recommend to the department that the indicated per diem should be reduced to 75 percent of the established payment rate for the ensuing six-month period and if the situation is not remedied on the subsequent Financial and Statistical Report, Form 470-0030, the health facility shall be suspended and eventually canceled from the nursing facility program, or

b. When a health facility continues to include as an item of cost an item or items which had in a prior audit been removed by an adjustment in the total audited costs, the auditor shall recommend to the department that the per diem be reduced to 75 percent of the current payment rate for the ensuing six-month period. The department may, after considering the seriousness of the exception, make the reduction.

81.14(2) *Audit of proper billing and handling of patient funds.*

a. Field auditors of the department of inspections and appeals, or representatives of Health and Human Services, upon proper identification, shall have the right to audit billings to the department and receipts of client participation, to ensure the facility is not receiving payment in excess of the contractual agreement and that all other aspects of the contractual agreement are being followed, as deemed necessary.

b. Field auditors of the department of inspections and appeals or representatives of Health and Human Services, upon proper identification, shall have the right to audit records of the facility to determine proper handling of patient funds in compliance with subrule 81.4(3).

c. The auditor shall recommend and the department shall request repayment by the facility to either the department or the resident(s) involved, any sums inappropriately billed to the department or collected from the resident.

d. The facility shall have 60 days to review the audit and repay the requested funds or present supporting documentation which would indicate that the requested refund amount, or part thereof, is not justified.

e. When the facility fails to comply with paragraph *"d,"* the requested refunds may be withheld from future payments to the facility. The withholding shall not be more than 25 percent of the average of the last six monthly payments to the facility. The withholding shall continue until the entire requested refund amount is recovered. If in the event the audit results indicate significant problems, the audit results may be referred to the attorney general's office for whatever action may be deemed appropriate.

f. When exceptions are taken during the scope of an audit which are similar in nature to the exceptions taken in a prior audit, the auditor shall recommend and the department may, after considering the seriousness of the exceptions, reduce payment to the facility to 75 percent of the current payment rate.

This rule is intended to implement Iowa Code sections 249A.2, 249A.3(2)*"a"* and 249A.4.

441—81.15(249A) Nurse aide training and testing programs. Rescinded IAB 12/9/92, effective 2/1/93.

441—81.16(249A) Nurse aide requirements and training and testing programs.

81.16(1) *Deemed meeting of requirements.* A nurse aide is deemed to satisfy the requirement of completing a training and competency evaluation approved by the department of inspections and appeals if the nurse aide successfully completed a training and competency evaluation program before July 1, 1989. The aide would have satisfied this requirement if:

a. At least 60 hours were substituted for 75 hours; and

b. The aide has made up at least the difference in the number of hours in the program the aide completed and 75 hours in supervised practical nurse aide training or in regular in-service nurse education; or

c. The person was found to be competent (whether or not by the state) after completion of a nurse aide training of at least 100 hours' duration; or

d. The person can demonstrate that the person served as a nurse aide at one or more facilities of the same employer in Iowa for at least 24 consecutive months before December 19, 1989; or

e. The person completed, before July 1, 1989, a nurse aide training and competency evaluation program that the department of inspections and appeals determines would have met the requirements for approval at the time it was offered.

81.16(2) *State review and approval of nurse aide training and competency evaluation programs or competency evaluation programs.*

a. The department of inspections and appeals shall, in the course of all surveys, determine whether the nurse aide training and evaluation requirements of 81.13(19)*"e"* and 81.16(1) are met.

b. Requirements for approval of programs.

(1) Before the department of inspections and appeals approves a nurse aide training and competency evaluation program or competency evaluation program, the department of inspections and appeals shall determine whether:

1. A nurse aide training and competency evaluation program meets the course requirements of 81.16(3).

2. A nurse aide competency evaluation program meets the requirements of 81.16(4).

(2) Except as provided by paragraph 81.16(2)*"f,"* the department of inspections and appeals shall not approve a nurse aide training and competency evaluation program or competency evaluation program offered by or in a facility which, in the previous two years:

1. Has operated under a nurse staffing waiver for a period in excess of 48 hours per week; or

2. Has been subject to an extended or partial extended survey; or

3. Has been assessed a civil money penalty of not less than $5,000; or

4. Has operated under temporary management appointed to oversee the operation of the facility and to ensure the health and safety of the facility's residents; or

5. Pursuant to state action, was closed or had its residents transferred; or

6. Has been terminated from participation in the Medicaid or Medicare program; or

7. Has been denied payment under subrule 81.40(1) or 81.40(2).

(3) Rescinded IAB 10/7/98, effective 12/1/98.

c. Application process. Applications shall be submitted to the department of inspections and appeals before a new program begins and every two years thereafter on Form 427-0517, Application for Nurse Aide Training. The department of inspections and appeals shall, within 90 days of the date of a request or receipt of additional information from the requester:

(1) Advise the requester whether or not the program has been approved; or

(2) Request additional information from the requesting entity.

d. Duration of approval. The department of inspections and appeals shall not grant approval of a nurse aide training and competency evaluation program for a period longer than two years. A program shall notify the department of inspections and appeals and the department of inspections and appeals shall review that program when there are substantive changes made to that program within the two-year period.

e. Withdrawal of approval.

(1) The department of inspections and appeals shall withdraw approval of a nurse aide training and competency evaluation program or nurse aide competency evaluation program offered by or in a facility described in 81.16(2)*"b"*(2).

(2) The department of inspections and appeals may withdraw approval of a nurse aide training and competency evaluation program or nurse aide competency evaluation program if the department of inspections and appeals determines that any of the applicable requirements for approval or registry, as set out in subrule 81.16(3) or 81.16(4), are not met.

(3) The department of inspections and appeals shall withdraw approval of a nurse aide training and competency evaluation program or a nurse aide competency evaluation program if the entity providing the program refuses to permit unannounced visits by the department of inspections and appeals.

(4) If the department of inspections and appeals withdraws approval of a nurse aide training and competency evaluation program or competency evaluation program, the department of inspections and appeals shall notify the program in writing, indicating the reasons for withdrawal of approval of the program. Students who have started a training and competency evaluation program from which approval has been withdrawn shall be allowed to complete the course.

f. An exception to subparagraph 81.16(2)*"b"*(2) may be granted by the department of inspections and appeals (DIA) for 75-hour nurse aide training courses offered in (but not by) a facility under the following conditions:

(1) The facility has submitted Form 470-3494, Nurse Aide Education Program Waiver Request, to the DIA to request a waiver for each 75-hour nurse aide training course to be offered in (but not by) the facility.

(2) The 75-hour nurse aide training is offered in a facility by an approved nurse aide training and competency evaluation program (NATCEP).

(3) No other NATCEP program is offered within 30 minutes' travel from the facility, unless the facility can demonstrate the distance or program would create a hardship for program participants.

(4) The facility is in substantial compliance with the federal requirements related to nursing care and services.

(5) The facility is not a poor performing facility.

(6) Employees of the facility do not function as instructors for the program unless specifically approved by DIA.

(7) The NATCEP sponsoring the 75-hour nursing aide training course is responsible for program administration and for ensuring that program requirements are met.

(8) The NATCEP has submitted an evaluation to the DIA indicating that an adequate teaching and learning environment exists for conducting the course.

(9) The NATCEP has developed policies for communicating and resolving problems encountered during the course, including notice by the facility to the program instructor and students on how to contact the DIA to register any concerns encountered during the course.

(10) The NATCEP shall require the program instructor and students to complete an evaluation of the course. The instructor shall return the completed evaluations to the NATCEP which shall return the evaluations to DIA.

81.16(3) *Requirements for approval of a nurse aide training and competency evaluation program.* The department has designated the department of inspections and appeals to approve required nurse aide training and testing programs. Policies and procedures governing approval of the programs are set forth in these rules.

a. For a nurse aide training and competency evaluation program to be approved by the department of inspections and appeals, it shall, at a minimum:

(1) Consist of no less than 75 clock hours of training.

(2) Include at least the subjects specified in 81.16(3).

(3) Include at least 15 hours of laboratory experience, 30 hours of classroom instruction (the first 16 hours of which must occur before the nurse aide has resident contact) and 30 hours of supervised clinical training. Supervised clinical training means training in a setting in which the trainee demonstrates knowledge while performing tasks on a resident under the general supervision of a registered nurse or licensed practical nurse.

(4) Ensure that students do not independently perform any services for which they have not been trained and found proficient by the instructor. It shall also ensure that students who are providing services to residents are under the general supervision of a licensed nurse or a registered nurse.

(5) Meet the following requirements for instructors who train nurse aides:

1. The training of nurse aides shall be performed by or under the general supervision of a registered nurse who possesses a minimum of two years of nursing experience, at least one year of which shall be in the provision of long-term care facility services.

2. Instructors shall be registered nurses and shall have completed a course in teaching adults or have experience teaching adults or supervising nurse aides.

3. In a facility-based program, when the director of nursing is a registered nurse, the training of nurse aides may be performed under the general supervision of the director of nursing for the facility. The director of nursing is prohibited from performing the actual training.

4. Other personnel from the health professions may supplement the instructor. Supplemental personnel shall have at least one year of experience in their fields.

5. The ratio of qualified trainers to students shall not exceed one instructor for every ten students in the clinical setting.

(6) Contain information regarding competency evaluation through written or oral and skills testing.

b. The curriculum of the nurse aide training program shall include:

(1) At least a total of 16 hours of training in the following areas prior to any direct contact with a resident:

1. Communication and interpersonal skills.
2. Infection control.
3. Safety and emergency procedures including the Heimlich maneuver.
4. Promoting residents' independence.
5. Respecting residents' rights.

(2) Basic nursing skills:

1. Taking and recording vital signs.
2. Measuring and recording height and weight.
3. Caring for the residents' environment.
4. Recognizing abnormal changes in body functioning and the importance of reporting these changes to a supervisor.
5. Caring for residents when death is imminent.

(3) Personal care skills, including, but not limited to:

1. Bathing.
2. Grooming, including mouth care.
3. Dressing.
4. Toileting.
5. Assisting with eating and hydration.
6. Proper feeding techniques.
7. Skin care.
8. Transfers, positioning, and turning.

(4) Mental health and social service needs:

1. Modifying aide's behavior in response to residents' behavior.
2. Awareness of developmental tasks associated with the aging process.
3. How to respond to resident behavior.
4. Allowing the resident to make personal choices, providing and reinforcing other behavior consistent with the resident's dignity.
5. Using the resident's family as a source of emotional support.

(5) Care of cognitively impaired residents:

1. Techniques for addressing the unique needs and behaviors of persons with dementia (Alzheimer's and others).
2. Communicating with cognitively impaired residents.
3. Understanding the behavior of cognitively impaired residents.
4. Appropriate responses to the behavior of cognitively impaired residents.
5. Methods of reducing the effects of cognitive impairments.

(6) Basic restorative services:

1. Training the resident in self-care according to the resident's ability.
2. Use of assistive devices in transferring, ambulation, eating and dressing.
3. Maintenance of range of motion.
4. Proper turning and positioning in bed and chair.
5. Bowel and bladder training.
6. Care and use of prosthetic and orthotic devices.

(7) Residents' rights:

1. Providing privacy and maintenance of confidentiality.
2. Promoting the residents' rights to make personal choices to accommodate their needs.
3. Giving assistance in resolving grievances and disputes.
4. Providing needed assistance in getting to and participating in resident and family groups and other activities.
5. Maintaining care and security of residents' personal possessions.
6. Promoting the residents' rights to be free from abuse, mistreatment, and neglect and the need to report any instances of this type of treatment to appropriate facility staff.
7. Avoiding the need for restraints in accordance with current professional standards.

c. Prohibition of charges.

(1) No nurse aide who is employed by, or who has received an offer of employment from, a facility on the date on which the aide begins a nurse aide training and competency evaluation program or competency evaluation program may be charged for any portion of the program including any fees for textbooks or other required evaluation or course materials.

(2) If a person who is not employed, or does not have an offer to be employed, as a nurse aide becomes employed by, or receives an offer of employment from, a facility not later than 12 months after completing a nurse aide training and competency evaluation program or competency evaluation program, the facility shall reimburse the nurse aide for costs incurred in completing the program or competency evaluation on a pro rata basis during the period in which the person is employed as a nurse aide. The formula for paying the nurse aides on a pro rata basis shall be as follows:

1. Add all costs incurred by the aides for the course, books, and tests.
2. Divide the total arrived at in No. 1 above by 12 to prorate the costs over a one-year period and establish a monthly rate.
3. The aide shall be reimbursed the monthly rate each month the aide works at the facility until one year from the time the aide completed the course.

d. Setting and equipment. The classroom shall have appropriate equipment, be of adequate size, and not interfere with resident activities.

e. Records and reports. Nurse aide education programs approved by the department of inspections and appeals shall:

(1) Notify the department of inspections and appeals:

1. Of dates of classroom and clinical sessions as well as location of classrooms and clinical practice sites before each course begins and if the course is canceled.
2. When a facility or other training entity will no longer be offering nurse aide training courses.
3. Whenever the person coordinating the training program is hired or terminates employment.

(2) Keep a list of faculty members and their qualifications available for department review.

(3) Provide each nurse aide a record of skills for which the nurse aide has been found competent during the course and which may be performed before completion of the competency evaluation.

(4) Complete a lesson plan for each unit which includes behavioral objectives, a topic outline and student activities and experiences.

(5) Provide the student, within 30 days of the last class period, evidence of having successfully completed the course.

81.16(4) *Nurse aide competency evaluation.* A competency evaluation program shall contain a written or oral portion and a skills demonstration portion.

a. Notification to person. The department of inspections and appeals shall advise in advance any person who takes the competency evaluation that a record of the successful completion of the evaluation will be included in the state's nurse aide registry.

b. Content of the competency evaluation program.

(1) Written or oral examinations. The competency evaluation shall:

1. Allow an aide to choose between a written and oral examination.

2. Address each of the course requirements listed in 81.16(3)*"b."*

3. Be developed from a pool of test questions, only a portion of which is used in any one examination.

4. Use a system that prevents disclosure of both the pool of questions and the individual competency evaluations.

5. If oral, be read from a prepared text in a neutral manner.

6. Be tested for reliability and validity using a nationally recognized standard as determined by the department of education.

7. Be in English, unless the prevailing language used in the facility where a nurse aide will be working is other than English.

(2) Demonstration of skills. The skills demonstration evaluation shall consist of a demonstration of randomly selected items drawn from a pool consisting of tasks generally performed by nurse aides. This pool of skills shall include all of the personal care skills listed in 81.16(3)*"b"*(3).

c. Administration of the competency evaluation.

(1) The competency examination shall be administered and evaluated only by an entity approved by the department of inspections and appeals, which is neither a skilled nursing facility that participates in Medicare nor a nursing facility that participates in Medicaid.

(2) Charging nurse aides for competency testing is prohibited in accordance with 81.16(3)*"c."*

(3) The skills demonstration part of the evaluation shall be performed in a facility or laboratory setting comparable to the setting in which the person will function as a nurse aide and shall be administered and evaluated by a registered nurse with at least one year's experience in providing care for the elderly or the chronically ill of any age.

d. Facility proctoring of the competency evaluation.

(1) The competency evaluation may, at the nurse aide's option, be conducted at the facility in which the nurse aide is or will be employed unless the facility is prohibited from being a competency evaluation site.

(2) The department of inspections and appeals may permit the competency evaluation to be proctored by facility personnel if the department of inspections and appeals finds that the procedure adopted by the facility ensures that the competency evaluation program:

1. Is secure from tampering.

2. Is standardized and scored by a testing, educational, or other organization approved by the department of inspections and appeals.

3. Requires no scoring by facility personnel.

(3) The department of inspections and appeals shall retract the right to proctor nurse aide competency evaluations from facilities in which the department of inspections and appeals finds any evidence of impropriety, including evidence of tampering by facility staff.

e. Successful completion of the competency evaluation program.

(1) A score of 70 percent or above is passing for both the written or oral and skills demonstration parts of the test.

(2) A record of successful completion of the competency evaluation shall be included in the nurse aide registry within 30 days of the date the person is found to be competent.

(3) The competency testing entity shall inform the nurse aide of the test score within 30 calendar days of the completion of the test and shall inform the nurse aide registry of the nurse aide's scores within 20 calendar days after the test is administered.

f. Unsuccessful completion of the competency evaluation program.

(1) If the person does not complete the evaluation satisfactorily, the person shall be advised in writing within ten working days after the test is scored:

1. Of the areas which the person did not pass.

2. That the person has three opportunities to take the evaluation.

(2) Each person shall have three opportunities to pass each part of the test. If one part of the test is failed, only that part need be taken a second or third time. If either part of the test is failed three times, the 75-hour course shall be taken or retaken before the test can be taken again.

g. Storage of evaluation instrument. The person responsible for administering a competency evaluation shall provide secure storage of the evaluation instruments when they are not being administered or processed.

h. Application process. Entities wishing to secure approval for a competency evaluation program shall submit a copy of the evaluation plan and procedures to the department of inspections and appeals. The department of inspections and appeals shall notify the applicant of its decision within 90 days of receipt of the application. The notification shall include the reason for not giving approval if approval is denied and the applicable rule citation.

81.16(5) *Registry of nurse aides.*

a. Establishment of registry. The department of inspections and appeals shall establish and maintain a registry of nurse aides that meets the following requirements. The registry:

(1) Shall include, at a minimum, the information required in 81.16(5)*"c."*

(2) Shall be sufficiently accessible to meet the needs of the public and health care providers promptly.

(3) Shall provide that any response to an inquiry that includes a finding of abuse, neglect, mistreatment of a resident or misappropriation of property also include any statement made by the nurse aide which disputes the finding.

b. Registry operation.

(1) Only the department of inspections and appeals may place on the registry findings of abuse, neglect, mistreatment of a resident or misappropriation of property.

(2) The department of inspections and appeals shall determine which persons:

1. Have successfully completed a nurse aide training and competency evaluation program or nurse aide competency evaluation program.

2. Have been deemed as meeting these requirements.

3. Do not qualify to remain on the registry because they have performed no nursing or nursing-related services for monetary compensation during a period of 24 consecutive months.

(3) The department of inspections and appeals shall not impose any charges related to registration on persons listed in the registry.

(4) The department of inspections and appeals shall provide information on the registry promptly.

c. Registry content.

(1) The registry shall contain at least the following information on each person who has successfully completed a nurse aide training and competency evaluation program or competency evaluation program which was approved by the department of inspections and appeals or who may function as a nurse aide because of having been deemed competent:

1. The person's full name.

2. Information necessary to identify each person.

3. The date the person became eligible for placement in the registry through successfully completing a nurse aide training and competency evaluation program or competency evaluation or by being deemed competent.

4. The following information on any finding by the department of inspections and appeals of abuse, neglect, mistreatment of residents or misappropriation of property by the person: documentation of the department of inspections and appeals' investigation, including the nature of the allegation and the evidence that led the department of inspections and appeals to conclude that the allegation was valid; the date of the hearing, if the person chose to have one, and its outcome; and a statement by the person disputing the allegation, if the person chooses to make one. This information must be included in the

registry within ten working days of the finding and shall remain in the registry permanently, unless the finding was made in error, the person was found not guilty in a court of law, or the department of inspections and appeals is notified of the person's death.

5. A record of known convictions by a court of law of a person convicted of abuse, neglect, mistreatment or misappropriation of resident property.

(2) The registry shall remove entries for persons who have performed no nursing or nursing-related services for monetary compensation for a period of 24 consecutive months unless the person's registry entry includes documented findings or convictions by a court of law of abuse, neglect, mistreatment or misappropriation of property.

d. Disclosure of information. The department of inspections and appeals shall:

(1) Disclose all of the information listed in 81.16(5)*"c"*(1), (3), and (4) to all requesters and may disclose additional information it deems necessary.

(2) Promptly provide persons with all information contained in the registry about them when adverse findings are placed on the registry and upon request. Persons on the registry shall have sufficient opportunity to correct any misstatements or inaccuracies contained in the registry.

e. Placement of names on nurse aide registry. The facility shall ensure that the name of each person employed as a nurse aide in a Medicare- or Medicaid-certified nursing facility in Iowa is submitted to the registry. The telephone number of the registry is (515)281-4963. The address is Nurse Aide Registry, Lucas State Office Building, Des Moines, Iowa 50319-0083.

(1) Persons employed as nurse aides shall complete Form 427-0496, Nurse Aide Registry Application, within the first 30 days of employment. This form shall be submitted to the department of inspections and appeals. Form 427-0496 may be obtained by calling or writing the nurse aide registry.

(2) A nurse aide who is not employed may apply for inclusion on the registry by submitting a copy of completed Form 427-0496 to the nurse aide registry.

(3) When the registry has received a signed application and entered the required training and testing information on the registry, a letter will be sent to the nurse aide that includes all the information the registry has on the nurse aide. A nurse aide may obtain a copy of the information on the registry by writing the nurse aide registry and requesting the information. The letter requesting the information must include the nurse aide's social security number, current or last facility of employment, date of birth and current mailing address and must be signed by the nurse aide.

81.16(6) *Hearing.* When there is an allegation of abuse against a nurse aide, the department of inspections and appeals shall investigate that allegation. When the investigation by the department of inspections and appeals makes a finding of an act of abuse, the nurse aide named will be notified of this finding and the right to a hearing. The nurse aide shall have 30 days to request a hearing. The request shall be in writing and shall be sent to the department of inspections and appeals. The hearing shall be held pursuant to department of inspections and appeals rules 481—Chapter 10. After 30 days, if the nurse aide fails to appeal, or when all appeals are exhausted, the nurse aide registry will include a notation that the nurse aide has a founded abuse report on record if the final decision indicates the nurse aide performed an abusive act.

81.16(7) *Appeals.* Adverse decisions made by the department of inspections and appeals in administering these rules may be appealed pursuant to department of inspections and appeals rules 481—Chapter 10.

This rule is intended to implement Iowa Code section 249A.4.

441—81.17(249A) Termination procedures. Rescinded IAB 5/10/95, effective 7/1/95.

441—81.18(249A) Sanctions.

81.18(1) *Penalty for falsification of a resident assessment.* An individual, who willfully and knowingly certifies a material and false statement in a resident assessment, is subject to a civil money penalty of not less than $100 or more than $1,000 for each falsified assessment. An individual who willfully and knowingly causes another individual to certify a material and false statement in a resident assessment is subject to a civil money penalty of not less than $500 nor more than $5,000 for each

falsified assessment. These fines shall be administratively assessed by the department of inspections and appeals.

a. Factors determining the size of fine. In determining the monetary amount of the penalty, the director of the department of inspections and appeals or the director's designee may consider evidence of the circumstances surrounding the violation, including, but not limited to, the following factors:

(1) The number of assessments willingly and knowingly falsified.

(2) The history of the individual relative to previous assessment falsifications.

(3) The intent of the individual who falsifies an assessment or causes an assessment to be falsified.

(4) The areas of assessment falsified or caused to be falsified and the potential for harm to the resident.

(5) The relationship of the falsification of assessment to falsification of other records at the time of the visit.

b. Notification of a fine imposed for falsification of assessments or causing another individual to falsify an assessment shall be served upon the individual personally or by certified mail.

c. Appeals of fines. Notice of intent to formally contest the fine shall be given to the department of inspections and appeals in writing and be postmarked within 20 working days after receipt of the notification of the fine. An administrative hearing will be conducted pursuant to Iowa Code chapter 17A and department of inspections and appeals rules 481—Chapter 10. An individual who has exhausted all administrative remedies and is aggrieved by the final action of the department of inspections and appeals may petition for judicial review in the manner provided by Iowa Code chapter 17A.

81.18(2) *Use of independent assessors.* If the department of inspections and appeals determines that there has been a knowing and willful certification of false assessments, or the causation of knowing and willful false assessments, the department of inspections and appeals may require that resident assessments be conducted and certified by individuals independent of the facility and who are approved by the state.

a. Criteria used to determine the need for independent assessors shall include:

(1) The involvement of facility management in the falsification of or causing resident assessments to be falsified.

(2) The facility's response to the falsification of or causing resident assessments to be falsified.

(3) The method used to prepare facility staff to do resident assessments.

(4) The number of individuals involved in the falsification.

(5) The number of falsified resident assessments.

(6) The extent of harm to residents caused by the falsifications.

b. The department of inspections and appeals will specify the length of time that these independent assessments will be conducted and when they will begin. This determination will be based on the extent of assessments and reassessments needed and the plan submitted by the facility to ensure falsifications will not occur in the future.

c. The individuals or agency chosen by the facility to conduct the independent assessments shall be approved by the department of inspections and appeals before conducting any assessments. The approval will be based on the ability of the individual or agency to conduct resident assessments in accordance with the applicable rules. Any costs incurred shall be the responsibility of the facility.

d. Notice of the requirement to obtain independent assessments will be in writing and sent to the facility by certified mail or personal service. The notice shall include the date independent assessors are to begin assessments, information on how independent assessors are to be approved and the anticipated length of time independent assessors will be needed.

e. Criteria for removal of the requirement for independent assessors.

(1) Independent assessors shall be utilized until all residents assessed by the disciplines involved have been reassessed by the independent assessor.

(2) The facility shall submit a plan to the department of inspections and appeals for completing its own assessments.

(3) The department of inspections and appeals will evaluate the facility's proposal for ensuring assessments will not be falsified in the future.

f. Appeal procedures.

(1) A written notice to appeal shall be postmarked or personally served to the department of inspections and appeals within five working days after receipt of the notice requiring independent assessors.

(2) An evidentiary hearing shall be held pursuant to department of inspections and appeals rules 481—Chapter 10 no later than 15 working days after receipt of the appeal.

(3) The written decision shall be rendered no later than ten working days after the hearing.

(4) The decision rendered is a proposed decision which may be appealed to the director of the department of inspections and appeals pursuant to department of inspections and appeals rules 481—Chapter 50.

(5) A notice of appeal stays the effective date of the requirement for independent assessments pending a final agency decision.

(6) Final agency action may be appealed pursuant to Iowa Code chapter 17A.

81.18(3) *Penalty for notification of time or date of survey.* Any individual who notifies, or causes to be notified, a nursing facility of the time or date on which a survey is scheduled to be conducted shall be subject to a fine not to exceed $2,000.

81.18(4) *Failure to meet requirements for participation.* Rescinded IAB 5/10/95, effective 7/1/95.

This rule is intended to implement Iowa Code section 249A.4.

441—81.19(249A) Criteria related to the specific sanctions. Rescinded IAB 5/10/95, effective 7/1/95.

441—81.20(249A) Out-of-state facilities. Payment will be made for care in out-of-state nursing facilities. Out-of-state facilities shall abide by the same policies as in-state facilities with the following exceptions:

81.20(1) *Out-of-state providers.* Except for Medicare-certified hospital-based nursing facilities and special population nursing facilities, out-of-state providers shall be reimbursed at the same nursing facility rate they would receive from the Medicaid program in their state of residence or an amount equal to the sum of the Iowa non-state-operated nursing facility direct care rate component limit pursuant to subparagraph 81.6(16)*"f"*(1) plus the non-direct care rate limit pursuant to subparagraph 81.6(16)*"f"*(1), whichever is lower.

a. Medicare-certified hospital-based nursing facilities providing skilled care in other states shall be reimbursed at an amount equal to the sum of the Iowa Medicare-certified hospital-based nursing facility direct care rate component limit pursuant to subparagraph 81.6(16)*"f"*(3) plus the non-direct care rate component limit pursuant to subparagraph 81.6(16)*"f"*(3) if one of the following criteria is met:

(1) The placement is recommended because moving the resident back to Iowa would endanger the resident's health, because services are not readily available in Iowa, or because the out-of-state placement is cost-effective.

(2) The placement is temporary until services are available to the resident in Iowa or until the program of treatment is completed.

b. Special population nursing facilities shall be reimbursed at the same nursing facility rate they would receive from Medicaid in their state of residence or, if not participating in the Medicaid program in their state, they shall be reimbursed pursuant to subparagraph 81.6(16)*"e"*(2), if one of the following criteria is met:

(1) The placement is recommended because moving the resident back to Iowa would endanger the resident's health, because services are not readily available in Iowa, or because the out-of-state placement is cost-effective.

(2) The placement is temporary until services are available to the resident in Iowa or until the program of treatment is completed.

81.20(2) Out-of-state facilities shall not submit financial and statistical reports as required in rule 441—81.6(249A).

81.20(3) Payment for periods when residents are absent for visitation or hospitalization will be made to out-of-state facilities at 75 percent of the rate paid to the facility by the Iowa Medicaid program.

81.20(4) Rescinded IAB 3/20/91, effective 3/1/91.

This rule is intended to implement Iowa Code section 249A.4.

441—81.21(249A) Outpatient services. Medicaid outpatient services provided by certified skilled nursing facilities are defined in the same way as the Medicare program.

This rule is intended to implement Iowa Code section 249A.4 and 1991 Iowa Acts, House File 479, section 132, subsection 1, paragraph *"i."*

441—81.22(249A) Rates for Medicaid eligibles.

81.22(1) *Maximum client participation.* A nursing facility may not charge more client participation for Medicaid-eligible clients as determined in rule 441—75.16(249A) than the maximum monthly allowable payment for their facility as determined according to subrule 79.1(9) or rule 441—81.6(249A). When the department makes a retroactive increase in the maximum daily rate, the nursing facility can charge the client the increased amount for the retroactive period.

81.22(2) *Beginning date of payment.* When a resident becomes eligible for Medicaid payments for facility care, the facility shall accept Medicaid rates effective when the resident's Medicaid eligibility begins. A nursing facility is required to refund any payment received from a resident or family member for any period of time during which the resident is determined to be eligible for Medicaid.

Any refund owing shall be made no later than 15 days after the nursing facility first receives Medicaid payment for the resident for any period of time. Facilities may deduct the resident's client participation for the month from a refund of the amount paid for a month of Medicaid eligibility.

The beginning date of eligibility is given on the Facility Card, Form 470-0371. When the beginning Medicaid eligibility date is a future month, the facility shall accept the Medicaid rate effective the first of that future month.

This rule is intended to implement Iowa Code section 249A.4.

441—81.23(249A) State-funded personal needs supplement. A Medicaid member living in a nursing facility who has countable income for purposes of rule 441—75.16(249A) of less than $50 per month shall receive a state-funded payment from the department for the difference between that countable income and $50 if the legislature has appropriated funding specifically for this purpose. This payment shall not be considered a benefit under Title XIX of the Social Security Act.

This rule is intended to implement Iowa Code Supplement section 249A.30A.

441—81.24 to **81.30** Reserved.

DIVISION II
ENFORCEMENT OF COMPLIANCE

PREAMBLE

These rules specify remedies that may by used when a nursing facility is not in substantial compliance with the requirements for participation in the Medicaid program. These rules also provide for ensuring prompt compliance and specify that these remedies are in addition to any others available under state or federal law.

441—81.31(249A) Definitions.

"CMS" means the Centers for Medicare and Medicaid Services of the federal Department of Health and Human Services.

"Deficiency" means a nursing facility's failure to meet a participation requirement.

"Department" means the Iowa department of human services.

"Immediate jeopardy" means a situation in which immediate corrective action is necessary because the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident.

"New admission" means a resident who is admitted to the facility on or after the effective date of a denial of payment remedy and, if previously admitted, has been discharged before that effective date. Residents admitted before the effective date of the denial of payment, and taking temporary leave, are not considered new admissions, nor are they subject to the denial of payment.

"Noncompliance" means any deficiency that causes a facility to not be in substantial compliance.

"Plan of correction" means a plan developed by the facility and approved by the department of inspections and appeals which describes the actions the facility shall take to correct deficiencies and specifies the date by which those deficiencies shall be corrected.

"Standard survey" means a periodic, resident-centered inspection which gathers information about the quality of service furnished in a facility to determine compliance with the requirements for participation.

"Substandard quality of care" means one or more deficiencies related to the participation requirements for resident behavior and facility practices, quality of life, or quality of care which constitute either immediate jeopardy to resident health or safety; a pattern of or widespread actual harm that is not immediate jeopardy; or a widespread potential for more than minimal harm, but less than immediate jeopardy, with no actual harm.

"Substantial compliance" means a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm.

"Temporary management" means the temporary appointment by the department of inspections and appeals of a substitute facility manager or administrator with authority to hire, terminate or reassign staff, obligate facility funds, alter facility procedures, and manage the facility to correct deficiencies identified in the facility's operation.

441—81.32(249A) General provisions.

81.32(1) *Purpose of remedies.* The purpose of remedies is to ensure prompt compliance with program requirements.

81.32(2) *Basis for imposition and duration of remedies.* The department of inspections and appeals, as the state survey agency under contract with the department, determines the remedy to be applied for noncompliance with program requirements. When the department of inspections and appeals chooses to apply one or more remedies specified in rule 441—81.34(249A), the remedies are applied on the basis of noncompliance found during surveys conducted by the department of inspections and appeals.

81.32(3) *Number of remedies.* The department of inspections and appeals may apply one or more remedies for each deficiency constituting noncompliance or for all deficiencies constituting noncompliance.

81.32(4) *Plan of correction requirement.*

a. Except as specified in paragraph *"b,"* regardless of which remedy is applied, each facility that has deficiencies with respect to program requirements shall submit a plan of correction for approval by the department of inspections and appeals.

b. A facility is not required to submit a plan of correction when the department of inspections and appeals determines the facility has deficiencies that are isolated and have a potential for minimal harm, but no actual harm has occurred.

81.32(5) *Disagreement regarding remedies.* If the department of inspections and appeals and CMS disagree on the decision to impose a remedy, the disagreement shall be resolved in accordance with rule 441—81.55(249A).

81.32(6) *Notification requirements.*

a. The department of inspections and appeals shall give the provider written notice of remedy, including the:

(1) Nature of the noncompliance.

(2) Which remedy is imposed.

(3) Effective date of the remedy.

(4) Right to appeal the determination leading to the remedy.

b. Except for civil money penalties and state monitoring imposed when there is immediate jeopardy, for all remedies specified in rule 441—81.34(249A) imposed when there is immediate jeopardy, the notice shall be given at least two calendar days before the effective date of the enforcement action.

c. Except for civil money penalties and state monitoring, notice shall be given at least 15 calendar days before the effective date of the enforcement action in situations where there is no immediate jeopardy.

d. The 2- and 15-day notice periods begin when the facility receives the notice, but in no event will the effective date of the enforcement action be later than 20 calendar days after the notice is sent.

e. For civil money penalties, the notices shall be given in accordance with rules 441—81.48(249A) and 441—81.51(249A).

f. For state monitoring imposed when there is immediate jeopardy, no prior notice is required.

81.32(7) *Informal dispute resolution.*

a. Opportunity to refute survey findings.

(1) For nonfederal surveys, the department of inspections and appeals (DIA) shall offer a facility an informal opportunity, at the facility's request, to dispute survey findings upon the facility's receipt of the official statement of deficiencies.

(2) For a federal survey, the Centers for Medicare and Medicaid Services (CMS) offers a facility an informal opportunity, at the facility's request, to dispute survey findings upon the facility's receipt of the official statement of deficiencies.

b. Delay of enforcement action.

(1) Failure of DIA or CMS, as appropriate, to complete informal dispute resolution timely cannot delay the effective date of any enforcement action against the facility.

(2) A facility may not seek a delay of any enforcement action against it on the grounds that informal dispute resolution has not been completed before the effective date of the enforcement action.

c. If a provider is subsequently successful, during the informal dispute resolution process, at demonstrating that deficiencies should not have been cited, the deficiencies are removed from the statement of deficiencies and any enforcement actions imposed solely as a result of those cited deficiencies are rescinded.

d. Notification. DIA shall provide the facility with written notification of the informal dispute resolution process.

441—81.33(249A) Factors to be considered in selecting remedies.

81.33(1) *Initial assessment.* In order to select the appropriate remedy, if any, to apply to a facility with deficiencies, the department of inspections and appeals shall determine the seriousness of the deficiencies.

81.33(2) *Determining seriousness of deficiencies.* To determine the seriousness of the deficiency, the department of inspections and appeals shall consider at least the following factors:

a. Whether a facility's deficiencies constitute:

(1) No actual harm with a potential for minimal harm.

(2) No actual harm with a potential for more than minimal harm, but not immediate jeopardy.

(3) Actual harm that is not immediate jeopardy.

(4) Immediate jeopardy to resident health or safety.

b. Whether the deficiencies:

(1) Are isolated.

(2) Constitute a pattern.

(3) Are widespread.

81.33(3) *Other factors which may be considered in choosing a remedy within a remedy category.* Following the initial assessment, the department of inspections and appeals may consider other factors, which may include, but are not limited to, the following:

a. The relationship of the one deficiency to other deficiencies resulting in noncompliance.

b. The facility's prior history of noncompliance in general and specifically with reference to the cited deficiencies.

441—81.34(249A) Available remedies. In addition to the remedy of termination of the provider agreement, the following remedies are available:

1. Temporary management.
2. Denial of payment for all new admissions.
3. Civil money penalties.
4. State monitoring.
5. Closure of the facility in emergency situations or transfer of residents, or both.
6. Directed plan of correction.
7. Directed in-service training.

441—81.35(249A) Selection of remedies.

81.35(1) *Categories of remedies.* Remedies specified in rule 441—81.34(249A) are grouped into categories and applied to deficiencies according to the severity of noncompliance.

81.35(2) *Application of remedies.* After considering the factors specified in rule 441—81.33(249A), if the department of inspections and appeals applies remedies, as provided in paragraphs 81.35(3)*"a,"* 81.35(4)*"a,"* and 81.35(5)*"a,"* for facility noncompliance, instead of, or in addition to, termination of the provider agreement, the department of inspections and appeals shall follow the criteria set forth in 81.35(3)*"b,"*81.35(4)*"b,"* and 81.35(5)*"b,"* as applicable.

81.35(3) *Category 1.*

a. Category 1 remedies include the following:

(1) Directed plan of correction.

(2) State monitoring.

(3) Directed in-services training.

b. The department of inspections and appeals shall apply one or more of the remedies in Category 1 when there:

(1) Are isolated deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy; or

(2) Is a pattern of deficiencies that constitutes no actual harm with a potential for more than minimal harm but not immediate jeopardy.

c. Except when the facility is in substantial compliance, the department of inspections and appeals may apply one or more of the remedies in Category 1 to any deficiency.

81.35(4) *Category 2.*

a. Category 2 remedies include the following:

(1) Denial of payment for new admissions.

(2) Civil money penalties of $50 to $3,000 per day.

b. The department of inspections and appeals shall apply one or more of the remedies in Category 2 when there are:

(1) Widespread deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy; or

(2) One or more deficiencies that constitute actual harm that is not immediate jeopardy.

c. Except when the facility is in substantial compliance, the department of inspections and appeals may apply one or more of the remedies in Category 2 to any deficiency.

81.35(5) *Category 3.*

a. Category 3 remedies include the following:

(1) Temporary management.

(2) Immediate termination.

(3) Civil money penalties of $3,050 to $10,000 per day.

b. When there is one or more deficiencies that constitute immediate jeopardy to resident health or safety, one or both of the following remedies shall be applied:

(1) Temporary management.

(2) Termination of the provider agreement.

In addition the department of inspections and appeals may impose a civil money penalty of $3,050 to $10,000 per day.

c. When there are widespread deficiencies that constitute actual harm that is not immediate jeopardy, the department of inspections and appeals may impose temporary management, in addition to Category 2 remedies.

81.35(6) *Plan of correction.*

a. Except as specified in paragraph *"b,"* each facility that has a deficiency with regard to a requirement for long-term care facilities shall submit a plan of correction for approval by the department of inspections and appeals, regardless of:

(1) Which remedies are applied.

(2) The seriousness of the deficiencies.

b. When there are only isolated deficiencies that the department of inspections and appeals determines constitute no actual harm with a potential for minimal harm, the facility need not submit a plan of correction.

81.35(7) *Appeal of a determination of noncompliance.*

a. A facility may request a hearing on a determination of noncompliance leading to an enforcement remedy. The affected nursing facility, or its legal representative or other authorized official, shall file the request for hearing in writing to the department of inspections and appeals within 60 days from receipt of the notice of the proposed denial, termination, or nonrenewal of participation, or imposition of a civil money penalty or other remedies.

(1) A request for a hearing shall be made in writing to the department of inspections and appeals within 60 days from receipt of the notice.

(2) Hearings shall be conducted pursuant to department of inspections and appeals rules 481—Chapter 10 and rule 481—50.6(10A), with an administrative law judge appointed as the presiding officer and with the department of inspections and appeals as the final decision maker, with subject matter jurisdiction.

b. A facility may not appeal the choice of remedy, including the factors considered by the department of inspections and appeals in selecting the remedy.

c. A facility may not challenge the level of noncompliance found by the department of inspections and appeals, except that in the case of a civil money penalty, a facility may challenge the level of noncompliance found by the department of inspections and appeals only if a successful challenge on this issue would affect the range of civil money penalty amounts that the department could collect.

d. Except when a civil remedy penalty is imposed, the imposition of a remedy shall not be stayed pending an appeal hearing.

441—81.36(249A) Action when there is immediate jeopardy.

81.36(1) *Terminate agreement or appoint temporary manager.* If there is immediate jeopardy to resident health or safety, the department of inspections and appeals shall appoint a temporary manager to remove the immediate jeopardy or the provider agreement shall be terminated within 23 calendar days of the last date of the survey.

The rules for appointment of a temporary manager in an immediate jeopardy situation are as follows:

a. The department of inspections and appeals shall notify the facility that a temporary manager is being appointed.

b. If the facility fails to relinquish control to the temporary manager, the provider agreement shall be terminated within 23 calendar days of the last day of the survey if the immediate jeopardy is not removed. In these cases, state monitoring may be imposed pending termination.

c. If the facility relinquishes control to the temporary manager, the department of inspections and appeals shall notify the facility that, unless it removes the immediate jeopardy, its provider agreement shall be terminated within 23 calendar days of the last day of the survey.

d. The provider agreement shall be terminated within 23 calendar days of the last day of survey if the immediate jeopardy has not been removed.

81.36(2) *Other remedies.* The department of inspections and appeals may also impose other remedies, as appropriate.

81.36(3) *Notification of CMS.* In a nursing facility or dually participating facility, if the department of inspections and appeals finds that a facility's noncompliance poses immediate jeopardy to resident health or safety, the department of inspections and appeals shall notify CMS of the finding.

81.36(4) *Transfer of residents.* The department shall provide for the safe and orderly transfer of residents when the facility is terminated from participation.

81.36(5) *Notification of physicians and state board.* If the immediate jeopardy is also substandard quality of care, the department of inspections and appeals shall notify attending physicians and the Iowa board of nursing home administrators of the finding of substandard quality of care.

441—81.37(249A) Action when there is no immediate jeopardy.

81.37(1) *Termination of agreement or limitation of participation.* If a facility's deficiencies do not pose immediate jeopardy to residents' health or safety, and the facility is not in substantial compliance, the facility's provider agreement may be terminated or the facility may be allowed to continue to participate for no longer than six months from the last day of the survey if:

a. The department of inspections and appeals finds that it is more appropriate to impose alternative remedies than to terminate the facility's provider agreement;

b. The department of inspections and appeals has submitted a plan of correction approved by CMS; and

c. The facility agrees to repay payments received after the last day of the survey that first identified the deficiencies if corrective action is not taken in accordance with the approved plan of correction and posts bond acceptable to the department to guarantee the repayment.

81.37(2) *Termination.* If a facility does not meet the criteria for continuation of payment under subrule 81.37(1), the facility's provider agreement shall be terminated.

81.37(3) *Denial of payment.* Payment shall be denied for new admissions when the facility is not in substantial compliance three months after the last day of the survey.

81.37(4) *Failure to comply.* The provider agreement shall be terminated and all payments stopped to a facility for which participation was continued under subrule 81.37(1) if the facility is not in substantial compliance within six months of the last day of the survey.

441—81.38(249A) Action when there is repeated substandard quality of care.

81.38(1) *General.* If a facility has been found to have provided substandard quality of care on the last three consecutive standard surveys, regardless of other remedies provided:

a. Payment for all new admissions shall be denied, as specified in rule 441—81.40(249A).

b. The department of inspections and appeals shall impose state monitoring, as specified in rule 441—81.42(249A) until the facility has demonstrated to the satisfaction of the department of inspections and appeals that it is in substantial compliance with all requirements and will remain in substantial compliance with all requirements.

81.38(2) *Repeated noncompliance.* For purposes of this rule, repeated noncompliance is based on the repeated finding of substandard quality of care and not on the basis that the substance of the deficiency or the exact deficiency was repeated.

81.38(3) *Standard surveys to which this provision applies.* Standard surveys completed by the department of inspections and appeals on or after October 1, 1990, are used to determine whether the threshold of three consecutive standard surveys is met.

81.38(4) *Program participation.*

a. The determination that a certified facility has repeated instances of substandard quality of care is made without regard to any variances in the facility's program participation (that is, any standard survey completed for Medicare, Medicaid or both programs will be considered).

b. Termination would allow the count of repeated substandard quality of care surveys to start over.

c. Change of ownership.

(1) A facility may not avoid a remedy on the basis that it underwent a change of ownership.

(2) In a facility that has undergone a change of ownership, the department of inspections and appeals may not restart the count of repeated substandard quality of care surveys unless the new owner can demonstrate to the department of inspections and appeals that the poor past performance no longer is a factor due to the change in ownership.

81.38(5) *Compliance.* Facility alleges corrections or achieves compliance after repeated substandard quality of care is identified.

a. If a penalty is imposed for repeated substandard quality of care, it will continue until the facility has demonstrated to the satisfaction of the department of inspections and appeals that it is in substantial compliance with the requirements and that it will remain in substantial compliance for a period of time specified by the department of inspections and appeals.

b. A facility will not avoid the imposition of remedies or the obligation to demonstrate that it will remain in compliance when it:

(1) Alleges correction of the deficiencies cited in the most recent standard survey; or

(2) Achieves compliance before the effective date of the remedies.

441—81.39(249A) Temporary management. The department of inspections and appeals may appoint a temporary manager from qualified applicants.

81.39(1) *Qualifications.* The temporary manager must:

a. Be qualified to oversee correction of deficiencies on the basis of experience and education, as determined by the department of inspections and appeals.

b. Not have been found guilty of misconduct by any licensing board or professional society in any state.

c. Have, or a member of the manager's immediate family have, no financial ownership interest in the facility.

d. Not currently serve or, within the past two years, have served as a member of the staff of the facility.

81.39(2) *Payment of salary.* The temporary manager's salary:

a. Is paid directly by the facility while the temporary manager is assigned to that facility.

b. Shall be at least equivalent to the sum of the following:

(1) The prevailing salary paid by providers for positions of this type in the facility's geographic area.

(2) Additional costs that would have reasonably been incurred by the provider if the person had been in an employment relationship.

(3) Any other transportation and lodging costs incurred by the person in furnishing services under the arrangement up to the maximum per diem for state employees.

c. May exceed the amount specified in paragraph *"b"* if the department of inspections and appeals is otherwise unable to attract a qualified temporary manager.

81.39(3) *Failure to relinquish authority to temporary management.*

a. If a facility fails to relinquish authority to the temporary manager, the provider agreement shall be terminated in accordance with rule 441—81.57(249A).

b. A facility's failure to pay the salary of the temporary manager is considered a failure to relinquish authority to temporary management.

81.39(4) *Duration of temporary management.* Temporary management ends when the facility meets any of the conditions specified in subrule 81.56(3).

441—81.40(249A) Denial of payment for all new admissions.

81.40(1) *Optional denial of payment.* Except as specified in subrule 81.40(2), the denial of payment for all new admissions may be imposed when a facility is not in substantial compliance with the requirements.

81.40(2) *Required denial of payment.* Payment for all new admissions shall be denied when:

a. The facility is not in substantial compliance three months after the last day of the survey identifying the noncompliance; or

b. The department of inspections and appeals has cited a facility with substandard quality of care on the last three consecutive standard surveys.

81.40(3) *Resumption of payments.* Repeated instances of substandard quality of care. When a facility has repeated instances of substandard quality of care, payments to the facility resume on the date that:

a. The facility achieves substantial compliance as indicated by a revisit or written credible evidence acceptable to the department of inspections and appeals.

b. The department of inspections and appeals determines that the facility is capable of remaining in substantial compliance.

81.40(4) *Resumption of payments.* No repeated instances of substandard quality of care. When a facility does not have repeated instances of substandard quality of care, payments to the facility resume prospectively on the date that the facility achieves substantial compliance, as indicated by a revisit or written credible evidence acceptable to the department of inspections and appeals.

81.40(5) *Restriction.* No payments to a facility are made for the period between the date that the denial of payment remedy is imposed and the date the facility achieves substantial compliance, as determined by the department of inspections and appeals.

441—81.41(249A) Secretarial authority to deny all payments.

81.41(1) *CMS option to deny all payment.* If a facility has not met a requirement, in addition to the authority to deny payment for all new admissions as specified in rule 441—81.40(249A), CMS may deny any further payment to the state for all Medicaid residents in the facility. When CMS denies payment to the state, the department shall deny payment to the facility.

81.41(2) *Resumption of payment.* When CMS resumes payment to the state, the department shall also resume payment to the facility. The department shall make payments to the facility for the same periods for which payment is made to the state.

441—81.42(249A) State monitoring.

81.42(1) *State monitor.* A state monitor:

a. Oversees the correction of deficiencies specified by the department of inspections and appeals at the facility site and protects the facility's residents from harm.

b. Is an employee or a contractor of the department of inspections and appeals.

c. Is identified by the department of inspections and appeals as an appropriate professional to monitor cited deficiencies.

d. Is not an employee of the facility.

e. Does not function as a consultant to the facility.

f. Does not have an immediate family member who is a resident of the facility to be monitored.

81.42(2) *Use of state monitor.* A state monitor shall be used when the department of inspections and appeals has cited a facility with substandard quality of care deficiencies on the last three consecutive standard surveys.

81.42(3) *Discontinuance of state monitor.* State monitoring is discontinued when:

a. The facility has demonstrated that it is in substantial compliance with the requirement, and it will remain in compliance for a period of time specified by the department of inspections and appeals.

b. Termination procedures are completed.

441—81.43(249A) Directed plan of correction. The department of inspections and appeals or the temporary manager (with department of inspections and appeals' approval) may develop a plan of correction and require a facility to take action within specified time frames.

441—81.44(249A) Directed in-service training.

81.44(1) *Required training.* The department of inspections and appeals may require the staff of a facility to attend an in-service training program if:

a. The facility has a pattern of deficiencies that indicate noncompliance; and

b. Education is likely to correct the deficiencies.

81.44(2) *Action following training.* After the staff has received in-service training, if the facility has not achieved substantial compliance, the department of inspections and appeals may impose one or more other remedies.

81.44(3) *Payment.* The facility is responsible for the payment for the directed in-service training.

441—81.45(249A) Closure of a facility or transfer of residents, or both.

81.45(1) *Closure during an emergency.* In an emergency, the department and the department of inspections and appeals have the authority to:

a. Transfer Medicaid and Medicare residents to another facility; or

b. Close the facility and transfer the Medicaid and Medicare residents to another facility.

81.45(2) *Required transfer in immediate jeopardy situations.* When a facility's provider agreement is terminated for a deficiency that constitutes immediate jeopardy, the department arranges for the safe and orderly transfer of all Medicaid and Medicare residents to another facility.

81.45(3) *All other situations.* Except for immediate jeopardy situations, as specified in subrule 81.45(2), when a facility's provider agreement is terminated, the department arranges for the safe and orderly transfer of all Medicare and Medicaid residents to another facility.

441—81.46(249A) Civil money penalties—basis for imposing penalty. The department of inspections and appeals may impose a civil money penalty for the number of days a facility is not in substantial compliance with one or more participation requirements, regardless of whether or not the deficiencies constitute immediate jeopardy.

The department of inspections and appeals may impose a civil money penalty for the number of days of past noncompliance since the last standard survey, including the number of days of immediate jeopardy.

441—81.47(249A) Civil money penalties—when penalty is collected.

81.47(1) *When facility requests a hearing.*

a. A facility shall request a hearing on the determination of the noncompliance that is the basis for imposition of the civil money penalty within the time limit specified in subrule 81.35(7).

b. If a facility requests a hearing within the time specified in subrule 81.35(7), the department of inspections and appeals initiates collection of the penalty when there is a final administrative decision that upholds the department of inspections and appeals' determination of noncompliance after the facility achieves substantial compliance or is terminated.

81.47(2) *When facility does not request a hearing.* If a facility does not request a hearing, in accordance with subrule 81.47(1), the department of inspections and appeals initiates collection of the penalty when the facility:

a. Achieves substantial compliance; or

b. Is terminated.

81.47(3) *When facility waives a hearing.* If a facility waives its right to a hearing in writing, as specified in rule 441—81.49(249A), the department of inspections and appeals initiates collection of the penalty when the facility:

a. Achieves substantial compliance; or

b. Is terminated.

81.47(4) *Accrual and computation of penalties.* Accrual and computation of penalties for a facility that:

a. Requests a hearing or does not request a hearing as specified in rule 441—81.50(249A);

b. Waives its right to a hearing in writing, as specified in subrule 81.49(2) and rule 441—81.50(249A).

81.47(5) *Collection.* The collection of civil money penalties is made as provided in rule 441—81.52(249A).

441—81.48(249A) Civil money penalties—notice of penalty. The department of inspections and appeals shall notify the facility of intent to impose a civil money penalty in writing. The notice shall include, at a minimum, the following information:

1. The nature of the noncompliance.
2. The statutory basis for the penalty.
3. The amount of penalty per day of noncompliance.
4. Any factors specified in subrule 81.50(6) that were considered when determining the amount of the penalty.
5. The date on which the penalty begins to accrue.
6. When the penalty stops accruing.
7. When the penalty is collected.
8. Instructions for responding to the notice, including a statement of the facility's right to a hearing, and the implication of waiving a hearing, as provided in rule 441—81.49(249A).

441—81.49(249A) Civil money penalties—waiver of hearing, reduction of penalty amount.

81.49(1) *Waiver of a hearing.* The facility may waive the right to a hearing, in writing, within 60 days from the date of the notice of intent to impose the civil money penalty.

81.49(2) *Reduction of penalty amount.*

a. If the facility waives its right to a hearing, the department of inspections and appeals reduces the civil money penalty amount by 35 percent.

b. If the facility does not waive its right to a hearing, the civil money penalty is not reduced by 35 percent.

441—81.50(249A) Civil money penalties—amount of penalty.

81.50(1) *Amount of penalty.* The penalties are within the following ranges, set at $50 increments:

a. Upper range—$3,050 to $10,000. Penalties in the range of $3,050 to $10,000 per day are imposed for deficiencies constituting immediate jeopardy, as specified in 81.50(4)*"b."*

b. Lower range—$50 to $3,000. Penalties in the range of $50 to $3,000 per day are imposed for deficiencies that do not constitute immediate jeopardy, but either caused actual harm, or caused no actual harm, but have the potential for more than minimal harm.

81.50(2) *Basis for penalty amount.* The amount of penalty is based on the department of inspections and appeals' assessment of factors listed in subrule 81.50(6).

81.50(3) *Decreased penalty amounts.* Except as specified in 81.50(4)*"b,"* if immediate jeopardy is removed, but the noncompliance continues, the department of inspections and appeals shall shift the penalty amount to the lower range.

81.50(4) *Increased penalty amounts.*

a. Before the hearing, the department of inspections and appeals may propose to increase the penalty amount for facility noncompliance which, after imposition of a lower level penalty amount, becomes sufficiently serious to pose immediate jeopardy.

b. The department of inspections and appeals shall increase the penalty amount for any repeated deficiencies for which a lower level penalty amount was previously imposed, regardless of whether the increased penalty amount would exceed the range otherwise reserved for nonimmediate jeopardy deficiencies.

c. Repeated deficiencies are deficiencies in the same regulatory grouping of requirements found at the last survey, subsequently corrected, and found again at the next survey.

81.50(5) *Review of the penalty.* When an administrative law judge (or director of the department of inspections and appeals) finds that the basis for imposing a civil money penalty exists, the administrative law judge (or director) may not:

a. Set a penalty of zero or reduce a penalty to zero.

b. Review the exercise of discretion by the department of inspections and appeals to impose a civil money penalty.

c. Consider any factors in reviewing the amount of the penalty other than those specified in subrule 81.50(6).

81.50(6) *Factors affecting the amount of penalty.* In determining the amount of penalty, the department of inspections and appeals shall take into account the following factors:

a. The facility's history of noncompliance, including repeated deficiencies.

b. The facility's financial condition.

c. The factors specified in rule 441—81.33(249A).

d. The facility's degree of culpability. Culpability includes, but is not limited to, neglect, indifference, or disregard for resident care, comfort or safety. The absence of culpability is not a mitigating circumstance in reducing the amount of the penalty.

441—81.51(249A) Civil money penalties—effective date and duration of penalty.

81.51(1) *When penalty begins to accrue.* The civil money penalty may start accruing as early as the date the facility was first out of compliance, as determined by the department of inspections and appeals.

81.51(2) *Duration of penalty.* The civil money penalty is computed and collectible, as specified in rules 441—81.47(249A) and 441—81.52(249A), for the number of days of noncompliance until the date the facility achieves substantial compliance or, if applicable, the date of termination when:

a. The department of inspections and appeals' decision of noncompliance is upheld after a final administrative decision;

b. The facility waives its right to a hearing in accordance with rule 441—81.49(249A); or

c. The time for requesting a hearing has expired and the department of inspections and appeals has not received a hearing request from the facility.

81.51(3) *Penalty due.* The entire accrued penalty is due and collectible, as specified in the notice sent to the provider under subrules 81.51(4) and 81.54(5).

81.51(4) *Notice after facility achieves compliance.* When a facility achieves substantial compliance, the department of inspections and appeals shall send a separate notice to the facility containing:

a. The amount of penalty per day;

b. The number of days involved;

c. The total amount due;

d. The due date of the penalty; and

e. The rate of interest assessed on the unpaid balance beginning on the due date, as provided in rule 441—81.52(249A).

81.51(5) *Notice to terminated facility.* In the case of a terminated facility, the department of inspections and appeals shall send this penalty information after the:

a. Final administrative decision is made;

b. Facility has waived its right to a hearing in accordance with rule 441—81.49(249A); or

c. Time for requesting a hearing has expired and the department of inspections and appeals has not received a hearing request from the facility.

81.51(6) *Accrual of penalties when there is no immediate jeopardy.*

a. In the case of noncompliance that does not pose immediate jeopardy, the daily accrual of civil money penalties is imposed for the days of noncompliance prior to the notice specified in rule 441—81.48(249A) and an additional period of no longer than six months following the last day of the survey.

b. After the period specified in paragraph *"a,"* if the facility has not achieved substantial compliance, the provider agreement may be terminated.

81.51(7) *Accrual of penalties when there is immediate jeopardy.*

a. When a facility has deficiencies that pose immediate jeopardy, the provider agreement shall be terminated within 23 calendar days after the last day of the survey if the immediate jeopardy remains.

b. The accrual of the civil money penalty stops on the day the provider agreement is terminated.

81.51(8) *Documenting substantial compliance.*

a. If an on-site revisit is necessary to confirm substantial compliance and the provider can supply documentation acceptable to the department of inspections and appeals that substantial compliance was achieved on a date preceding the revisit, penalties only accrue until that date of correction for which there is written credible evidence.

b. If an on-site revisit is not necessary to confirm substantial compliance, penalties only accrue until the date of correction for which the department of inspections and appeals receives and accepts written credible evidence.

441—81.52(249A) Civil money penalties—due date for payment of penalty.

81.52(1) *When payments are due.*

a. A civil money penalty payment is due 15 days after a final administrative decision is made when:

(1) The facility achieves substantial compliance before the final administrative decision; or

(2) The effective date of termination occurs before the final administrative decision.

b. A civil money penalty is due 15 days after the time period for requesting a hearing has expired and a hearing request was not received when:

(1) The facility achieves substantial compliance before the hearing request was due; or

(2) The effective date of termination occurs before the hearing request was due.

c. A civil money penalty payment is due 15 days after receipt of the written request to waive a hearing when:

(1) The facility achieved substantial compliance before the department of inspections and appeals received the written waiver of hearing; or

(2) The effective date of termination occurs before the department of inspections and appeals received the written waiver of hearing.

d. A civil money penalty payment is due 15 days after substantial compliance is achieved when:

(1) The final administrative decision is made before the facility came into compliance;

(2) The facility did not file a timely hearing request before it came into substantial compliance; or

(3) The facility waived its right to a hearing before it came into substantial compliance.

e. A civil money penalty payment is due 15 days after the effective date of termination, if before the effective date of termination:

(1) The final administrative decision was made;

(2) The time for requesting a hearing has expired and the facility did not request a hearing; or

(3) The facility waived its right to a hearing.

f. In the cases specified in paragraph *"d,"* the period of noncompliance may not extend beyond six months from the last day of the survey.

81.52(2) *Deduction of penalty from amount owed.* The amount of the penalty, when determined, may be deducted from any sum then or later owing by the department to the facility.

81.52(3) *Interest.* Interest of 10 percent per year is assessed on the unpaid balance of the penalty, beginning on the due date.

81.52(4) *Penalties collected by the department.*

a. Civil money penalties collected by the department shall be applied to the protection of the health or property of residents of facilities that the department of inspections and appeals finds deficient, such as:

(1) Payment for the cost of relocating residents to other facilities;

(2) State costs related to the operation of a facility pending correction of deficiencies or closure; and

(3) Reimbursement of residents for personal funds or property lost at a facility as a result of actions by the facility or by individuals used by the facility to provide services to residents.

b. Reserved.

441—81.53(249A) Civil money penalties—settlement of penalties. The department of inspections and appeals has the authority to settle cases at any time prior to the evidentiary hearing decision.

441—81.54(249A) Continuation of payments to a facility with deficiencies.

81.54(1) *Criteria.*

a. The department may continue payments to a facility that is not in substantial compliance for the periods specified in subrule 81.54(3) if the following criteria are met:

(1) The department of inspections and appeals finds that it is more appropriate to impose alternative remedies than to terminate the facility;

(2) The department of inspections and appeals has submitted a plan and timetable for corrective action approved by CMS; and

(3) The facility agrees to repay the department for all payments received under this provision if corrective action is not taken in accordance with the approved plan and timetable for corrective action and posts a bond acceptable to the department to guarantee agreement to repay.

b. The facility provider agreement may be terminated before the end of the correction period if the criteria in 81.54(1)*"a"* are not met.

81.54(2) *Cessation of payments.* If termination is not sought, either by itself or along with another remedy or remedies, or any of the criteria in 81.54(1)*"a"* are not met or agreed to by either the facility or the department, the facility shall receive no payments, as applicable, from the last day of the survey.

81.54(3) *Period of continued payments.* If the conditions in 81.54(1)*"a"* are met, the department may continue payments to a facility with noncompliance that does not constitute immediate jeopardy for up to six months from the last day of the survey.

81.54(4) *Failure to achieve substantial compliance.* If the facility does not achieve substantial compliance by the end of the period specified in subrule 81.54(3), the provider agreement for the facility may be terminated.

441—81.55(249A) State and federal disagreements involving findings not in agreement when there is no immediate jeopardy. This rule applies when CMS and the department of inspections and appeals disagree over findings of noncompliance or application of remedies.

81.55(1) *Disagreement over whether facility has met requirements.*

a. The department of inspections and appeals' finding of noncompliance takes precedence when:

(1) CMS finds the facility is in substantial compliance with the participation requirements; and

(2) The department of inspections and appeals finds the facility has not achieved substantial compliance.

b. CMS's findings of noncompliance take precedence when:

(1) CMS finds that a facility has not achieved substantial compliance; and

(2) The department of inspections and appeals finds the facility is in substantial compliance with the participation requirements.

c. When CMS's survey findings take precedence, CMS may:

(1) Impose any of the alternative remedies specified in rule 441—81.34(249A);

(2) Terminate the provider agreement subject to the applicable conditions of rule 441—81.54(249A); and

(3) Stop federal financial participation to the department for a nursing facility.

81.55(2) *Disagreement over decision to terminate.*

a. CMS's decision to terminate the participation of a facility takes precedence when:

(1) Both CMS and the department of inspections and appeals find that the facility has not achieved substantial compliance; and

(2) CMS, but not the department of inspections and appeals, finds that the facility's participation should be terminated. CMS will permit continuation of payment during the period prior to the effective date of termination, not to exceed six months, if the applicable conditions of rule 441—81.54(249A) are met.

b. The department of inspections and appeals' decision to terminate a facility's participation and the procedures for appealing the termination take precedence when:

(1) The department of inspections and appeals, but not CMS, finds that a facility's participation should be terminated; and

(2) The department of inspections and appeals' effective date for the termination of the nursing facility's provider agreement is no later than six months after the last day of survey.

81.55(3) *Disagreement over timing of termination of facility.* The department of inspections and appeals' timing of termination takes precedence if it does not occur later than six months after the last day of the survey when both CMS and the department of inspections and appeals find that:

a. A facility is not in substantial compliance; and

b. The facility's participation should be terminated.

81.55(4) *Disagreement over remedies.*

a. When CMS or the department of inspections and appeals, but not both, establishes one or more remedies, in addition to or as an alternative to termination, the additional or alternative remedies will also apply when:

(1) Both CMS and the department of inspections and appeals find that a facility has not achieved substantial compliance; and

(2) Both CMS and the department of inspections and appeals find that no immediate jeopardy exists.

b. When CMS and the department of inspections and appeals establish one or more remedies, in addition to or as an alternative to termination, only the CMS remedies apply when both CMS and the department of inspections and appeals find that a facility has not achieved substantial compliance.

81.55(5) *One decision.* Regardless of whether CMS's or the department of inspections and appeals' decision controls, only one noncompliance and enforcement decision is applied to the Medicaid agreement, and for a dually participating facility, that same decision will apply to the Medicare agreement.

441—81.56(249A) Duration of remedies.

81.56(1) *Remedies continue.* Except as specified in subrule 81.56(2), alternative remedies continue until:

a. The facility has achieved substantial compliance as determined by the department of inspections and appeals based upon a revisit or after an examination of credible written evidence that it can verify without an on-site visit; or

b. The provider agreement is terminated.

81.56(2) *State monitoring.* In the cases of state monitoring and denial of payment imposed for repeated substandard quality of care, remedies continue until:

a. The department of inspections and appeals determines that the facility has achieved substantial compliance and is capable of remaining in substantial compliance; or

b. The provider agreement is terminated.

81.56(3) *Temporary management.* In the case of temporary management, the remedy continues until:

a. The department of inspections and appeals determines that the facility has achieved substantial compliance and is capable of remaining in substantial compliance;

b. The provider agreement is terminated; or

c. The facility which has not achieved substantial compliance reassumes management control. In this case, the department of inspections and appeals initiates termination of the provider agreement and may impose additional remedies.

81.56(4) *Facility in compliance.* If the facility can supply documentation acceptable to the department of inspections and appeals that it was in substantial compliance, and was capable of

remaining in substantial compliance, if necessary, on a date preceding that of the revisit, the remedies terminate on the date that the department of inspections and appeals can verify as the date that substantial compliance was achieved.

441—81.57(249A) Termination of provider agreement.

81.57(1) *Effect of termination.* Termination of the provider agreement ends payment to the facility and any alternative remedy.

81.57(2) *Basis of termination.*

a. A facility's provider agreement may be terminated if a facility:

(1) Is not in substantial compliance with the requirements of participation, regardless of whether or not immediate jeopardy is present; or

(2) Fails to submit an acceptable plan of correction within the time frame specified by the department of inspections and appeals.

b. A facility's provider agreement shall be terminated if a facility:

(1) Fails to relinquish control to the temporary manager, if that remedy is imposed by the department of inspections and appeals; or

(2) Does not meet the eligibility criteria for continuation of payment as set forth in 81.37(1)*"a."*

81.57(3) *Notice of termination.* Before a provider agreement is terminated, the department of inspections and appeals shall notify the facility and the public:

a. At least two calendar days before the effective date of termination for a facility with immediate jeopardy deficiencies; and

b. At least 15 calendar days before the effective date of termination for a facility with nonimmediate jeopardy deficiencies that constitute noncompliance.

These rules are intended to implement Iowa Code section 249A.4.

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[1] Effective date of 81.16(4) delayed 30 days by the Administrative Rules Review Committee at its September 12, 1990, meeting; at the October 9, 1990, meeting the delay was extended to 70 days. Amendment effective 12/1/90 superseded the 70-day delay.

[2] Effective date of 81.10(5) delayed until adjournment of the 1991 session of the General Assembly by the Administrative Rules Review Committee at its November 13, 1990, meeting.

[3] Effective date of 81.13(7)*"c"*(1) delayed 70 days by the Administrative Rules Review Committee at its meeting held July 14, 1992; delay lifted by the Committee at its meeting held August 11, 1992, effective August 12, 1992.

[4] Effective date of 81.6(3), first unnumbered paragraph, delayed 70 days by the Administrative Rules Review Committee at its meeting held April 5, 1993.

[5] At a special meeting held January 24, 2002, the Administrative Rules Review Committee voted to delay until adjournment of the 2002 Session of the General Assembly the effective date of amendments published in the February 6, 2002, Iowa Administrative Bulletin as **ARC 1365B**.

OBJECTION

At its meeting held August 11, 1992, the Administrative Rules Review Committee voted to object to the amendments published in **ARC 3069A** on the grounds the amendments are unreasonable. This filing is published in IAB Vol. XIV No. 253 (06-10-92). It is codified as an amendment to paragraph 441 IAC 81.13(7)*"c"*(1).

In brief, this filing provides that care facilities shall not employ persons who have been found guilty in a court of law of abusing, neglecting or mistreating facility residents, or who have had a "finding" entered into the state nurse aide registry concerning abuse, neglect, mistreatment of residents or misappropriation of their property. Additionally, the filing eliminates a previous provision which allowed the Department of Inspections and Appeals some discretion in deciding whether the lifetime ban on employment should be applied.

This language originated in the federal government which mandated that the department adopt these provisions or possibly face sanctions. The Committee does not believe these amendments are an improvement to Iowa's system and has the following objection. The Committee believes that the amendments published in **ARC 3069A** are unreasonable because of the inconsistency in the burdens of proof and the levels of procedural safeguards in the two proceedings. A facility employee may either be found guilty in a court of law or have an administrative finding entered into the registry. In either case the result is the same, the employee is permanently banned from further employment in a care facility; however, the two paths to the result are significantly different. The first proceeding is a criminal tribunal in which the burden of proof is "beyond a reasonable doubt." The second proceeding is a simple administrative hearing in which the burden is "preponderance of the evidence." The two proceedings also differ in the level of many other due process protections accorded to the individual. A criminal proceeding provides the accused with the opportunity for a trial by jury, competent legal counsel, strict rules of evidence and many procedural protections not present in administrative hearings. It should also be noted that the penalty in this situation—a lifetime ban on employment—is more serious than is usually imposed in contested cases. In licensee discipline cases, a license can be revoked, but the possibility of reinstatement exists; under this new rule no reinstatement is allowed, the facility employee is banned from employment no matter how serious or minor the offense or how far in the past it occurred. Because of the magnitude of this penalty, the Committee believes that the accused should be provided with greater procedural protections than are generally found in administrative hearings.

The Committee also believes this filing is unreasonable because it eliminates the discretion accorded to the Department of Inspections and Appeals to not apply the lifetime ban on employment. Under the previous rule, the department's discretion in applying the employment ban acted as a safeguard against unjust results. It recognized that a person would make amends for past offenses and earn a second chance. The provision was a genuine improvement in the process; it recognized that flexibility was needed in government decision making and that some decisions should be made on a case-by-case basis. There does not appear to be any rational basis to justify the elimination of this safeguard and, therefore, the Committee believes this action to be unreasonable.

NOTE: The Committee voted to retain this objection at their meeting held February 8, 1993.

CHAPTER 85
SERVICES IN PSYCHIATRIC INSTITUTIONS

PREAMBLE

Inpatient psychiatric services are provided in three types of psychiatric facilities in addition to general hospitals with psychiatric units: acute care psychiatric hospitals, psychiatric medical institutions for children, and nursing facilities for the mentally ill. Except for services in the state mental health institutes, Medicaid covers only persons under the age of 21 and persons aged 65 and older in acute care psychiatric hospitals. Medicaid covers only persons under the age of 21 in psychiatric medical institutions for children, and only persons aged 65 and older in nursing facilities for the mentally ill. These rules establish conditions of participation for providers, record-keeping requirements, reimbursement methodologies, and client eligibility requirements.

DIVISION I
PSYCHIATRIC HOSPITALS

441—85.1(249A) Acute care in psychiatric hospitals. These rules do not apply to general hospitals with psychiatric units.

85.1(1) *Psychiatric hospitals serving persons aged 21 and older.* A psychiatric hospital serving persons aged 21 and older shall meet the federal criteria for an institution for mental disease and shall be licensed pursuant to department of inspections and appeals rule 481—51.36(135B). An out-of-state facility shall be licensed as a psychiatric hospital, shall meet the federal criteria for an institution for mental disease, and shall be certified to participate in the Medicare program. An institution is an institution for mental disease only if its overall character is that of a facility established and maintained primarily for the care and treatment of persons with mental diseases. The following guidelines are used by the department in evaluating the overall character of a facility. These guidelines are all useful in identifying institutions for mental disease; however, no single guideline is necessarily determinative in any given case.

a. The facility:

(1) Is licensed as a psychiatric facility for the care and treatment of persons with mental diseases.

(2) Advertises or holds itself out as a facility for the care and treatment of persons with mental diseases.

(3) Is accredited as a psychiatric facility by the Joint Commission on the Accreditation of Health Care Organizations or by any other federally recognized accrediting organization that has comparable standards or surveys and is approved by the department of inspections and appeals.

(4) Specializes in providing psychiatric or psychological care and treatment. This may be ascertained through review of patients' records. It may also be indicated by the fact that an unusually large proportion of the staff has specialized psychiatric or psychological training or that a large proportion of the patients are receiving psychopharmacological drugs.

(5) Is under the jurisdiction of the division of behavioral, developmental, and protective services for families, adults, and children of the department.

b. More than 50 percent of all the patients in the facility have mental diseases which require inpatient treatment according to the patient's medical records.

c. A large proportion of the patients in the facility has been transferred from a state mental institution for continuing treatment of their mental disorders.

d. Independent review teams report a preponderance of mental illness in the diagnoses of the patients in the facility.

e. The average patient age is significantly lower than that of a typical nursing home.

f. Part or all of the facility consists of locked wards.

85.1(2) *Psychiatric hospitals serving persons under the age of 21.* A psychiatric hospital serving persons under the age of 21 shall be licensed pursuant to department of inspections and appeals rule 481—51.36(135B) or shall be licensed in another state as a hospital, shall be accredited by the Joint

Commission on the Accreditation of Health Care Organizations, the Commission of Accreditation of Rehabilitation Facilities, the Council on Accreditation of Services for Families and Children, or by any other federally recognized accrediting organization that has comparable standards or surveys and is approved by the department of inspections and appeals, and shall meet federal service requirements.

441—85.2(249A) Out-of-state placement. Placement in an out-of-state psychiatric hospital for acute care requires prior approval by the bureau of managed care and clinical services and shall be approved only if special services are not available in Iowa facilities as determined by the division of behavioral, developmental, and protective services for families, adults, and children.

441—85.3(249A) Eligibility of persons under the age of 21.

85.3(1) *Age.* To be eligible for payment for the cost of care provided by a psychiatric hospital, the person shall be under 21 years of age. When treatment in the hospital is provided immediately preceding the person's twenty-first birthday, coverage continues to be available until the twenty-second birthday or until service is no longer required, whichever is earlier.

85.3(2) *Period of eligibility.* The person is considered to be an inpatient until unconditionally discharged. Coverage extends until the last day of the month of the discharge or the twenty-second birthday. While on inpatient status the eligible person is entitled to the full scope of Medicaid benefits.

85.3(3) *Certification of need for care.* For persons eligible for Medicaid prior to admission, an independent team shall certify that ambulatory care resources available in the community do not meet the treatment needs of the recipient, that proper treatment of the recipient's psychiatric condition requires services on an inpatient basis under the direction of a physician, and that the services can reasonably be expected to improve the recipient's condition or prevent further regression so that the services will no longer be needed. Team members are independent when they are not employees of or consultants to the facility. Form 470-2780, Certification of Need for Inpatient Psychiatric Services, may be used to document these criteria.

a. For persons eligible for Medicaid prior to admission, this preadmission certification shall be performed within 45 days prior to the proposed date for admission to the facility by an independent team that includes a physician who has competence in diagnosis and treatment of mental illness, preferably in child psychiatry, and who has knowledge of the person's situation. If a social worker is a part of the team, the social worker may be from the county office of the department of human services.

The evaluation shall be submitted to the facility on or prior to the date of the patient's admission.

b. When a person makes application for Medicaid subsequent to admission or has an application in process at the time of admission, a certification by the team responsible for the plan of care shall be provided within 14 days after admission and shall cover any period prior to application for which claims are to be made.

c. For emergency admissions, a certification shall be provided by the team responsible for the plan of care within 14 days after admission.

85.3(4) *Financial eligibility for persons under the age of 21.* To be eligible for payments for the cost of care provided by a psychiatric facility, persons under the age of 21 must be eligible under one of the coverage groups listed in rule 441—75.1(249A).

441—85.4(249A) Eligibility of persons aged 65 and over. To be eligible for payment for the cost of care provided by an institution for mental disease, persons must be aged 65 or over and be eligible under one of the coverage groups listed in rule 441—75.1(249A).

441—85.5(249A) Client participation.

85.5(1) *Before July 2005.* For months before July 2005, the resident shall be liable to pay client participation toward the cost of care on a monthly basis. The state will pay the balance of the cost of care for the month. The facility shall make arrangements directly with the resident for payment of client participation. Client participation is determined according to rule 441—75.16(249A).

85.5(2) *July 2005 and after.* Effective with the month of July 2005, the resident shall not be liable to pay client participation toward the cost of care, and no client participation amount shall be deducted from the state payment to the hospital.

441—85.6(249A) Responsibilities of hospitals.

85.6(1) *Medical record requirements.* The medical records maintained by the psychiatric hospital shall permit determination of the degree and intensity of the treatment provided to persons who are furnished services in the hospital.

a. Development of assessment and diagnostic data. Medical records shall stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the patient is hospitalized.

(1) The identification data shall include the patient's legal status.

(2) A provisional or admitting diagnosis shall be made on every patient at the time of admission, and shall include the diagnoses of intercurrent diseases as well as the psychiatric diagnoses.

(3) The reasons for admission shall be clearly documented as stated by the patient or others significantly involved.

(4) The social service records, including reports of interviews with patients, family members, and others, shall provide an assessment of home plans and family attitudes and community resource contacts, as well as a social history.

(5) When indicated, a complete neurological examination shall be recorded at the time of the admission physical examination.

b. Psychiatric evaluation. Each patient shall receive a psychiatric evaluation that shall:

(1) Be completed within 60 hours of admission.

(2) Include a medical history.

(3) Contain a record of mental status.

(4) Note the onset of illness and the circumstances leading to admission.

(5) Describe attitudes and behavior.

(6) Estimate intellectual functioning, memory functioning, and orientation.

(7) Include an inventory of the patient's assets in descriptive, not interpretive, fashion.

c. Treatment plan.

(1) Each patient shall have an individual comprehensive treatment plan that shall be based on an inventory of the patient's strengths and disabilities. The written plan shall include a substantiated diagnosis, short-term and long-range goals, the specific treatment modalities utilized, the responsibilities of each member of the treatment team, and adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out.

(2) The treatment received by the patient shall be documented in a way to ensure that all active therapeutic efforts are included.

d. Recording progress. Progress notes shall be recorded by the doctor of medicine or osteopathy responsible for the care of the patient, nurse, social worker and, when appropriate, others significantly involved in active treatment modalities. The frequency of progress notes is determined by the condition of the patient but shall be recorded at least weekly for the first two months and at least once a month thereafter and shall contain recommendations for revisions in the treatment plan as indicated, as well as precise assessment of the patient's progress in accordance with the original or revised treatment plan.

e. Discharge planning and discharge summary. The record of each patient who has been discharged shall have a discharge summary that includes a recapitulation of the patient's hospitalization and recommendations from appropriate services concerning follow-up or aftercare, as well as a brief summary of the patient's condition on discharge.

f. The facility shall obtain a professional review organization (PRO) determination that the person requires acute psychiatric care when a person applying or eligible for Medicaid enters the facility, returns from an acute care general hospital, or enters the facility after 30 consecutive days of visitation.

85.6(2) *Fiscal records.*

a. A Case Activity Report, Form 470-0042, shall be submitted to the department whenever a Medicaid applicant or recipient enters the facility, changes level of care, is hospitalized in a general hospital, leaves for visitation, or is discharged from the facility.

b. The facility shall bill after each calendar month for the previous month's services.

85.6(3) *Additional requirements.* Additional requirements are mandated for persons under the age of 21.

a. *Active treatment.* Inpatient psychiatric services shall involve active treatment. Active treatment means implementation of a professionally developed and supervised individual plan of care that is developed and implemented by an interdisciplinary team no later than 14 days after admission and is designed to achieve the recipient's discharge from inpatient status at the earliest possible time.

b. *Individual plan of care.* An individual plan of care is a written plan developed for each recipient to improve the recipient's condition to the extent that inpatient care is no longer necessary. The plan shall be reviewed every 30 days by the team to determine that services being provided are or were required on an inpatient basis and to recommend changes in the plan as indicated by the recipient's overall adjustment as an inpatient. The plan of care shall:

(1) Be based on a diagnostic evaluation that includes examination of the medical, psychological, social, behavioral and developmental aspects of the recipient's situation and reflects the need for inpatient psychiatric care.

(2) Be developed by a team of professionals, as specified in paragraph *"c"* below, in consultation, if possible, with the recipient and the recipient's parents, legal guardians or others in whose care the recipient will be released after discharge.

(3) State the treatment objectives.

(4) Prescribe an integrated program of therapies, activities and experiences designed to meet the objectives.

(5) Include, at an appropriate time, postdischarge plans and coordination of inpatient services with partial discharge plans and related community services to ensure continuity of care with the recipient's family, school and community upon discharge.

c. *Interdisciplinary team.* The individual plan of care shall be developed by an interdisciplinary team of physicians and other personnel who are employed by the facility or who provide services to patients in the facility.

(1) Based on education and experience, preferably including competence in child psychiatry, the team shall be capable of assessing the recipient's immediate and long-range therapeutic needs, developmental priorities, and personal strengths and liabilities; assessing the potential resources of the recipient's family; setting treatment objectives; and prescribing therapeutic modalities to achieve the plan's objectives.

(2) The team shall include, as a minimum, either a board-eligible or board-certified psychiatrist, a clinical psychologist who has a doctoral degree and a physician licensed to practice in medicine or osteopathy, or a physician licensed to practice medicine or osteopathy with specialized training and experience in the diagnosis and treatment of mental diseases and a psychologist who has a master's degree in clinical psychology and has been licensed by the state.

(3) The team shall also include one of the following: a social worker with a master's degree in social work with specialized training or one year's experience in treating persons with mental illness, a registered nurse with specialized training or one year's experience in treating persons with mental illness, an occupational therapist who is licensed and who has specialized training or one year of experience in treating persons with mental illness, or a psychologist who has a master's degree in clinical psychology or who has been licensed by the state.

441—85.7(249A) Psychiatric hospital reimbursement.

85.7(1) *Reimbursement formula.* Acute care in psychiatric hospitals shall be reimbursed on a per diem rate based on Medicare principles.

a. The reimbursement principles follow and comply with the retrospective Principles of Medicare reimbursement found in Title 18 of the Social Security Act and amendments to that Act, Medicare regulations found in the Health Insurance Regulation Manual (HIRM-1), and General Instructions-Health Insurance Manual sections 10, 11, 12 and 15 when applicable.

b. Allowable costs are those defined as allowable in 42 CFR, Subpart A, Sections 413.5 and 413.9, as amended to December 2, 1996, and 42 CFR 447.250 as amended to September 23, 1992. Only those costs are considered in calculating the Medicaid inpatient reimbursement.

c. Medicare and Medicaid principles of reimbursement require hospitals to be paid at the lower of customary charges or reasonable cost and to adhere to all Medicare cost principles in the calculation of the facility rates.

d. Payment for inpatient hospital care for recipients for whom the PRO has determined that the level of care that is medically necessary is only that of skilled care or nursing care will be made at a rate equal to the statewide average Medicaid skilled nursing facility rate or the average state nursing facility rate. Periodic PRO determinations of the need for continuing care are also required.

e. Each participating Medicaid provider shall file a CMS 2552 Medicare Cost Report or a substitute accepted by the Centers for Medicare and Medicaid Services. In addition, supplemental information sheets are furnished to all Medicaid providers to be filed with the annual cost report. This report must be filed with the Iowa Medicaid enterprise provider audits and rate-setting unit for Iowa within 150 days after the close of the hospital's fiscal year.

f. Compensation for a disproportionate share of indigent patients is determined as described in 441—subrule 79.1(5).

g. Medicaid reimbursement shall be reduced by any payments from a third party toward the cost of a patient's care.

85.7(2) *Medical necessity.* The medical necessity of admission and continued stay will be determined by the PRO. Payment shall not be made for admissions which are determined not to be medically necessary nor will payment be approved for stays beyond the time at which inpatient specialized hospital care at the acute level has been determined not to be medically necessary.

85.7(3) *Reserve bed day payment.* No reserve bed day payments are made to acute care psychiatric hospitals.

85.7(4) *Outpatient services.* No coverage is available for outpatient psychiatric hospital services.

These rules are intended to implement Iowa Code section 249A.4.

441—85.8(249A,81GA,ch167) Eligibility of persons aged 21 through 64.

85.8(1) *Facility.* Acute care in a psychiatric hospital is covered for persons aged 21 through 64 only at the state mental health institutes at Cherokee, Clarinda, Independence, and Mount Pleasant.

85.8(2) *Basis of eligibility.* To be eligible for payment for the cost of care provided by one of the covered facilities, a person aged 21 through 64 must be either:

a. Eligible for one of the coverage groups listed in 441—75.1(249A); or

b. Eligible under the IowaCare program pursuant to 441—Chapter 92.

85.8(3) *Period of eligibility.* A person is considered to be an inpatient until unconditionally discharged. Coverage extends until the last day of the month of discharge.

85.8(4) *Extent of eligibility.*

a. While on inpatient status, a person eligible under a coverage group listed in 441—75.1(249A) is entitled to the full scope of Medicaid benefits.

b. While on inpatient status, a person eligible under the IowaCare program is entitled to the services listed at 441—92.8(249A,81GA,ch167).

441—85.9 to **85.20** Reserved.

DIVISION II
PSYCHIATRIC MEDICAL INSTITUTIONS FOR CHILDREN

441—85.21(249A) Conditions for participation. Psychiatric medical institutions for children shall be issued a license by the department of inspections and appeals under Iowa Code chapter 135H and shall hold either a license from the department of human services under Iowa Code section 237.3, subsection 2, paragraph *"a,"* subparagraph (3) or, for facilities which provide substance abuse treatment, a license from the department of public health under Iowa Code section 125.13.

This rule is intended to implement Iowa Code sections 135H.4 and 249A.4.

441—85.22(249A) Eligibility of persons under the age of 21.

85.22(1) *Age.* To be eligible for payment for the cost of care provided by a psychiatric medical institution for children, the person shall be under 21 years of age. When treatment in the facility is provided immediately preceding the individual's twenty-first birthday, coverage continues to be available until the twenty-second birthday or until service is no longer required, whichever is earlier.

85.22(2) *Period of eligibility.* The person is considered to be an inpatient until unconditionally discharged. Coverage extends until the last day of the month of the discharge or the twenty-second birthday. While on inpatient status, the eligible individual is entitled to the full scope of Medicaid benefits.

85.22(3) *Certification for need for care.* For persons eligible for Medicaid prior to admission, an independent team shall certify that ambulatory care resources available in the community do not meet the treatment needs of the recipient, that proper treatment of the recipient's psychiatric condition requires services on an inpatient basis under the direction of a physician, and that the services can reasonably be expected to improve the recipient's condition or prevent further regression so that the services will no longer be needed. Team members are independent when they are not employees of or consultants to the facility. Form 470-2780, Certification of Need for Inpatient Psychiatric Services, may be used to document these criteria.

a. For persons determined eligible for Medicaid prior to admission, this preadmission certification shall be performed within 45 days prior to the proposed date for admission to the facility by an independent team that includes a physician who has competence in diagnosis and treatment of mental illness, preferably in child psychiatry, and who has knowledge of the person's situation. If a social worker is a part of the team, the social worker may be from the county office of the department of human services.

The evaluation shall be submitted to the facility on or prior to the date of the patient's admission.

b. When a person makes application for Medicaid subsequent to admission or has an application in process at the time of admission, a certification by the team responsible for the plan of care shall be provided within 14 days after admission and shall cover any period prior to application for which claims are to be made.

c. For emergency admissions, a certification shall be provided by the team responsible for the plan of care within 14 days after admission.

85.22(4) *Financial eligibility for persons under the age of 21.* To be eligible for payments for the cost of care provided by psychiatric medical institutions, persons under the age of 21 shall be eligible under one of the coverage groups listed in rule 441—75.1(249A), except medically needy.

441—85.23(249A) Client participation. The resident's client participation and medical payments from a third party shall be paid toward the total cost of care on a monthly basis. The state will pay the balance of the cost of care for the month. The facility shall make arrangements directly with the resident for payment of client participation. Client participation is determined according to rule 441—75.16(249A).

441—85.24(249A) Responsibilities of facilities.

85.24(1) *Medical record requirements.* The medical records maintained by psychiatric medical institutions for children shall permit determination of the degree and intensity of the treatment provided to persons who are furnished services in the facility.

a. Development of assessment and diagnostic data. Medical records shall stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the patient is admitted.

(1) The identification data shall include the patient's legal status.

(2) A provisional or admitting diagnosis shall be made on every patient at the time of admission, and shall include the diagnoses of intercurrent diseases as well as the psychiatric diagnoses.

(3) The reasons for admission shall be clearly documented as stated by the patient or others significantly involved.

(4) The social service records, including reports of interviews with patients, family members, and others, shall provide an assessment of home plans and family attitudes and community resource contacts, as well as a social history.

(5) When indicated, a complete neurological examination shall be recorded at the time of the admission physical examination.

b. Psychiatric evaluation. Each patient shall receive a psychiatric evaluation that shall:

(1) Be completed within seven days of admission.

(2) Include a medical history.

(3) Contain a record of mental status.

(4) Note the onset of illness and the circumstances leading to admission.

(5) Describe attitudes and behavior.

(6) Estimate intellectual functioning, memory functioning, and orientation.

(7) Include an inventory of the patient's assets in descriptive, not interpretive, fashion.

c. Treatment plan.

(1) Each patient shall have an individual comprehensive treatment plan that shall be based on an inventory of the patient's strengths and disabilities. The written plan shall include a substantiated diagnosis, short-term and long-range goals, the specific treatment modalities utilized, the responsibilities of each member of the treatment team, and adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out.

(2) The treatment received by the patient shall be documented in a way to ensure that all active therapeutic efforts are included.

d. Recording progress. Progress notes shall be recorded by the doctor of medicine or osteopathy responsible for the care of the patient, nurse, social worker and, when appropriate, others significantly involved in active treatment modalities. The frequency of progress notes is determined by the condition of the patient but shall be recorded at least weekly for the first two months and at least once a month thereafter and shall contain recommendations for revisions in the treatment plan as indicated, as well as precise assessment of the patient's progress in accordance with the original or revised treatment plan.

e. Discharge planning and discharge summary. The record of each patient who has been discharged shall have a discharge summary that includes a recapitulation of the patient's stay at the facility and recommendations from appropriate services concerning follow-up or aftercare, as well as a brief summary of the patient's condition on discharge.

f. The facility shall obtain a professional review organization (PRO) determination that the person requires psychiatric medical institution level of care when a person applying or eligible for Medicaid enters the facility, returns from an acute care hospital stay longer than 10 days, or enters the facility after 30 consecutive days of visitation. Periodic PRO determinations of the need for continuing care are also required.

85.24(2) *Fiscal records.*

a. A Case Activity Report, Form 470-0042, shall be submitted to the department whenever a Medicaid applicant or recipient enters the facility, changes level of care, is hospitalized, leaves for visitation, or is discharged from the facility.

b. The facility shall bill after each calendar month for the previous month's services.

85.24(3) *Additional requirements.* Additional requirements are mandated for persons under the age of 21.

a. Active treatment. Inpatient psychiatric services shall involve active treatment. Active treatment means implementation of a professionally developed and supervised individual plan of care that is developed and implemented by an interdisciplinary team no later than 14 days after admission and is designed to achieve the recipient's discharge from inpatient status at the earliest possible time.

b. Individual plan of care. An individual plan of care is a written plan developed for each recipient to improve the recipient's condition to the extent that inpatient care is no longer necessary. The plan shall be reviewed every 30 days by the team to determine that services being provided are or were required on an inpatient basis and to recommend changes in the plan as indicated by the recipient's overall adjustment as an inpatient. The plan of care shall:

(1) Be based on a diagnostic evaluation that includes examination of the medical, psychological, social, behavioral and developmental aspects of the recipient's situation and reflects the need for inpatient psychiatric care.

(2) Be developed by a team of professionals, as specified in paragraph *"c"* below, in consultation, if possible, with the recipient and the recipient's parents, legal guardians or others in whose care the recipient will be released after discharge.

(3) State the treatment objectives.

(4) Prescribe an integrated program of therapies, activities and experiences designed to meet the objectives.

(5) Include, at an appropriate time, postdischarge plans and coordination of inpatient services with partial discharge plans and related community services to ensure continuity of care with the recipient's family, school and community upon discharge.

c. Interdisciplinary team. The individual plan of care shall be developed by an interdisciplinary team of physicians and other personnel who are employed by the facility or who provide services to patients in the facility. Membership in the interdisciplinary plan of care team includes those physicians and other professionals who are involved in the direct provision of treatment services, involved in the organization of the plan of care, or involved in consulting with or supervising those professionals involved in the direct provision of care.

(1) Based on education and experience, preferably including competence in child psychiatry, the team shall be capable of assessing the recipient's immediate and long-range therapeutic needs, developmental priorities, and personal strengths and liabilities; assessing the potential resources of the recipient's family; setting treatment objectives; and prescribing therapeutic modalities to achieve the plan's objectives.

(2) The team shall include, as a minimum, either a board-eligible or board-certified psychiatrist, a clinical psychologist who has a doctoral degree and a physician licensed to practice in medicine or osteopathy, or a physician licensed to practice medicine or osteopathy with specialized training and experience in the diagnosis and treatment of mental diseases and a psychologist who has a master's degree in clinical psychology and has been licensed by the state.

(3) The team shall also include one of the following: a social worker with a master's degree in social work with specialized training or one year's experience in treating persons with mental illness, a registered nurse with specialized training or one year's experience in treating persons with mental illness, an occupational therapist who is licensed and who has specialized training or one year of experience in treating persons with mental illness, or a psychologist who has a master's degree in clinical psychology or who has been licensed by the state.

441—85.25(249A) Reimbursement to psychiatric medical institutions for children.

85.25(1) *Computation of inpatient rate.* Facilities are paid at a per diem rate based on the facility's cost for the service not to exceed the upper limit as provided in 441—subrule 79.1(2).

a. Rates for new facilities are based on historical costs submitted on Form 470-0664, Financial and Statistical Report for Purchase of Service Contracts, if the institution is established and has the historical data. If the institution is newly established, the rate shall be based on a proposed budget submitted on Form 470-0664. A Form 470-0664 with actual cost data shall be submitted after at least six months of participation in the program for a new rate adjustment.

b. After the initial cost report period, the institution shall submit Form 470-0664 annually within three months of the close of the facility's fiscal year. Failure to submit the report within this time shall reduce payment to 75 percent of the current rate. The reduced rate shall be paid for no longer than three months, after which time no further payments will be made.

c. For services rendered July 1, 2009, through June 30, 2010, rates paid shall be adjusted to 100 percent of the facility's actual average costs per patient day, based on the cost information submitted pursuant to paragraphs 85.25(1)*"a"* and *"b,"* subject to the upper limit provided in 441—subrule 79.1(2) for non-state-owned facilities. Facilities may submit a projected cost report for purposes of determining the rates initially paid for services rendered July 1, 2009, through June 30, 2010, before rate adjustment based on actual costs.

85.25(2) *Reserve bed payments.*

a. Reserve bed day payment for days a resident of a psychiatric medical institution for children is absent from the facility for hospitalization in an acute care general hospital is paid in accordance with the following policies:

(1) The intent of the department and the facility shall be for the resident to return to the facility after the hospitalization.

(2) Staff from the psychiatric medical institution shall be available to provide support to the child and family during the hospitalization.

(3) Payment for reserve bed days shall be canceled and payment returned if the facility refuses to accept the child back except when the department and the facility agree that the return would not be in the child's best interests. If the department and the facility agree that the return would not be in the child's best interests, payment shall be canceled effective the day after the joint decision not to return the child.

(4) Payment will not be authorized for over ten days per calendar month and will not be authorized for over ten days for any continuous hospital stay.

b. Reserve bed days for visitation shall be made for days a resident is absent from a psychiatric medical institution for children at the time of a nightly census for the purpose of visitation when the absence is in accordance with the following policies:

(1) The visits are consistent with the child's case permanency plan and the facility's individual case plan.

(2) The intent of the department and the facility shall be for the child to return to the facility after the visitation.

(3) Staff from the psychiatric medical institution shall be available to provide support to the child and family during the visit.

(4) Payment for reserve bed days shall be canceled and payments returned if the facility refuses to accept the child back except when the department and the facility agree that the return would not be in the child's best interests. If the department and the facility agree that the return would not be in the child's best interests, payment shall be canceled effective the day after the joint decision not to return the child.

(5) Payment for reserve bed days shall be canceled effective the day after a decision not to return the child is made by the court or, in a voluntary placement, by the parent.

(6) Payment for reserve bed days shall not exceed 14 consecutive days or 30 days per year, except upon written approval of the regional administrator. In no case shall payment exceed 60 days per year for visitation or other absences.

c. Reserve bed payment shall be made for days a resident is absent from a psychiatric medical institution for children at the time of the nightly census for reasons such as detention, shelter care, or running away when the absence is in accordance with the following policies:

(1) The intent of the department and the psychiatric medical institution for children shall be for the child to return to the facility after the absence.

(2) Payment for reserve bed days shall be canceled and payments returned if the facility refuses to accept the child back except when the department and the facility agree that the return would not be in the child's best interests. If the department and the facility agree that the return would not be in the

child's best interests, payment shall be canceled effective the day after the joint decision not to return the child.

(3) Payment for reserve bed days shall be canceled effective the day after a decision is made not to return the child by the court or, in a voluntary placement, by the parent.

(4) Payment for reserve bed days shall not exceed 14 consecutive days or 30 days per year, except upon written approval of the regional administrator. In no case shall payment exceed 60 days per year for visitation or other absences.

(5) Reserve bed day payment is not available until the child has been physically admitted to the psychiatric medical institution.

(6) The psychiatric medical institution shall notify the department social worker within 24 hours after the child is out of the facility for running away or other unplanned reasons.

85.25(3) *Day treatment rates.* Outpatient day treatment services are paid on a fixed fee basis.

[**ARC 8649B**, IAB 4/7/10, effective 3/11/10]

441—85.26(249A) Outpatient day treatment for persons aged 20 or under. Payment to a psychiatric medical institution for children will be approved for day treatment services for persons aged 20 or under if the psychiatric medical institution for children is certified by the department of inspections and appeals for day treatment services and the services are provided on the licensed premises of the psychiatric medical institution for children.

EXCEPTION: Field trips away from the premises are a covered service when the trip is therapeutic and integrated into the day treatment program's description and milieu plan. All conditions for the day treatment program for persons aged 20 or under as outlined in 441—subrule 78.16(7) for community mental health centers shall apply to psychiatric medical institutions for children.

These rules are intended to implement Iowa Code section 249A.4.

441—85.27 to **85.40** Reserved.

DIVISION III
NURSING FACILITIES FOR PERSONS WITH MENTAL ILLNESS

441—85.41(249A) Conditions of participation. A nursing facility for persons with mental illness shall be licensed pursuant to department of inspections and appeals rules 481—Chapter 65, or, if the facility is a distinct part of a hospital, pursuant to department of inspections and appeals rule 481—51.33(135B). A distinct part of a general hospital may be considered a psychiatric institution. In addition, the facility shall be certified to participate in the Iowa Medicaid program as a nursing facility pursuant to 441—Chapter 81 and shall be 16 beds or more. The facility shall also meet the criteria set forth in subrule 85.1(1).

441—85.42(249A) Out-of-state placement. Placement in out-of-state nursing facilities for persons with mental illness is not payable.

441—85.43(249A) Eligibility of persons aged 65 and over. To be eligible for payment for the cost of care provided by nursing facilities for persons with mental illness, persons must be aged 65 or over and be eligible under one of the coverage groups listed in rule 441—75.1(249A), except for medically needy.

441—85.44(249A) Client participation. The resident's client participation and medical payments from a third party shall be paid toward the total cost of care on a monthly basis. The state will pay the balance of the cost of care for the month. The facility shall make arrangements directly with the resident for payment of client participation. Client participation is determined according to rule 441—75.16(249A).

441—85.45(249A) Responsibilities of nursing facility.

85.45(1) *Medical record requirements.* The facility shall obtain a PRO determination that the person requires psychiatric care when a person applying or eligible for Medicaid enters the facility, returns from an acute care hospital stay longer than 10 days, or enters the facility after 30 consecutive days of visitation. Periodic PRO determinations of the need for continuing care are also required.

85.45(2) *Fiscal records.*

a. A Case Activity Report, Form 470-0042, shall be submitted to the department whenever a Medicaid applicant or recipient enters the facility, changes level of care, is hospitalized, leaves for visitation, or is discharged from the facility.

b. The facility shall bill after each calendar month for the previous month's services.

441—85.46(249A) Policies governing reimbursement. Cost reporting, reserve bed day payment, and reimbursement shall be the same for nursing facilities for persons with mental illness as for nursing facilities as set forth in 441—Chapter 81.

441—85.47(249A) State-funded personal needs supplement. A Medicaid member living in an intermediate care facility for persons with mental illness who has countable income for purposes of rule 441—75.16(249A) of less than $50 per month shall receive a state-funded payment from the department for the difference between that countable income and $50 if the legislature has appropriated funding specifically for this purpose. This payment shall not be considered a benefit under Title XIX of the Social Security Act.

This rule is intended to implement Iowa Code Supplement section 249A.30A.

These rules are intended to implement Iowa Code section 249A.4.

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CHAPTER 109
CHILD CARE CENTERS

[Filed as Chapter 108, 2/14/75 and renumbered 7/1/75]
[Prior to 7/1/83, Social Services[770] Ch 109]
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PREAMBLE

The intent of this chapter is to specify minimum requirements for licensed child care centers and preschools and to define those child-caring environments that are governed by the licensing standards. The licensing standards govern licensing procedures, administration, parental participation, personnel, records, health and safety policies, physical facilities, activity programs, and food services.

441—109.1(237A) Definitions.

"Adult" means a person 18 years of age or older.

"Child" means either of the following:

1. A person 12 years of age or younger.
2. A person 13 years of age or older but younger than 19 years of age who has a developmental disability, as defined under the federal Developmental Disabilities Assistance and Bill of Rights Act of 2000, Public Law No. 106-402, codified in 42 U.S.C. 15002(8).

"Child care" means the care, supervision, or guidance of a child by a person other than the parent, guardian, or custodian for periods of less than 24 hours per day per child on a regular basis in a place other than the child's home, but does not include care, supervision, or guidance of a child by any of the following:

1. An instructional program administered by a public or nonpublic school system accredited by the department of education or the state board of regents or a program provided under Iowa Code sections 279.49 and 280.3A.
2. Any of the following church-related programs:
   - An instructional program.
   - A youth program other than a preschool, before or after school child care program, or other child care program.
   - A program providing care to children on church premises while the children's parents are attending church-related or church-sponsored activities on the church premises.
3. Short-term classes of less than two weeks' duration held between school terms or during a break within a school term.
4. A child care center for sick children operated as part of a pediatrics unit in a hospital licensed by the department of inspections and appeals pursuant to Iowa Code chapter 135B.
5. A program operated not more than one day per week by volunteers that meets all the following conditions:
   - Not more than 11 children are served per volunteer.
   - The program operates for less than 4 hours during any 24-hour period.
   - The program is provided at no cost to the children's parent, guardian, or custodian.
6. A nationally accredited camp.
7. A program administered by a political subdivision of the state which is primarily for recreational or social purposes and is limited to children who are five years of age or older and attending school.
8. An instructional program for children at least four years of age who are attending prekindergarten, as defined by the state board of education, or a higher grade level, administered by a nonpublic school system which is not accredited by the department of education or the state board of regents.
9. An after-school program continuously offered throughout the school year to children who are at least five years of age and enrolled in school and attend the program intermittently, or a summer-only program for such children. The program must be provided through a nominal membership fee or at no cost.

10. A special activity program which meets less than four hours per day for the sole purpose of the special activity. Special activity programs include but are not limited to music or dance classes, organized athletic or sports programs, recreational classes, scouting programs, and hobby or craft clubs or classes.

11. A structured program for the purpose of providing therapeutic, rehabilitative, or supervisory services to children under any of the following:

- A purchase of service or managed care contract with the department.
- A contract approved by a local decategorization governance board.
- An arrangement approved by a juvenile court order.

12. Care provided on site to children of parents residing in an emergency, homeless, or domestic violence shelter.

13. A child care facility providing respite care to a licensed foster family home for a period of 24 hours or more to a child who is placed with that licensed foster family home.

14. A program offered to a child whose parent, guardian, or custodian is engaged solely in a recreational or social activity, remains immediately available and accessible on the physical premises on which the child's care is provided, and does not engage in employment while the care is provided.

"Child care center" or *"center"* means a facility providing child day care for seven or more children, except when the facility is registered as a child development home. For the purposes of this chapter, the word "center" shall apply to a child care center or preschool, unless otherwise specified.

"Child care facility" or *"facility"* means a child care center, a preschool, or a registered child development home.

"Department" means the department of human services.

"Direct responsibility for child care" means being charged with the care, supervision, or guidance of a child.

"Extended evening care" means child care provided by a child care center between the hours of 9 p.m. and 5 a.m.

"Facility" means a building or physical plant established for the purpose of providing child day care.

"Get-well center" means a facility that cares for a child with an acute illness of short duration for short enrollment periods.

"Involvement with child care" means licensed or registered as a child care facility, employed in a child care facility, residing in a child care facility, receiving public funding for providing child care, providing child care as a child care home provider, or residing in a child care home.

"National Health and Safety Performance Standards" means the National Health and Safety Performance Standards: Guidelines for Out-of-Home Child Care Programs produced by the American Public Health Association and the American Academy of Pediatrics with the support of the Maternal and Child Health Bureau, Department of Health and Human Services.

"Parent" means parent or legal guardian.

"Person subject to an evaluation" means a person who has committed a transgression and who is described by any of the following:

1. The person is being considered for licensure or is licensed.
2. The person is being considered by a child care facility for employment involving direct responsibility for a child or with access to a child when the child is alone, or the person is employed with such responsibilities.
3. The person will reside or resides in a child care facility.
4. The person has applied for or receives public funding for providing child care.

"Preschool" means a child day care facility which provides care to children aged three through five, for periods of time not exceeding three hours per day. The preschool's program is designed to help the children develop intellectual, social and motor skills, and to extend their interest in and understanding of the world about them.

"Regulatory fee" means the amount payable to the department for licensure of a child care center based on the capacity of the center.

"Transgression" means the existence of any of the following in a person's record:

1. Conviction of a crime.
2. A record of having committed founded child or dependent adult abuse.
3. Listing in the sex offender registry established under Iowa Code chapter 692A.
4. A record of having committed a public or civil offense.
5. Department revocation or denial of a child care facility registration or license due to the person's continued or repeated failure to operate the child care facility in compliance with licensing and registration laws and rules.

"Unrestricted access" means that a person has contact with a child alone or is directly responsible for child care.

[**ARC 8650B**, IAB 4/7/10, effective 6/1/10]

441—109.2(237A) Licensure procedures.

109.2(1) *Application for license.*

a. Any adult or agency has the right to apply for a license. The application for a license shall be made to the department on Form 470-0722, Application for a License to Operate a Child Care Center, provided by the department.

b. Requested reports including the fire marshal's report and other information relevant to the licensing determination shall be furnished to the department upon application and renewal. A building owned or leased by a school district or accredited nonpublic school that complies with rules adopted by the state fire marshal for school buildings under 661—Chapter 5 is considered appropriate for use by a child care facility.

c. When a center makes a sufficient application for an initial license, it may operate for a period of up to 120 calendar days from the date of issuance of Form 470-4690, Permission to Open Without a License, pending a final licensing decision. A center has made a sufficient application when it has submitted the following to the department:

(1) An application for a license.

(2) An approved fire marshal's report.

(3) A floor plan indicating room descriptions and dimensions, including location of windows and doors.

(4) Information sufficient to determine that the center director meets minimum personnel qualifications.

d. Applicants shall be notified of approval or denial of initial applications within 120 days from the date the application is submitted.

(1) If the applicant has been issued Form 470-4690, Permission to Open Without a License, the applicant shall be notified of approval or denial within 120 calendar days of the date of issuance of Form 470-4690.

(2) No full or provisional license shall be issued before payment of the applicable regulatory fee as determined pursuant to subrule 109.2(7).

e. The department shall not act on a licensing application for 12 months after an applicant's child care center license has been denied or revoked.

f. When the department has denied or revoked a license, the applicant or person shall be prohibited from involvement with child care unless the department specifically permits involvement through a record check decision.

109.2(2) *License.*

a. An applicant showing full compliance with center licensing laws and these rules, including department approval of center plans and procedures and submission of the regulatory fee as specified in subrule 109.2(7) to the department by the date due, shall be issued a license for 24 months. In determining whether or not a center is in compliance with the intent of a licensing standard outlined in this chapter, the department shall make the final decision.

b. A new license shall be applied for when the center moves, expands, or the facility is remodeled to change licensed capacity.

c. A new license shall be applied for when another adult or agency assumes ownership or legal responsibility for the center.

109.2(3) *Provisional license.*

a. A provisional license may be issued or a previously issued license may be reduced to a provisional license for a period up to one year when the center does not meet all standards imposed by law and these rules.

b. A provisional license shall be renewable when written plans giving specific dates for completion to bring the center up to standards are submitted to and approved by the department. A provisional license shall not be reissued for more than two consecutive years when the lack of compliance with the same standards has not been corrected within two years.

c. When the center submits documentation or it can otherwise be verified that the center fully complies with all standards imposed by law or these rules, the license shall be upgraded to a full license.

109.2(4) *Denial.* Initial applications or renewals shall be denied when:

a. The center does not comply with center licensing laws and these rules in order to qualify for a full or provisional license.

b. The center is operating in a manner which the department determines impairs the safety, health, or well-being of children in care.

c. A person subject to an evaluation has transgressions that merit prohibition of involvement with child care and of licensure, as determined by the department.

d. Information provided either orally or in writing to the department or contained in the center's files is shown to have been falsified by the provider or with the provider's knowledge.

e. The center is not able to obtain an approved fire marshal's certificate as prescribed by the state fire marshal in 661—Chapter 5 or Iowa Code chapter 100 or fails to comply in correcting or repairing any deficiencies in the time determined by the fire marshal or the fire marshal determines the facility is not safe for occupancy.

f. The regulatory fee as specified in subrule 109.2(7) is not received by the department's division of fiscal management by the due date indicated on Form 470-4834, Child Care Center Licensing Fee Invoice.

109.2(5) *Revocation and suspension.* A license shall be revoked or suspended if corrective action has not been taken when:

a. The center does not comply with center licensing laws or these rules.

b. The center is operating in a manner which the department determines impairs the safety, health, or well-being of the children in care.

c. A person subject to an evaluation has transgressions that merit prohibition of involvement with child care and of licensure, as determined by the department.

d. Information provided to the department or contained in the center's files is shown to have been falsified by the provider or with the provider's knowledge.

e. The facility is not able to obtain an approved fire marshal's certificate as prescribed by the state fire marshal in 661—Chapter 5 or Iowa Code chapter 100 or fails to comply in correcting or repairing any deficiencies in the time determined by the fire marshal or the fire marshal determines the facility is not safe for occupancy.

f. The regulatory fee as specified in subrule 109.2(7) is not paid in full due to insufficient funds to cover a check submitted to the department for the fee.

109.2(6) *Adverse actions.*

a. Notice of adverse actions for a denial, revocation, or suspension and the right to appeal the licensing decision shall be given to applicants and licensees in accordance with 441—Chapter 7.

b. An applicant or licensee affected by an adverse action may request a hearing by means of a written request directed to the Department of Human Services, Appeals Section, 1305 E. Walnut Street, Fifth Floor, Des Moines, Iowa 50319-0114. The request shall be submitted within 30 days after the date the department mailed the official notice containing the nature of the denial, revocation, or suspension.

c. A letter received by an owner or director of a licensed center initiating action to deny, suspend, or revoke the facility's license shall be conspicuously posted at the main entrance to the facility where

it can be read by parents or any member of the public. The letter shall remain posted until resolution of the action to deny, suspend or revoke the license. If the action to deny, suspend, or revoke is upheld, the center shall return the license to the department.

d. If the center's license is denied, suspended or revoked, the department shall notify the parent, guardian, or legal custodian of each child for whom the facility provides child care. The center shall cooperate with the department in providing the names and address of the parent, guardian, or legal custodian of each child for whom the facility provides child care.

109.2(7) *Regulatory fees.* For relicensures with an effective date on or after August 1, 2010, as indicated on the license certificate, and for initial applications for licensure submitted on or after June 1, 2010, a fee based upon center capacity is due to the department before the issuance of the license in accordance with this subrule.

a. *Fee structure.* The amount of the fee is based on the capacity of the center as indicated below:

Center Capacity	Fee Amount
0 to 20 children	$50
21 to 50 children	$75
51 to 100 children	$100
101 to 150 children	$125
151 or more children	$150

b. *Determination of capacity.* The licensing consultant shall determine center capacity by dividing the amount of usable space by the amount of space required per child, as specified in subrule 109.11(1) and subparagraphs 109.11(3)*"a"*(2) and (3). Upon approval by the department, the final determination of center capacity may include evaluation of other factors that influence capacity, as long as physical space requirements per child as defined in subrule 109.11(1) and subparagraphs 109.11(3)*"a"*(2) and (3) are maintained.

c. *Notification.* Upon final determination of center capacity by the licensing consultant, the licensing consultant or designee shall sign and provide Form 470-4834, Child Care Center Licensing Fee Invoice, to the center.

d. *Payment.* The center shall return Form 470-4834 to the department with the licensing fee payment within 30 calendar days from the date of the licensing consultant's or designee's signature on Form 470-4834. Payment may be in the form of cash, check, money order, or cashier's check.

(1) Payment must be received before the department will issue a full or provisional license.

(2) Regulatory fees are nonrefundable and nontransferrable.

[**ARC 8650B**, IAB 4/7/10, effective 6/1/10]

441—109.3(237A) Inspection and evaluation. The department shall conduct an on-site visit in order to make a licensing recommendation for all initial and renewal applications for licensure and shall determine compliance with licensing standards imposed by licensing laws and these rules when a complaint is received.

109.3(1) At least one unannounced on-site visit shall be conducted each calendar year.

109.3(2) After each visit and complaint, the department shall document whether a center was in compliance with center licensing standards imposed by licensing laws and these rules.

109.3(3) The written documentation of the department's conclusion as to whether a center was in compliance with licensing standards for all licensing visits and complaints shall be available to the public. However, the identity of the complainant shall be withheld unless expressly waived by the complainant.

441—109.4(237A) Administration.

109.4(1) *Purpose and objectives.* Incorporated and unincorporated centers shall submit a written statement of purpose and objectives. The plan and practices of operation shall be consistent with this statement.

109.4(2) *Required written policies.* The child care center owner, board or director shall:

a. Develop fee policies and financial agreements for the children served.

b. Develop and implement policies for enrollment and discharge of children, field trips and non-center activities, transportation, discipline, nutrition, and health and safety policies.

c. Develop a curriculum or program structure that uses developmentally appropriate practices and an activity program appropriate to the developmental level and needs of the children.

d. Develop and implement a written plan for staff orientation to the center's policies and to the provisions of 441—Chapter 109 where applicable to staff.

e. Develop and implement a written plan for ongoing training and staff development in compliance with professional growth and development requirements established by the department in rule 441—109.7(237A).

f. Make available for review a copy of the center policies and program to all staff at the time of employment and each parent at the time a child is admitted to the center. A copy of the fee policies and financial agreements shall be provided to each parent at the time a child is admitted to the center.

g. Develop and implement a policy for responding to incidents of biting that includes the following elements.

(1) An explanation of the center's perspective on biting.

(2) A description of how the center will respond to individual biting incidents and episodes of ongoing biting.

(3) A description of how the center will assess the adequacy of caregiver supervision and the context and the environment in which the biting occurred.

(4) A description of how the center will respond to the individual child or caregiver who was bitten.

(5) A description of the process for notification of parents of children involved in the incident.

(6) A description of how the incident will be documented.

(7) A description of how confidentiality will be protected.

(8) A description of first-aid procedures that the center will use in response to biting incidents.

h. Develop a policy to ensure that people do not have unauthorized access to children at the center. The policy shall be subject to review for minimum safety standards by the licensing consultant. The policy shall include but is not limited to the following:

(1) The center's criteria for allowing people to be on the property of the facility when children are present.

(2) A description of how center staff will supervise and monitor people who are permitted on the property of the center when children are present, but who have not been cleared for involvement with child care through the formal record check process as outlined in subrule 109.6(6). The description shall include definitions of "supervision" and "monitoring."

(3) A description of how responsibility for supervision and monitoring of people in the center will be delegated to center staff, which includes provisions that address conflicts of interest.

(4) A description of how the policy will be shared with parents, guardians, and custodians of all children who are enrolled at the center.

109.4(3) *Required postings.*

a. Postings are required for the certificate of license, notice of exposure of children to a communicable disease, and notice of actions to deny, suspend, or revoke the center's license and shall be conspicuously placed at the main entrance to the center. If the center is located in a building used for additional purposes and shares the main entrance to the building, the required postings shall be conspicuously placed in the center in an area that is frequented daily by parents or the public.

b. Postings are required for mandatory reporter requirements, the notice of availability of the handbook required in subrule 109.4(5), and the program activities and shall be placed in an area that is frequented daily by parents or the public.

109.4(4) *Mandatory reporters.* Requirements and procedures for mandatory reporting of suspected child abuse as defined in Iowa Code section 232.69 shall be posted where they can be read by staff and parents. Methods of identifying and reporting suspected child abuse and neglect shall be discussed with all staff within 30 days of employment.

109.4(5) *Handbook.* A copy of Form SS-0711, Child Care Centers and Preschools Licensing Standards and Procedures, shall be available in the center, and a notice stating that a copy is available for review upon request from the center director shall be conspicuously posted. The name, office mailing address and telephone number of the child care consultant shall be included in the notice.

109.4(6) *Certificate of license.* The child care license shall be posted in a conspicuous place and shall state the particular premises in which child care may be offered and the number of children who may be cared for at any one time. Notwithstanding the requirements in rule 441—109.8(237A), no greater number of children than is authorized by the license shall be cared for at any one time.

[**ARC 8650B**, IAB 4/7/10, effective 6/1/10]

441—109.5(237A) Parental participation.

109.5(1) *Unlimited access.* Parents shall be afforded unlimited access to their children and to the provider caring for their children during the center's hours of operation or whenever their children are in the care of a provider, unless parental contact is prohibited by court order. The provider shall inform all parents of this policy in writing at the time the child is admitted to the center.

109.5(2) *Parental evaluation.* If requested by the department, centers shall assist the department in conducting an annual survey of parents being served by their center by providing to parents Form 470-3409, Parent Survey: Child Care Centers. The department shall notify centers of the time frames for distribution and completion of the survey and the procedures for returning the survey to the department. The purpose of the survey shall be to increase parents' understanding of developmentally appropriate and safe practice, solicit statewide information regarding parental satisfaction with the quality of care being provided to children and obtain the parents' perspective regarding the center's compliance with licensing requirements.

441—109.6(237A) Personnel. The board or director of the center shall develop policies for hiring and maintaining staff that demonstrate competence in working with children and that meet the following minimum requirements:

109.6(1) *Center director requirements.* Centers that have multiple sites shall have a center director or on-site supervisor in each center. The center director is responsible for the overall functions of the center, including supervising staff, designing curriculum and administering programs. The director shall ensure services are provided for the children within the framework of the licensing requirements and the center's statement of purpose and objectives. The center director shall have overall responsibility for carrying out the program and ensuring the safety and protection of the children. Information shall be submitted in writing to the child care consultant prior to the start of employment. Final determination shall be made by the department. Information shall be submitted sufficient to determine that the director meets the following minimum qualifications:

a. Is at least 21 years of age.

b. Has obtained a high school diploma or passed a general education development test.

c. Has completed at least one course in business administration or 12 contact hours in administrative-related training related to personnel, supervision, record keeping, or budgeting or has one year of administrative-related experience.

d. Has certification in infant, child, and adult cardiopulmonary resuscitation (CPR), first aid, and Iowa's training for the mandatory reporting of child abuse.

e. Has achieved a total of 100 points obtained through a combination of education, experience, and child development-related training as outlined in the following chart:

EDUCATION		EXPERIENCE (Points multiplied by years of experience)		CHILD DEVELOPMENT-RELATED TRAINING
Bachelor's or higher degree in early childhood, child development, or elementary education	75	Full-time (20 hours or more per week) in a child care center or preschool setting	20	One point per contact hour of training
Associate's degree in child development or bachelor's degree in a child-related field	50	Part-time (less than 20 hours per week) in a child care center or preschool setting	10	
Child development associate (CDA) or one-year diploma in child development from a community college or technical school	40	Full-time (20 hours or more per week) child development-related experience	10	
Bachelor's degree in a non-child-related field	40	Part-time (less than 20 hours per week) child development-related experience	5	
Associate's degree in a non-child-related field or completion of at least two years of a four-year degree	20	Registered child development home provider	10	
		Nonregistered family home provider	5	

(1) In obtaining the total of 100 points, a minimum of two categories must be used, no more than 75 points may be achieved in any one category, and at least 20 points shall be obtained from the experience category.

(2) Points obtained in the child development-related training category shall have been taken within the past five years.

(3) For directors in centers predominantly serving children with special needs, the directors may substitute a disabilities-related or nursing degree for the bachelor's degree in early childhood, child development or elementary education in determining point totals. In addition, experience in working with children with special needs in an administrative or direct care capacity shall be equivalent to full-time experience in a child care center or preschool in determining point totals.

(4) For directors in centers serving predominantly school-age children, the directors may substitute a degree in secondary education, physical education, recreation or related fields for the bachelor's degree in early childhood, child development or elementary education in determining point totals. In addition, child-related experience working with school-age children shall be equivalent to full-time experience in a child care center or preschool in determining point totals.

109.6(2) *On-site supervisor.* The on-site supervisor is responsible for the daily supervision of the center and must be on site daily either during the hours of operation that children are present or a minimum of eight hours of the center's hours of operation. Information shall be submitted in writing to the child care consultant prior to the start of employment. Final determination shall be made by the department. Information shall be submitted sufficient to determine that the on-site supervisor meets the following minimum qualifications:

a. Is an adult.

b. Has obtained a high school diploma or passed a general education development test.

c. Has certification in infant, child, and adult cardiopulmonary resuscitation (CPR), first aid, and Iowa's mandatory reporting of child abuse.

d. Has achieved a total of 75 points obtained through a combination of education, experience, and child development-related training as outlined in the following chart:

EDUCATION		EXPERIENCE (Points multiplied by years of experience)		CHILD DEVELOPMENT-RELATED TRAINING
Bachelor's or higher degree in early childhood, child development, or elementary education	75	Full-time (20 hours or more per week) in a child care center or preschool setting	20	One point per contact hour of training
Associate's degree in child development or bachelor's degree in a child-related field	50	Part-time (less than 20 hours per week) in a child care center or preschool setting	10	
Child development associate (CDA) or one-year diploma in child development from a community college or technical school	40	Full-time (20 hours or more per week) child development-related experience	10	
Bachelor's degree in a non-child-related field	40	Part-time (less than 20 hours per week) child development-related experience	5	
Associate's degree in a non-child-related field or completion of at least two years of a four-year degree	20	Registered child development home provider	10	
		Nonregistered family home provider	5	

(1) In obtaining the total of 75 points, a minimum of two categories must be used, no more than 50 points may be achieved in any one category, and at least 10 points shall be obtained from the experience category.

(2) Points obtained in the child development-related training category shall have been taken within the past five years.

(3) For on-site supervisors in centers predominantly serving children with special needs, the on-site supervisor may substitute a disabilities-related or nursing degree for the bachelor's degree in early childhood, child development or elementary education in determining point totals. In addition, experience in working with children with special needs in an administrative or direct care capacity shall be equivalent to full-time experience in a child care center or preschool in determining point totals.

(4) For on-site supervisors in centers serving predominantly school-age children, the on-site supervisor may substitute a degree in secondary education, physical education, recreation or related fields for the bachelor's degree in early childhood, child development or elementary education in determining point totals. In addition, child-related experience working with school-age children shall be equivalent to full-time experience in a child care center or preschool in determining point totals.

109.6(3) *Director and on-site supervisor functions combined.* In a center where the functions of the center director and the on-site supervisor are accomplished by the same person, the educational and experience requirements for a center director shall apply. If the center director is serving in the role of the on-site supervisor, the director shall be on site daily either during the hours of operation or a minimum of at least eight hours of the center's hours of operation. If the staff person designated as the on-site supervisor is temporarily absent from the center, another responsible adult staff shall be designated as the interim on-site supervisor.

109.6(4) *Transition period for staff.* In achieving the qualifications outlined in rule 441—109.6(237A), staff hired prior to April 1, 1998, shall obtain the education, experience or child-developmental training sufficient to meet the required point totals by April 1, 1999.

109.6(5) *Volunteers and substitutes.* A volunteer shall be at least 16 years of age. All volunteers and substitutes shall:

a. Sign a statement indicating whether or not they have one of the following:

(1) A conviction of any law in any state or any record of founded child abuse or dependent adult abuse in any state.

(2) A communicable disease or other health concern that could pose a threat to the health, safety, or well-being of the children.

b. Sign a statement indicating the volunteer or substitute has been informed of the volunteer's or substitute's responsibilities as a mandatory reporter.

c. Undergo the record check process when the person is responsible for child care for a child other than the person's own child or has access to other children when they are alone. Records of the record check process shall be maintained as required in subparagraph 109.9(1)*"b."*

109.6(6) *Record checks.*

a. Applicability.

(1) Criminal and child abuse record checks shall be conducted for:

1. Each owner, director, staff member, substitute, volunteer, or subcontracted staff person with direct responsibility for child care or with access to a child when the child is alone;

2. Anyone living in the child care facility who is 14 years of age or older.

(2) Parents, guardians, and custodians are exempt from the record check process in relation to access to their own children or wards.

(3) Professional staff who hold a current, valid license issued by the educational examiners board are exempt from the record check process in relation to children in the center to whom they provide professional services consistent with Iowa Code chapter 272 and rules adopted by the educational examiners board.

b. Authorization. The person subject to record checks shall complete Form 595-1396, DHS Criminal History Record Check Form B, and any other forms required by the department of public safety to authorize the release of records.

c. Iowa records checks. Checks and evaluations of Iowa child abuse and criminal records, including the sex offender registry, shall be completed before the person's involvement with child care at the center. Iowa records checks shall be repeated at a minimum of every two years and when the department or the center becomes aware of any possible transgressions. The department is not responsible for the cost of conducting the Iowa records check.

(1) The child care center may access the single-contact repository (SING) as necessary to conduct a criminal and child abuse record check of the person in Iowa. If the results of the check indicate a potential transgression, the center shall send a copy of the results to the department for determination of whether or not the person may be involved with child care, regardless of the person's status with the center.

(2) Unless a record check has already been conducted in accordance with subparagraph (1), the department shall conduct a criminal and child abuse record check in Iowa for a person who is subject to a record check. When the department conducts the records check, the fee shall be $25 for each record check through June 30, 2010, and $35 effective July 1, 2010. The center shall submit the fee before the department initiates the record check process. Payment must be in the form of cash, check, money order, or cashier's check. The department may access SING to conduct the records check. The department may also conduct dependent adult abuse, sex offender, and other public or civil offense record checks in Iowa for a person who is subject to a record check.

(3) Centers that participate in student intern programs may seek a waiver for substitution of the state record check process with a check performed by the student's educational institution. Requests for a waiver shall be submitted on Form 470-4893, Record Check Waiver, to the address listed on the form.

d. National criminal history checks. National criminal history checks based on fingerprints are required for all persons subject to record checks under this subrule effective with a center's initial licensure or relicensure on or after June 1, 2010. The national criminal history check shall be repeated for each person every four years and when the department or center becomes aware of any new transgressions committed by that person in another state. The department is not responsible for the cost of conducting the national criminal history check.

(1) The child care center is responsible for obtaining the fingerprints of all persons subject to record checks. Fingerprints may be taken by law enforcement agencies, by agencies or companies

that specialize in taking fingerprints, or by center staff or subcontractors who have received appropriate training in the taking of fingerprints.

(2) If the results of the Iowa records checks do not warrant prohibition of the person's involvement with child care or otherwise present protective concerns, the person may be involved with child care on a provisional basis until the national criminal history check and evaluation have been completed.

(3) The child care center shall provide fingerprints to the department of public safety no later than 30 days after the subject's approval for employment at the center. The center shall submit the fingerprints on forms or in a manner allowed by the department of public safety.

(4) Centers that are required to submit fingerprint-based checks of the FBI national criminal database to comply with federal regulations may seek a waiver to substitute that record check for the procedure required in this subrule. Requests for a waiver shall be submitted on Form 470-4893, Record Check Waiver, to the address listed on the form.

(5) Centers that participate in student intern programs may seek a waiver to substitute the fingerprint-based check of the FBI national criminal database performed by the student's educational institution for the procedure required in this subrule. Requests for a waiver shall be submitted on Form 470-4893, Record Check Waiver, to the address listed on the form.

(6) A center considering involvement of a person who has had a national criminal history check at another center may request information from that center. That center may provide the following information in writing upon a center's request, using Form 470-4896, National Criminal History Check Confirmation:

1. Date of most recent national criminal history check conducted by the center on the person in question, and

2. Whether or not the national check process resulted in clearance of the person for involvement with child care.

(7) If the results of the national criminal history check indicate that the person has committed a transgression, the center, if interested in continuing the person's involvement in child care, shall send a copy of the results to the department for evaluation. The department shall determine whether or not the person may be involved with child care.

(8) A center shall submit all required fingerprints to the department of public safety before the issuance or renewal of the center's license on or after June 1, 2010. EXCEPTION: Centers that have an initial or renewal licensure date of June 1, 2010, shall have until July 1, 2010, to submit the fingerprints to the department of public safety.

e. Mandatory prohibition. A person with the following convictions or founded abuse reports is prohibited from involvement with child care:

(1) Founded child or dependent adult abuse that was determined to be sexual abuse.

(2) Placement on the sex offender registry.

(3) Felony child endangerment or neglect or abandonment of a dependent person.

(4) Felony domestic abuse.

(5) Felony crime against a child including, but not limited to, sexual exploitation of a minor.

(6) Forcible felony.

f. Mandatory time-limited prohibition.

(1) A person with the following convictions or founded abuse reports is prohibited from involvement with child care for five years from the date of the conviction or founded abuse report:

1. Conviction of a controlled substance offense under Iowa Code chapter 124.

2. Founded child abuse that was determined to be physical abuse.

(2) After the five-year prohibition period imposed pursuant to 109.6(6)*"f"*(1), the person may request the department to perform an evaluation under paragraph 109.6(6)*"g"* to determine whether prohibition of the person's involvement with child care continues to be warranted.

g. Evaluation required. For all other transgressions, and as requested under subparagraph 109.6(6)*"f"*(2), the department shall notify the affected person and the licensee that an evaluation shall be conducted to determine whether prohibition of the person's involvement with child care is warranted.

(1) The person with the transgression shall complete and return Form 470-2310, Record Check Evaluation, within ten calendar days of the date on the form. The department shall use the information the person with the transgression provides on this form to assist in the evaluation. Failure of the person with the transgression to complete and return this form by the specified date shall result in denial or revocation of the license or denial of employment.

(2) The department may use information from the department's case records in performing the evaluation.

(3) In an evaluation, the department shall consider all of the following factors:

1. The nature and seriousness of the transgression in relation to the position sought or held.
2. The time elapsed since the commission of the transgression.
3. The circumstances under which the transgression was committed.
4. The degree of rehabilitation.
5. The likelihood that the person will commit the transgression again.
6. The number of transgressions committed by the person.

h. *Evaluation decision.* Within 30 days of receipt of a completed Form 470-2310, Record Check Evaluation, the department shall make a decision on the person's involvement with child care. The department has final authority in determining whether prohibition of the person's involvement with child care is warranted and in developing any conditional requirements and corrective action plan under this paragraph.

(1) The department shall mail to the individual on whom the evaluation was completed Form 470-2386, Record Check Decision, that explains the decision reached regarding the evaluation of the transgression and Form 470-0602, Notice of Decision.

(2) If the department determines through an evaluation of a person's transgressions that the person's prohibition of involvement with child care is warranted, the person shall be prohibited from involvement with child care. The department may identify a period of time after which the person may request that another record check and evaluation be performed.

(3) The department may permit a person who is evaluated to maintain involvement with child care if the person complies with the department's conditions and corrective action plan relating to the person's involvement with child care.

(4) The department shall send a letter to the employer that informs the employer whether the person subject to an evaluation has been approved or denied involvement with child care. If the person has been approved, the letter shall inform the employer of any conditions and corrective action plan relating to the person's involvement with child care.

i. *Notice to parents.* The department shall notify the parent, guardian, or legal custodian of each child for whom the person provides child care if there has been founded child abuse committed by an owner, director, or staff member of the child care center. The center shall cooperate with the department in providing the names and addresses of the parent, guardian, or legal custodian of each child for whom the facility provides child care.

109.6(7) *Use of controlled substances and medications.* All owners, personnel, and volunteers shall be free of the use of illegal drugs and shall not be under the influence of alcohol or of any prescription or nonprescription drug that could impair their ability to function.

[**ARC 8650B**, IAB 4/7/10, effective 6/1/10]

441—109.7(237A) Professional growth and development. The center director, on-site supervisor, and staff counted as part of the staff ratio shall meet the following minimum staff training requirements:

109.7(1) *Required training within the first six months of employment.* During their first six months of employment, all staff shall receive the following training:

a. Two hours of Iowa's training for mandatory reporting of child abuse.

b. At least one hour of training regarding universal precautions and infectious disease control.

109.7(2) *Center directors and staff employed 20 hours or more per week.* The requirements of this subrule apply to all center directors, regardless of whether the director works on a full-time or part-time basis.

a. During their first year of employment, all center directors and all staff employed 20 hours or more per week shall receive the following training:

(1) Certification in American Red Cross or American Heart Association infant, child, and adult cardiopulmonary resuscitation (CPR) or equivalent certification approved by the department. A valid certificate indicating the date of training and expiration date shall be maintained.

(2) Certification in infant, child, and adult first aid that uses a nationally recognized curriculum or is received from a nationally recognized training organization including the American Red Cross, American Heart Association, the National Safety Council, and Emergency Medical Planning (Medic First Aid) or an equivalent certification approved by the department. A valid certificate indicating the date of training and expiration date shall be maintained.

(3) Ten contact hours of training from one or more of the following content areas:

1. Planning a safe, healthy learning environment (includes nutrition).
2. Steps to advance children's physical and intellectual development.
3. Positive ways to support children's social and emotional development (includes guidance and discipline).
4. Strategies to establish productive relationships with families (includes communication skills and cross-cultural competence).
5. Strategies to manage an effective program operation (includes business practices).
6. Maintaining a commitment to professionalism.
7. Observing and recording children's behavior.
8. Principles of child growth and development.

(4) At least four hours of the ten contact hours of training shall be received in a group setting as defined in subrule 109.7(7). Six hours may be received in self-study using a training package approved by the department as defined in subrule 109.7(8). Training received for cardiopulmonary resuscitation (CPR), first aid, mandatory reporting of child abuse, and universal precautions shall not count toward the ten contact hours. A provider shall not use a specific training or class to meet minimum continuing education requirements more than one time every five years.

(5) Center directors and on-site supervisors shall receive all ten hours of training in a group setting as defined in subrule 109.7(7).

(6) Staff who have completed a comprehensive training package of at least ten contact hours offered through a child care resource and referral agency or community college within six months prior to initial employment shall have the first year's ten contact hours of training waived.

b. Following their first year of employment, all center directors and all staff who are employed 20 hours or more a week shall:

(1) Maintain current certification for Iowa's training for the mandatory reporting of child abuse; infant, child and adult CPR; and infant, child and adult first aid.

(2) Receive six contact hours of training annually from one or more of the content areas listed in subparagraph 109.7(2)*"a"*(3). A provider shall not use a specific training or class to meet minimum continuing education requirements more than one time every five years.

(3) Center directors and on-site supervisors shall receive eight contact hours of training annually from one or more of the content areas listed in subparagraph 109.7(2)*"a"*(3). At least four of the eight contact hours shall be in a group setting as defined in subrule 109.7(7).

109.7(3) *Staff employed less than 20 hours per week.*

a. During their first year of employment, all staff who are employed less than 20 hours a week shall receive the following training:

(1) Five contact hours of training from one or more of the following topical areas: child development, guidance and discipline, developmentally appropriate practices, nutrition, health and safety, communication skills, professionalism, business practices, and cross-cultural competence.

(2) At least two of the five contact hours shall be in a sponsored group setting.

(3) Staff who have completed a comprehensive training package of at least ten contact hours offered through a child care resource and referral agency or community college within six months prior to initial employment shall have the five contact hours required in the first year waived.

b. Following their first year of employment, all staff who are employed less than 20 hours a week shall:

(1) Maintain current certification for Iowa's training for mandatory reporting of child abuse.

(2) Receive four contact hours of training annually from one or more of the following topical areas: child development, guidance and discipline, developmentally appropriate practices, nutrition, health and safety, communication skills, professionalism, business practices, and cross-cultural competence. At least two of the four contact hours shall be in a sponsored group setting.

109.7(4) *Staff employed in centers that operate summer-only programs.* Staff who are employed in centers that operate only in the summer months when school is not in session shall receive the following training:

a. Two hours of Iowa's training for mandatory reporting of child abuse.

b. At least one hour of training regarding universal precautions and infectious disease control.

c. At least one staff person on duty in the center and outdoor play area when children are present and on field trips shall have certification in American Red Cross or American Heart Association infant, child, and adult cardiopulmonary resuscitation (CPR) or equivalent certification approved by the department. A valid certificate indicating the date of training and expiration date shall be maintained.

d. At least one staff person on duty in the center and outdoor play area when children are present and on field trips shall receive certification in infant, child and adult first aid that uses a nationally recognized curriculum or is received from a nationally recognized training organization including the American Red Cross, American Heart Association, the National Safety Council, and Emergency Medical Planning (Medic First Aid) or an equivalent certification approved by the department. A valid certificate indicating the date of training and expiration date shall be maintained.

109.7(5) *Training plans.* Training shall supplement educational and experience requirements in rule 441—109.6(237A) and shall enhance the staff's skill in working with the developmental and cultural characteristics of the children served.

109.7(6) *Substitution.* A provider who submits documentation from a child care resource and referral agency that the provider has completed the Iowa Program for Infant/Toddler Care (IA PITC), ChildNet, or Beyond Business Basics training series may use those hours to fulfill a maximum of two years' training requirements, not including first-aid and mandatory reporter training.

109.7(7) *Group training.* Training received in a group setting is not self-study, but is training received with other adults, either in or out of the child care center.

a. The training must be conducted by a trainer who is employed by or under contract with one of the following entities or who uses curriculum or training materials developed or obtained with the written permission of one of the following entities:

(1) An accredited university or college.

(2) A community college.

(3) Iowa State University Extension.

(4) A child care resource and referral agency.

(5) An area education agency.

(6) The regents' center for early developmental education at the University of Northern Iowa.

(7) A hospital (for health and safety, first-aid, and CPR training).

(8) The American Red Cross, the American Heart Association, the National Safety Council, or Medic First Aid (for first-aid and CPR training).

(9) An Iowa professional association, including the Iowa Association for the Education of Young Children (Iowa AEYC), the Iowa Family Child Care Association (IFCCA), the Iowa After School Alliance, and the Iowa Head Start Association.

(10) A national professional association, including the National Association for the Education of Young Children (NAEYC), the National Child Care Association (NCCA), the National Association for Family Child Care (NAFCC), the National After School Association, and the American Academy of Pediatrics.

(11) The Child and Adult Care Food Program and the Special Supplemental Nutrition Program for Women, Infants and Children (WIC).

(12) The Iowa department of public health, department of education, or department of human services.

(13) Head Start agencies or the Head Start technical assistance system.

b. Training received in a group setting must follow a presentation format that incorporates a variety of adult learning methods. The material or content of the training must be obtained from one of the entities listed in paragraph *"a"* or an entity approved under paragraph *"g."* Approved training shall be made available to Iowa child care providers through the child care provider training registry beginning July 1, 2009.

c. Training received in a group setting may include distance learning opportunities such as training conducted over the Iowa communications network, on-line courses, or Web conferencing (webinars) if:

(1) The training meets the requirements in subrule 109.7(9);

(2) The training is taught by an instructor and requires interaction between the instructor and the participants, such as required chats or message boards; and

(3) The training organization meets the requirements listed in this subrule or is approved by the department.

d. The department will not approve more than eight hours of training delivered in a single day.

e. The department may randomly monitor any state-approved training for quality control purposes.

f. Training conducted with staff either during the hours of operation of the facility, staff lunch hours, or while children are resting must not diminish the required staff ratio coverage. Staff shall not be actively engaged in care and supervision and simultaneously participate in training.

g. A training organization not approved by the department may submit training for approval to the department on Form 470-4528, Request for Child Care Training Approval. All approvals, unless otherwise specified, shall be valid for five years. The department shall issue its decision within 30 business days of receipt of a complete request.

109.7(8) *Self-study training.*

a. Self-study training packages approved by the department include curriculum developed and materials distributed by:

(1) Department child care licensing consultants,

(2) Iowa State University Extension, or

(3) A child care resource and referral agency.

b. Self-study training materials not distributed by these entities may be submitted by the training organization to the department for approval on Form 470-4528, Request for Child Care Training Approval. All approvals, unless otherwise specified, shall be valid for five years. The department shall issue its decision within 30 business days of receipt of a complete request.

109.7(9) *Approved training.* Training provided to Iowa child care providers shall offer:

a. Instruction that is consistent with:

(1) Iowa child care regulatory standards;

(2) The Iowa early learning standards; and

(3) The philosophy of developmentally appropriate practice as defined by the National Association for the Education of Young Children, the Program for Infant/Toddler Care, and the National Health and Safety Performance Standards.

b. Content equal to at least one contact hour of training.

c. An opportunity for ongoing interaction and timely feedback, including questions and answers within the contact hours if training is delivered in a group setting.

d. A certificate of training for each participant that includes:

(1) The name of the participant.

(2) The title of the training.

(3) The dates of training.

(4) The content area addressed.

(5) The name of the training organization.

(6) The name of the instructor.

(7) The number of contact hours.

(8) An indication of whether the training was delivered through self-study or in a group setting.
[**ARC 8650B**, IAB 4/7/10, effective 6/1/10]

441—109.8(237A) Staff ratio requirements.

109.8(1) *Staff requirements.* Persons counted as part of the staff ratio shall meet the following requirements:

a. Be at least 16 years of age. If less than 18 years of age, the staff shall be under the direct supervision of an adult.

b. Be involved with children in programming activities.

c. At least one staff person on duty in the center and outdoor play area when children are present and present on field trips shall be over the age of 18 and hold current certification in first aid and cardiopulmonary resuscitation (CPR) as required in rule 441—109.7(237A).

109.8(2) *Staff ratio.* The staff-to-child ratio shall be as follows:

Age of children	Minimum ratio of staff to children
Two weeks to two years	One to every four children
Two years	One to every six children
Three years	One to every eight children
Four years	One to every twelve children
Five years to ten years	One to every fifteen children
Ten years and over	One to every twenty children

a. Combinations of age groupings for children four years of age and older may be allowed and may have staff ratio determined on the age of the majority of the children in the group. If children three years of age and under are included in the combined age group, the staff ratio for children aged three and under shall be maintained for these children. Preschools shall have staff ratios determined on the age of the majority of the children, including children who are three years of age.

b. If a child between the ages of 18 and 24 months is placed outside the infant area, as defined at subrule 109.11(2), the staff ratio of 1 to 4 shall be maintained as would otherwise be required for the group until the child reaches the age of two.

c. Every child-occupied program room shall have adult supervision present in the room.

d. During nap time, at least one staff shall be present in every room where children are resting. Staff ratio requirements may be reduced to one staff per room where children are resting for a period of time not to exceed one hour provided staff ratio coverage can be maintained in the center. The staff ratio shall always be maintained in the infant area.

e. The minimum staff ratio shall be maintained at mealtimes and for any outdoor activities at the center.

f. When seven or more children over the age of three are present on the licensed premises or are being transported in one vehicle, at least two adult staff shall be present. Only one adult is required when a center is transporting children in a center-owned vehicle with parent authorization for the sole purpose of transporting children to and from school. When a center contracts with another entity to provide transportation other than for the purpose of transporting school-age children to or from school, at least one adult staff in addition to the driver shall be present if at least seven children provided care by the center are transported.

g. Any child care center-sponsored program activity involving five or more children conducted away from the licensed facility shall provide a minimum of one additional staff over the required staff ratio for the protection of the children.

h. For a period of two hours or less at the beginning or end of the center's hours of operation, one staff may care for six children or less, provided no more than two of the children are under the age of two years.

i. For centers or preschools serving school-age children, the ratio for school-age children may be exceeded for a period of no more than four hours during a day when school classes start late or are

dismissed early due to inclement weather or structural damage provided the children are already enrolled at the center and the center does not exceed the licensed capacity.

441—109.9(237A) Records.

109.9(1) *Personnel records.* The center shall maintain personnel information sufficient to ensure that persons employed in the center meet minimum staff and training requirements and do not pose any threat to the health, safety, or well-being of the children. Each employee's file shall contain, at a minimum, the following:

a. A statement signed by each individual indicating whether or not the individual has any conviction of violating any law in any state or has any record of founded child abuse or dependent adult abuse in any state.

b. Copies of all records checks kept in accordance with state and federal law regarding confidentiality of records checks. These records shall include:

(1) A copy of Form 595-1396, DHS Criminal History Record Check Form B, or any other permission form approved by the department of public safety for conducting an Iowa or national criminal history record check.

(2) A copy of Form 470-0643, Request for Child Abuse Information, when applicable.

(3) Copies of the results of Iowa records checks conducted through the SING for review by the department upon request.

(4) Copies of national criminal history check results.

(5) Any department-issued documents sent to the center related to a records check, regardless of findings.

c. Reserved.

d. A physical examination report. Personnel shall have good health as evidenced by a preemployment examination, including testing for communicable diseases which shall include testing for tuberculosis, performed within six months prior to beginning employment by a licensed medical doctor, doctor of osteopathy, physician's assistant or advanced registered nurse practitioner and repeated at least every three years after initial employment.

e. Documentation showing the minimum staff training requirements as outlined at rule 441—109.7(237A) are met, including current certifications in first aid and cardiopulmonary resuscitation (CPR) and Iowa's training for the mandatory reporting of child abuse.

f. A photocopy of a valid driver's license if the staff will be involved in the transportation of children.

109.9(2) *Child's file.* Centers shall maintain sufficient information in a file for each child, which shall be updated at least annually or when the parent notifies the center of a change or the center becomes aware of a change, to ensure that:

a. A parent or an emergency contact authorized by the parent can be contacted at any time the child is in the care of the center.

b. Appropriate emergency medical and dental services can be secured for the child while in the center's care.

c. Information is available in the center regarding the specific health and medical needs of a child, including information regarding any professionally prescribed treatment. Information shall include a physical examination report as required at subrule 109.10(1). For a center serving school-age children that operates in the same school facility in which the child attends school, documentation shall include a statement signed by the parent that the immunization information is available in the school file.

d. A child is released only to authorized persons.

e. Documentation of injuries, accidents, or other incidents involving the child is maintained.

f. Parent authorization is obtained for a child to attend center-sponsored field trips and non-center activities. If parental authorization is obtained on an authorization form inclusive of all children participating in the activity, the authorization form shall be kept on file at the center.

109.9(3) *Immunization certificates.* Signed and dated Iowa immunization certificates, provided by the state department of public health, shall be on file for each child enrolled as prescribed by the department of public health at 641—Chapter 7.

109.9(4) *Daily activities.* For each child under two years of age, the center shall make a daily written record. At the end of the child's day at the center, the daily written record shall be provided verbally or in writing to the parent or the person who removes the child from the center. The record shall contain information on each of these areas:

a. The time periods in which the child has slept.

b. The amount of food consumed and the times at which the child has eaten.

c. The time of and any irregularities in the child's elimination patterns.

d. The general disposition of the child.

e. A general summary of the activities in which the child participated.

[**ARC 8650B**, IAB 4/7/10, effective 6/1/10]

441—109.10(237A) Health and safety policies. The child care center shall establish definite health policies, including the criteria for excluding a sick child from the center. The policies shall be consistent with the recommendations of the National Health and Safety Performance Standards and shall include, but are not limited to:

109.10(1) *Physical examination report.*

a. *Preschool-age children.* For each child five years of age and younger not enrolled in kindergarten, the child care center shall require an admission physical examination report, submitted within 30 days from the date of admission, signed by a licensed medical doctor, doctor of osteopathy, physician's assistant or advanced registered nurse practitioner. The date of the physical examination shall be no more than 12 months prior to the first day of attendance at the center. The written report shall include past health history, status of present health including allergies, medications, and acute or chronic conditions, and recommendations for continued care when necessary. Annually thereafter, a statement of health condition, signed by a licensed medical doctor, doctor of osteopathy, physician's assistant or advanced registered nurse practitioner, shall be submitted that includes any change in functioning, allergies, medications, or acute or chronic conditions.

b. *School-age children.* For each child five years of age and older and enrolled in school, the child care center shall require, prior to admission, a statement of health status signed by the parent or legal guardian that certifies that the child is free of communicable disease and that specifies any allergies, medications, or acute or chronic conditions. The statement from the parent shall be submitted annually thereafter.

c. *Religious exemption.* Nothing in this rule shall be construed to require medical treatment or immunization for staff or the child of any person who is a member of a church or religious organization which has guidelines governing medical treatment for disease that are contrary to these rules. In these instances, an official statement from the organization shall be incorporated in the personnel or child's file.

109.10(2) *Medical and dental emergencies.* The center shall have sufficient information and authorization to meet the medical and dental emergencies of children. The center shall have written procedures for medical and dental emergencies and shall ensure, through orientation and training, that all staff are knowledgeable of and able to implement the procedures.

109.10(3) *Medications.* The center shall have written procedures for the dispensing, storage, authorization, and recording of all prescription and nonprescription medications, including the following:

a. All medications shall be stored in their original containers, with accompanying physician or pharmacist's directions and label intact and stored so they are inaccessible to children and the public. Nonprescription medications shall be labeled with the child's name.

b. For every day an authorization for medication is in effect and the child is in attendance, there shall be a notation of administration including the name of the medicine, date, time, dosage given or

applied, and the initials of the person administering the medication or the reason the medication was not given.

c. In the case of medications that are administered on an ongoing, long-term basis, authorization shall be obtained for a period not to exceed the duration of the prescription.

109.10(4) *Daily contact.* Each child shall have direct contact with a staff person upon arrival for early detection of apparent illness, communicable disease, or unusual condition or behavior which may adversely affect the child or the group. The center shall post notice at the main entrance to the center where it is visible to parents and the public of exposure of a child receiving care by the center to a communicable disease, the symptoms, and the period of communicability. If the center is located in a building used for other purposes and shares the main entrance to the building, the notice shall be conspicuously posted in the center in an area that is frequented daily by parents or the public.

109.10(5) *Infectious disease control.* Centers shall establish policies and procedures related to infectious disease control and the use of universal precautions with the handling of any bodily excrement or discharge, including blood and breast milk. Soiled diapers shall be stored in containers separate from other waste.

109.10(6) *Quiet area for ill or injured.* The center shall provide a quiet area under supervision for a child who appears to be ill or injured. The parents or a designated person shall be notified of the child's status in the event of a serious illness or emergency.

109.10(7) *Staff hand washing.* The center shall ensure that staff demonstrate clean personal hygiene sufficient to prevent or minimize the transmission of illness or disease. All staff shall wash their hands at the following times:

a. Upon arrival at the center.

b. Immediately before eating or participating in any food service activity.

c. After diapering a child.

d. Before leaving the rest room either with a child or by themselves.

e. Before and after administering nonemergency first aid to a child if gloves are not worn.

f. After handling animals and cleaning cages.

109.10(8) *Children's hand washing.* The center shall ensure that staff assist children in personal hygiene sufficient to prevent or minimize the transmission of illness or disease. For each infant or child with a disability, a separate cloth for washing and one for rinsing may be used in place of running water. Children's hands shall be washed at the following times:

a. Immediately before eating or participating in any food service activity.

b. After using the rest room or being diapered.

c. After handling animals.

109.10(9) *First-aid kit.* The center shall ensure that a clearly labeled first-aid kit is available and easily accessible to staff at all times whenever children are in the center, in the outdoor play area, and on field trips. The kit shall be sufficient to address first aid related to minor injury or trauma and shall be stored in an area inaccessible to children.

109.10(10) *Recording incidents.* Incidents involving a child, including minor injuries, minor changes in health status, or behavioral concerns, shall be reported to the parent on the day of the incident. Incidents resulting in an injury to a child shall be reported to the parent on the day of the incident. Incidents resulting in a serious injury to a child or significant change in health status shall be reported immediately to the parent. A written report shall be provided to the parent or person authorized to remove the child from the center. The written report shall be prepared by the staff member who observed the incident and a copy shall be retained in the child's file.

109.10(11) *Smoking.* Smoking and the use of tobacco products shall be prohibited at all times in the center and in every vehicle used to transport children. Smoking and the use of tobacco products shall be prohibited in the outdoor play area during hours of operation of the center. Nonsmoking signs shall be posted at every entrance of the child care center and in every vehicle used to transport children. All signs shall include:

a. The telephone number for reporting complaints, and

b. The Internet address of the department of public health (www.iowasmokefreeair.gov).

109.10(12) *Transportation.* As outlined in Iowa Code section 321.446, all children transported in a motor vehicle subject to registration, except a bus, shall be individually secured by a safety belt, safety seat, or harness in accordance with federal motor vehicle safety standards and the manufacturer's instructions.

a. Children under the age of 6 shall be secured during transit in a federally approved child restraint system. Children under 1 year of age and weighing less than 20 pounds shall be secured during transit in a rear-facing child restraint system.

b. Children under the age of 12 shall not be located in the front seating section of the vehicle.

c. Drivers of vehicles shall possess a valid driver's license and shall not operate a vehicle while under the influence of alcohol, illegal drugs, prescription or nonprescription drugs that could impair the drivers' ability to operate a motor vehicle.

d. Vehicles that are owned or leased by the center shall receive regular maintenance and inspection according to manufacturer-recommended guidelines for vehicle and tire maintenance and inspection.

109.10(13) *Field trip emergency numbers.* Emergency telephone numbers for each child shall be taken by staff when transporting children to and from school and on field trips and non-center-sponsored activities away from the premises.

109.10(14) *Pets.* Animals kept on site shall be in good health with no evidence of disease, be of such disposition as to not pose a safety threat to children, and be maintained in a clean and sanitary manner. Documentation of current vaccinations shall be available for all cats and dogs. No ferrets, reptiles, including turtles, or birds of the parrot family shall be kept on site. Pets shall not be allowed in kitchen or food preparation areas.

109.10(15) *Emergency plans.*

a. The center shall have written emergency plans for responding to fire, tornado, flood (if area is susceptible to flood), intruders within the center, intoxicated parents and lost or abducted children. In addition, the center shall have guidelines for responding or evacuating in case of blizzards, power failures, bomb threats, chemical spills, earthquakes, or other disasters that could create structural damage to the center or pose health hazards. If the center is located within a ten-mile radius of a nuclear power plant or research facility, the center shall also have plans for nuclear evacuations. Emergency plans shall include written procedures including plans for transporting children and notifying parents, emergency telephone numbers, diagrams, and specific considerations for immobile children.

b. Emergency instructions, telephone numbers, and diagrams for fire, tornado, and flood (if area is susceptible to floods) shall be visibly posted by all program and outdoor exits. Emergency plan procedures shall be practiced and documented at least once a month for fire and for tornado. Records on the practice of fire and tornado drills shall be maintained for the current and previous year.

c. The center shall develop procedures for annual staff training on these emergency plans and shall include information on responding to fire, tornadoes, intruders, intoxicated parents and lost or abducted children in the orientation provided to new employees.

d. The center shall conduct a daily check to ensure that all exits are unobstructed.

109.10(16) *Supervision and access.*

a. The center director and on-site supervisor shall ensure that each staff member, substitute, or volunteer knows the number and names of children assigned to that staff member, substitute, or volunteer for care. Assigned staff, substitutes, and volunteers shall provide careful supervision.

b. Any person in the center who is not an owner, staff member, substitute, or volunteer who has a record check and department approval to be involved with child care shall not have unrestricted access to children for whom that person is not the parent, guardian, or custodian.

c. Persons who are exempt from the record check process are granted access in accordance with 109.6(6)*"a"*(2) unless the provisions of paragraph 109.10(16)*"d"* apply.

d. A sex offender who has been convicted of a sex offense against a minor and who is required to register with the Iowa sex offender registry under the provisions contained in Iowa Code chapter 692A shall not operate, manage, be employed by, or act as a contractor or volunteer at a child care center. The sex offender also shall not be present upon the property of a child care center without the written

permission of the center director, except for the time reasonably necessary to transport the offender's own minor child or ward to and from the center.

(1) Written permission shall include the conditions under which the sex offender may be present, including:

1. The precise location in the center where the sex offender may be present;
2. The reason for the sex offender's presence at the facility;
3. The duration of the sex offender's presence;
4. Description of the supervision that the center staff will provide the sex offender to ensure that no child is alone with the sex offender.

(2) Before giving written permission, the center director shall consult with the center licensing consultant. The written permission shall be signed and dated by the center director and the sex offender and kept on file for review by the center licensing consultant.

[**ARC 8650B**, IAB 4/7/10, effective 6/1/10]

441—109.11(237A) Physical facilities.

109.11(1) *Room size.* The program room size shall be a minimum of 80 square feet of useable floor space or sufficient floor space to provide 35 square feet of useable floor space per child. In rooms where floor space occupied by cribs is counted as useable floor space, there shall be 40 square feet of floor space per child. Kitchens, bathrooms, halls, lobby areas, storage areas and other areas of the center not designed as activity space for children shall not be used as regular program space or counted as useable floor space.

109.11(2) *Infants' area.* An area shall be provided properly and safely equipped for the use of infants and free from the intrusion of children two years of age and older. Children over 18 months of age may be grouped outside this area if appropriate to the developmental needs of the child. Upon the recommendation of a child's physician or the area education agency serving the child, a child who is two years of age or older with a disability that results in significant developmental delays in physical and cognitive functioning who does not pose a threat to the safety of the infants may, if appropriate and for a limited time approved by the department, remain in the infant area.

109.11(3) *Facility requirements.*

a. The center shall ensure that:

(1) The facility and premises are sanitary, safe and hazard-free.

(2) Adequate indoor and outdoor program space that is adjacent to the center is provided. Centers shall have a safe outdoor program area with at least sufficient square footage to accommodate 30 percent of the enrollment capacity at any one time at 75 square feet per child. The outdoor area shall include safe play equipment and an area of shade.

(3) Sufficient program space is provided for dining to allow ease of movement and participation by children and to allow staff sufficient space to attend to the needs of the children during routine care and emergency procedures.

(4) Sufficient lighting shall be provided to allow children to adequately perform developmental tasks without eye strain.

(5) Sufficient ventilation is provided to maintain adequate indoor air quality.

(6) Sufficient heating is provided to allow children to perform tasks comfortably without excessive clothing.

(7) Sufficient cooling is provided to allow children to perform tasks without being excessively warm or subject to heat exposure.

(8) Sufficient bathroom and diapering facilities are provided to attend immediately to children's toileting needs and maintained to reduce the transmission of disease.

(9) Equipment, including kitchen appliances, placed in a program area is maintained so as not to result in burns, shock or injury to children.

(10) Sanitation and safety procedures for the center are developed and implemented to reduce the risk of injury or harm to children and reduce the transmission of disease.

b. Approval may be given by the department to waive the outdoor space requirement for programs of three hours or less, provided there is suitable substitute space and equipment available.

c. Approval may be given by the department for centers operating in a densely developed area to use alternative outdoor play areas in lieu of adjacent outdoor play areas.

d. The director or designated person shall complete and keep a record of at least monthly inspections of the outdoor recreation area and equipment for the purpose of assessing and rectifying potential safety hazards. If the outdoor play area is not used for a period of time due to inclement weather conditions, the center shall document the reasons why the monthly inspection did not occur and shall complete and document an inspection prior to resuming use of the area.

e. Centers that operate in a public school building, including before and after school programs and summer programs serving school-age children, may receive limited exemption from a facility requirement at subrule 109.11(3), particularly relating to ventilation and bathroom facilities, if complying with the requirement would require a structural or mechanical change to the school building. Centers shall ensure that the space occupied by the center is sanitary, safe, and hazard-free and shall conduct monthly playground inspections or provide documentation that one has been completed by the public school personnel.

109.11(4) *Bathroom facilities.* At least one functioning toilet and one sink for each 15 children shall be provided in a room with natural or artificial ventilation. Training seats or chairs may be used for children under two years of age. New construction after November 1, 1995, shall provide for at least one sink in the same area as the toilet and, for centers serving children two weeks to two years of age, shall provide for at least one sink in the central diapering area. At least one sink shall be provided in program rooms for infants and toddlers or in an adjacent area other than the kitchen. New construction after April 1, 1998, shall have at least one sink provided in the program rooms for infants and toddlers.

109.11(5) *Telephone.* A working nonpay telephone shall be available in the center with emergency telephone numbers for police or 911, fire, ambulance, and poison information center posted adjacent to the telephone. The street address and telephone number of the center shall be included in the posting. A separate file or listing of emergency telephone numbers for each child shall be maintained near the telephone.

109.11(6) *Kitchen appliances and microwaves.* Gas or electric ranges or ovens shall not be placed in the program area. If kitchen appliances are maintained in the program area for food preparation activities, the area shall be sectioned off and shall not be counted as useable floor space for room size. Centers using microwave ovens for warming infant bottles or infant food shall ensure that the formula or food item is not served immediately to the child after being removed from the microwave. The infant bottle shall be shaken or food stirred and the formula or food item tested by the caregiver before being fed to the infant. Breast milk shall not be warmed in a microwave.

109.11(7) *Environmental hazards.*

a. Within one year of being issued an initial or renewal license, centers operating in facilities built prior to 1960 shall conduct a visual assessment for lead hazards that exist in the form of peeling or chipping paint. If the presence of peeling or chipping paint is found, the paint shall be presumed to be lead-based paint unless a certified inspector as defined in department of public health rules at 641—Chapter 70 determines that it is not lead-based paint. If the presence of peeling or chipping paint is found, interim controls using safe work methods as defined by the state department of public health shall be accomplished prior to a full license being issued.

b. Within one year of being issued an initial or renewal license, centers operating in facilities that are at ground level, use a basement area as program space, or have a basement beneath the program area shall have radon testing performed as prescribed by the state department of public health at 641—Chapter 43. Testing shall be required if test kits are available from the local health department or the Iowa Radon Coalition. Retesting shall be accomplished at least every two years from the date of the initial measurement if test kits are available from the local health department or the Iowa Radon Coalition. If testing determines confirmed radon gas levels in excess of 4.0 picocurie per liter, a plan using radon mitigation procedures established by the state department of public health shall be developed with and approved by the state department of public health prior to a full license being issued.

c. To reduce the risk of carbon monoxide poisoning, all centers shall, on an annual basis prior to the heating season, have a professional inspect all fuel-burning appliances, including oil and gas furnaces, gas water heaters, gas ranges and ovens, and gas dryers, to ensure the appliances are in good working order with proper ventilation. All centers shall install one carbon monoxide detector on each floor of the center that is listed with Underwriters Laboratory (UL) as conforming to UL Standard 2034.

d. Centers that operate before and after school programs and summer-only programs that serve only school-age children and that operate in a public school building are exempted from testing for lead, radon, and carbon monoxide.

441—109.12(237A) Activity program requirements.

109.12(1) *Activities.* The center shall have a written curriculum or program structure that uses developmentally appropriate practices and a written program of activities planned according to the developmental level of the children. The center shall post a schedule of the program in a visible place. The child care program shall complement but not duplicate the school curriculum. The program shall be designed to provide children with:

a. A curriculum or program of activities that promotes self-esteem and positive self-image; social interaction; self-expression and communication skills; creative expression; and problem-solving skills.

b. A balance of active and quiet activities; individual and group activities; indoor and outdoor activities; and staff-initiated and child-initiated activities.

c. Activities which promote both gross and fine motor development.

d. Experiences in harmony with the ethnic and cultural backgrounds of the children.

e. A supervised nap or quiet time for all children under the age of six not enrolled in school who are present at the center for five or more hours.

109.12(2) *Discipline.* The center shall have a written policy on the discipline of children which provides for positive guidance, with direction for resolving conflict and the setting of well-defined limits. The written policy shall be provided to staff at the start of employment and to parents at time of admission. The center shall not use as a form of discipline:

a. Corporal punishment including spanking, shaking, and slapping.

b. Punishment which is humiliating or frightening or which causes pain or discomfort to the child. Children shall never be locked in a room, closet, box or other device. Mechanical restraints shall never be used as a form of discipline. When restraints are part of a treatment plan for a child with a disability authorized by the parent and a psychologist or psychiatrist, staff shall receive training on the safe and appropriate use of the restraint.

c. Punishment or threat of punishment associated with a child's illness, lack of progress in toilet training, or in connection with food or rest.

d. No child shall be subjected to verbal abuse, threats, or derogatory remarks about the child or the child's family.

109.12(3) *Policies for children requiring special accommodations.* Reasonable accommodations, based on the special needs of the child, shall be made in providing care to a child with a disability. Accommodation can be a specific treatment prescribed by a professional or a parent, or a modification of equipment, or removal of physical barriers. The accommodation shall be recorded in the child's file.

109.12(4) *Play equipment, materials and furniture.* The center shall provide sufficient and safe indoor play equipment, materials, and furniture that conform with the standards or recommendations of the Consumer Product Safety Commission or the American Society for Testing and Materials for juvenile products. Play equipment, materials, and furniture shall meet the developmental, activity, and special needs of the children.

Rooms shall be arranged so as not to obstruct the direct observation of children by staff. Individual covered mats, beds, or cots and appropriate bedding shall be provided for all children who nap. The center shall develop procedures to ensure that all equipment and materials are maintained in a sanitary manner. Sufficient spacing shall be maintained between equipment to reduce the transmission of disease, to allow ease of movement and participation by children and to allow staff sufficient space to attend to the needs of the children during routine care and emergency procedures. The center shall provide sufficient

toilet articles for each child for hand washing. Parents may provide items for oral hygiene (if appropriate to the developmental age and needs of the child). The center shall ensure that sanitary procedures are followed for use and storage of the articles.

109.12(5) *Infant environment.* A child care center serving children two weeks to two years old must provide an environment which protects the children from physical harm, but is not so restrictive as to inhibit physical, intellectual, emotional, and social development.

a. Stimulation shall be provided to each child through being held, rocked, played with and talked with throughout the time care is provided. Insofar as possible, the same adult should provide complete care for the same child.

b. Each infant and toddler shall be diapered in a sanitary manner as frequently as needed at a central diapering area. Diapering, sanitation, and hand-washing procedures shall be posted and implemented in every diapering area. There shall be at least one changing table for every 15 infants.

c. Highchairs or hook-on seats shall be equipped with a safety strap which shall be engaged when the chair is in use and shall be constructed so the chair will not topple.

d. Safe, washable toys, large enough so they cannot be swallowed and with no removable parts, shall be provided. All hard-surface toys used by children shall be sanitized daily.

e. Children under the age of one year shall be placed on their backs when sleeping unless otherwise authorized by a parent or physician. A crib or criblike furniture which has a waterproof mattress covering and sufficient bedding to enable a child to rest comfortably and which meets the current standards or recommendations from the Consumer Product Safety Commission or the American Society for Testing and Materials for juvenile products shall be provided for each child under two years of age if developmentally appropriate. Crib railings shall be fully raised and secured when the child is in the crib. A crib or criblike furniture shall be provided for the number of children present at any one time. The center shall develop procedures for maintaining all cribs or criblike furniture and bedding in a clean and sanitary manner. There shall be no restraining devices of any type used in cribs.

f. When playpens are provided, no more than one child shall be placed in one at any time.

g. Infant walkers shall not be used.

h. For programs operating five hours or less on a daily basis, the center shall have a sufficient number of cribs or criblike furniture which has a waterproof mattress covering and sufficient bedding to enable a child to rest comfortably and which meets the current standards from the Consumer Product Safety Commission or the American Society for Testing and Materials for juvenile products for children who may nap during the time in attendance. Cribs or criblike furniture shall be used by only one child at a time and shall be maintained in a clean and sanitary manner.

441—109.13(237A) Extended evening care. A center providing extended evening care shall comply with the licensing requirements for centers contained in Iowa Code chapter 237A and this chapter, with the additional requirements set forth below.

109.13(1) *Facility requirements.*

a. The center shall ensure that sufficient cribs, beds, cots and bedding are provided appropriate to the child's age and that sufficient furniture, lighting, and activity materials are available for the children. Equipment and materials shall be maintained in a safe and sanitary manner.

b. The center shall ensure that a separate space is maintained for school-age boys and girls to provide privacy during bathroom and bedtime activities. Bathroom doors used by children shall be nonlockable.

c. The center shall ensure that parents have provided the personal effects needed to meet their child's personal hygiene and prepare for sleep. The center shall supplement those items needed for personal hygiene which the parent does not provide. The center shall obtain written information from the parent regarding the child's snacking, toileting, personal hygiene and bedtime routines.

109.13(2) *Activities.*

a. Evening activities shall be primarily self-selected by the child.

b. Every child-occupied room except those rooms used only by school-age children for sleeping shall have adult supervision present in the room. Staff counted for purposes of meeting child-to-staff

ratios shall be present and awake at all times. In rooms where only school-age children are sleeping, visual monitoring equipment may be used. If a visual monitor is used, the monitoring must allow for all children to be visible at all times. Staff shall be present in the room with the monitor and shall enter the room used for sleeping to conduct a check of the children every 15 minutes.

441—109.14(237A) Get-well center. A get-well center shall comply with the licensing requirements for centers contained in Iowa Code chapter 237A and this chapter with the additional requirements and exceptions set forth below.

109.14(1) *Staff requirements.*

a. The center shall have a medical advisor for the center's health policy. The medical advisor shall be a medical doctor or a doctor of osteopathy currently in pediatrics or family practice.

b. A center shall have a licensed LPN or RN on duty at all times that children are present. If the nurse on duty is an LPN, the medical advisor or an RN shall be available in the proximate area as defined in state board of nursing rules at 655—6.1(152).

109.14(2) *Health policies.*

a. The center shall have a written health policy, consistent with the National Health and Safety Performance Standards, approved and signed by the owner or the chair of the board and by the medical advisor before the center can begin operations. Changes in the health policy shall be approved by the medical advisor and submitted in writing to the department. A written summary of the health policy shall be given to the parent when a child is enrolled in the center. The center's health policy at a minimum shall address procedures in the following areas:

(1) Medical consultation, medical emergencies, triage policies, storage and administration of medications, dietary considerations, sanitation and infection control, categorization of illness, length of enrollment periods, exclusion policy, and employee health policy.

(2) Reportable disease policies as required by the state department of public health.

b. The child shall be given a brief evaluation by an LPN or RN upon each arrival at the center.

c. The parent shall receive a brief written summary when the child is picked up at the end of the day. The summary must include:

(1) Admitting symptoms.

(2) Medications administered and time they were administered.

(3) Nutritional intake.

(4) Rest periods.

(5) Output.

(6) Temperature.

109.14(3) *Exceptions.* The following exceptions to 441—Chapter 109 shall be applied to get-well centers:

a. A center shall maintain a minimum staff ratio of one-to-four for infants and one-to-five for children over the age of two.

b. All staff that have contact with children shall have a minimum of 17 clock hours of special training in caring for mildly ill children. Current certification of the training shall be contained in the personnel files. Special training shall be department-approved and include the following:

(1) Four hours' training in infant and child cardiopulmonary resuscitation (CPR), four hours' training in pediatric first aid, and one hour of training in infection control within the first month of employment.

(2) Six hours' training in care of ill children, and two hours' training in child abuse identification and reporting within the first six months of employment and every five years thereafter.

c. There shall be 40 square feet of program space per child.

d. There shall be a sink with hot and cold running water in every child-occupied room.

e. Outdoor space may be waived with the approval of the department if the program is in an area adjacent to the pediatrics unit of a hospital.

f. Grouping of children shall be allowed by categorization of illness or by transmission route without regard to age, and shall be in separate rooms with full walls and doors.

441—109.15(237A) Food services. Centers participating in the USDA Child and Adult Care Food Program (CACFP) may have requirements that differ from those outlined in this rule in obtaining CACFP reimbursement and shall consult with a state CACFP consultant.

109.15(1) *Nutritionally balanced meals or snacks.* The center shall serve each child a full, nutritionally balanced meal or snack as defined by the USDA Child and Adult Care Food Program (CACFP) guidelines and shall ensure that staff provide supervision at the table during snacks and meals. Children remaining at the center two hours or longer shall be offered food at intervals of not less than two hours or more than three hours apart unless the child is asleep.

109.15(2) *Menu planning.* The center shall follow the minimum CACFP menu patterns for meals and snacks and serving sizes for children aged infant to 13 years. Menus shall be planned at least one week in advance, made available to parents, and kept on file at the center. Substitutions in the menu, including substitutions made for infants, shall be noted and kept on file. Foods with a high incident rate of causing choking in young children shall be avoided or modified. Provisions of this subrule notwithstanding, exceptions shall be allowed for special diets because of medical reasons in accordance with the child's needs and written instructions of a licensed physician or health care provider.

109.15(3) *Feeding of children under two years of age.*

a. All children under 12 months of age shall be fed on demand, unless the parent provides other written instructions. Meals and snacks provided by the center shall follow the CACFP infant menu patterns. Foods shall be appropriate for the infant's nutritional requirements and eating abilities. Menu patterns may be modified according to written instructions from the parent, physician or health care provider. Special formulas prescribed by a physician or health care provider shall be given to a child who has a feeding problem.

b. All children under six months of age shall be held or placed in a sitting-up position sufficient to prevent aspiration during feeding. No bottles shall be propped for children of any age. A child shall not be placed in a crib with a bottle or left sleeping with a bottle. Spoon feeding shall be adapted to the developmental capabilities of the child.

c. Single-service, ready-to-feed formulas, concentrated or powdered formula following the manufacturer's instructions or breast milk shall be used for children 12 months of age and younger unless otherwise ordered by a parent or physician.

d. Whole milk for children under age two who are not on formula or breast milk unless otherwise directed by a physician.

e. Cleaned and sanitized bottles and nipples shall be used for bottles prepared on site. Prepared bottles shall be kept under refrigeration when not in use.

109.15(4) *Food brought from home.*

a. The center shall establish policies regarding food brought from home for children under five years of age who are not enrolled in school. A copy of the written policy shall be given to the parent at admission. Food brought from home for children under five years of age who are not enrolled in school shall be monitored and supplemented if necessary to ensure CACFP guidelines are maintained.

b. The center may not restrict a parent from providing meals brought from home for school-age children or apply nutritional standards to the meals.

c. Perishable foods brought from home shall be maintained to avoid contamination or spoilage.

d. Snacks that may not meet CACFP nutrition guidelines may be provided by parents for special occasions such as birthdays or holidays.

109.15(5) *Food preparation, storage, and sanitation.* Centers shall ensure that food preparation and storage procedures are consistent with the recommendations of the National Health and Safety Performance Standards and provide:

a. Sufficient refrigeration appropriate to the perishable food to prevent spoilage or the growth of bacteria.

b. Sanitary and safe methods in food preparation, serving, and storage sufficient to prevent the transmission of disease, infestation of insects and rodents, and the spoilage of food. Staff preparing food who have injuries on their hands shall wear protective gloves. Staff serving food shall have clean hands or wear protective gloves and use clean serving utensils.

c. Sanitary methods for dish-washing techniques sufficient to prevent the transmission of disease.

d. Sanitary methods for garbage disposal sufficient to prevent the transmission of disease and infestation of insects and rodents.

109.15(6) *Water supply.* The center shall ensure that suitable water and sanitary drinking facilities are available and accessible to children. Centers that serve infants and toddlers shall provide individual cups for drinking in addition to drinking fountains that may be available in the center.

a. Private water supplies shall be of satisfactory bacteriological quality as shown by an annual laboratory analysis. Water for the analysis shall be drawn between May 1 and June 30 of each year. When the center provides care for children under two years of age, a nitrate analysis shall also be obtained.

b. When public or private water supplies are determined unsuitable for drinking, commercially bottled water certified as chemically and bacteriologically potable or water treated through a process approved by the health department or designee shall be provided.

These rules are intended to implement Iowa Code section 232.69 and chapter 237A.

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TITLE XIV
GRANT/CONTRACT/PAYMENT ADMINISTRATION

CHAPTER 150
PURCHASE OF SERVICE

[Prior to 7/1/83, Social Services[770] Ch 145]
[Previously appeared as Ch 145—renumbered IAB 2/29/84]
[Prior to 2/11/87, Human Services[498]]

DIVISION I
TERMS AND CONDITIONS FOR IOWA PURCHASE OF SOCIAL SERVICES AGENCY AND INDIVIDUAL CONTRACTS, IOWA PURCHASE OF ADMINISTRATIVE SUPPORT, AND IOWA DONATIONS OF FUNDS CONTRACT AND PROVISIONS FOR PUBLIC ACCESS TO CONTRACTS

441—150.1(234) Definitions.

"Accounting year" means a 12 consecutive month period for which accounting records are maintained. It can be either a calendar year or another designated fiscal year.

"Accrual basis accounting" means the accounting basis which shows all expenses incurred and income earned for a given time even though the expenses may not have been paid or income received in cash during the period.

"Administrative support" means technical assistance, studies, surveys, or securing volunteers to assist the department in fulfilling its administrative responsibilities.

"Agency" means an organization or organizational unit that provides social services.

1. Public agency means a general or special-purpose unit of government and organizations administered by that unit to deliver social services, for example, county boards of supervisors, community colleges, and state agencies.

2. Private nonprofit agency means a voluntary agency operated under the authority of a board of directors for purposes other than generating profit and incorporated under Iowa Code chapter 504A. An out-of-state agency must meet requirements of similar laws governing nonprofit organizations in its state.

3. Private proprietary agency means a for-profit agency operated by an owner or board for the operator's financial benefit.

"Bureau of purchased services" means a bureau of the division of fiscal management, which is responsible for administering the purchase of service system.

"Cash basis accounting" means the accounting basis which records expenses when bills are paid and income when money is received.

"Ceiling" means the maximum limit for payment for a service which has been established by an administrative rule or by the Iowa Code specifically for that service.

"Client" means an individual or family group who has applied for and been found to be eligible for social services from the Iowa department of human services.

"Common ownership" means that relationship existing when an individual or individuals possess significant ownership or equity in the provider and the institution or organization serving the provider.

"Components of service" means the elements or activities that make up a specific service.

"Contract" means formal written agreement between the Iowa department of human services and another legal entity, except for those government agencies whose services are covered under provision of Iowa Code chapter 28E.

"Contractor" means an institution, organization, facility or individual who is a legal entity and has entered into a contract with the department of human services.

"Control" means that relationship existing where an individual or an organization has the power, directly or indirectly, significantly to influence or direct the actions or policies of an organization or institution.

"Department" means the Iowa department of human services.

"Direct cost" means those expenses which can be identified specifically and solely to a particular program.

"Donor" means a local source of funding (public or private) that enters into an Iowa donation of funds contract.

"Effective date."

1. Contract effective date for agency contracts means the first day of a month on which the contract shall become in force.

2. Effective date of rate means the date specified in a purchase of service contract on which the specified rate of payment for service provided begins.

"Field staff" means department employees outside of central office reporting to the deputy director of field operations.

"Grant" means an award of funds to develop specific programs or achieve specific outcomes.

"Indirect cost" means those expenses which cannot be related directly to a specific program and are, therefore, allocated to more than one program.

"Project manager" means a department employee who is assigned to assist in developing, monitoring and evaluating a contract and to provide related technical assistance.

"Provider" means an institution, organization, facility, or individual who is a legal entity and has entered into a contract with the department to provide social services to clients of the department.

"Purchase of service system" means the system within the department for contracting and payment for services, including contracts for funding and contracts for technical assistance.

"Related to provider" means that the provider to a significant extent is associated or affiliated with or has control of, or is controlled by, the organization furnishing the services, facilities, or supplies.

"Relatives" include the following persons: husband and wife, natural parent and child, sibling, adopted child and adoptive parent, stepparent, stepchild, stepbrother, stepsister, father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, sister-in-law, grandparent and grandchild.

"Social services" means a set of actions purposefully directed toward human needs which are socially identified as requiring assistance from others for their resolution.

"Unit of service" means a specified quantity of service or a specific outcome as a result of the service provided.

441—150.2(234) Categories of contracts.

150.2(1) *Iowa purchase of social services contract.* An Iowa purchase of social services contract is a legal contract between the department and a provider for a specified service or services to clients referred by the department. This contract establishes the components of service to be provided, the rate per unit of service, a maximum number of units to be available, and other negotiated conditions. The department has three types of contracts for purchasing social services.

a. An agency contract is a contract written with an agency. Iowa Purchase of Social Services Agency Contract, Form 470-0628, shall be completed prior to services being purchased from the agency.

b. A child care certificate is an agreement written with a licensed child care center, a family day care home, a group day care home, an in-home care provider, or a relative care provider. Policies governing child care certificates may be found in 441—Chapter 170.

c. An individual in-home health-related provider agreement is an agreement written with an individual provider of in-home health services. Policies governing individual in-home health-related provider agreements may be found in 441—Chapter 177.

150.2(2) *Iowa purchase of administrative support contract.* An Iowa purchase of administrative support contract is between the department and a contractor for the provision of administrative support. This contract establishes the support services to be provided, the rate and the method of payment, and other negotiated conditions. A contractor or the division of a contractor who is a multiservice organization holding an administrative support contract may not provide direct client services during the period of the contract.

a. A volunteer contract is the administrative support contract between an individual or agency and the department to secure volunteers to assist the department in service delivery.

b. A general use administrative support contract is between the department and a contractor for the provision of administrative support.

150.2(3) *County board of supervisors' participation contract.* Rescinded IAB 7/8/92, effective 7/1/92.

150.2(4) *Iowa donation of funds contract.* The department may accept donated funds.

a. Upon mutual agreement regarding the scope and use of the funds to be donated, the department may negotiate and shall execute a contract between the department and the donor in accordance with department of administrative services rules in 11—Chapters 106 and 107. The contract shall contain specifications concerning amendment, termination, transmittal of funds, accounting, and reversion of unspent funds.

b. Except for restrictions permitted by the contract, all funds shall be donated on an unrestricted basis for use as if they were appropriated funds and shall be under the administrative control of the department. The donor may specify the geographic area to be served and the specific service to be provided.

c. No funds donated and transmitted to the department will be returned to the donor unless specified in the contract.

441—150.3(234) Iowa purchase of social services agency contract.

150.3(1) *Initiation of contract proposal.* When the department issues a request for proposal to select providers, the process and conditions for approving contract proposals shall be as specified in the request, and the department shall not be required to contract with a provider that is not selected. Otherwise, the following procedures for initiation of contract proposals shall apply.

a. *Right to request a contract.* All potential provider agencies have a right to request a contract.

b. *Initial contact.* The initial contact should be between the potential provider and the service area manager for the service area in which the provider's headquarters is located. In the case of out-of-state providers, this contact can be with the service area manager for either the closest service area or the service area initiating the contact. At the beginning of the process of developing a contract, the bureau of purchased services shall give the provider:

(1) Information about the contracting process; and

(2) Instructions on how to access the Purchase of Service Provider Handbook electronically.

c. *Contract proposal development.* When the service area manager determines that a contract is to be developed, a project manager will be assigned who will assist in contract development and processing. The project manager will assist the contractor in completing the contract proposal and fiscal information appropriate to the contract. This information shall include documentation that the conditions of participation are met. Form 470-0663, Iowa Purchase of Social Services Agency Contract Face Sheet, shall be completed at the same time as Form 470-0628, Iowa Purchase of Social Services Agency Contract, or Form 470-0630, Amendment or Renewal of the Iowa Purchase of Social Services Agency Contract, is prepared.

d. *Contract proposal approval or rejection.* Before a contract can be effective, it shall be signed by the following persons within the time frames provided:

(1) Authorized representative of the provider agency.

(2) Service area manager, within one week from receipt.

(3) Rescinded IAB 5/11/05, effective 5/1/05.

(4) Chief of the bureau of purchased services, within 30 days from receipt.

The provider shall be given a notice and explanation in writing of delays in the process or of rejection of the proposal. Payment cannot be made until the contract is signed by the provider's authorized representative and the chief of the bureau of purchased services.

e. *Criteria for rejection.* The following criteria may cause a proposed contract to be rejected:

(1) The service is not needed by department clients.

(2) The service is not in the social services block grant plan for the counties to be served by the program.

(3) No funds are available for the service being proposed.

(4) The proposed contract does not meet applicable rules, regulations, or guidelines, including service definition.

f. *Contract effective date.* When the agreed-upon contract conditions have been met, the effective date of the contract is the first day of an agreed-upon month following signature by the chief of the bureau of purchased services.

150.3(2) *Contract administration.*

a. *Contract management.* During the contract period the assigned project manager shall be the contract liaison between the department and the provider. The project manager shall be contacted on all interpretations and problems relating to the contract and shall follow the issues through to their resolution. The project manager shall also monitor performance under the contract and shall provide or arrange for technical assistance to improve the provider's performance, if needed. Report of On-Site Visit, Form 470-0670, may be used to monitor performance under the contract.

b. *Contract amendment.* The contract shall be amended only upon agreement of both parties. Amendments which affect the cost of services shall include reestablishment of applicable rates. Amendment or Renewal of Iowa Purchase of Social Services Agency Contract, Form 470-0630, shall be used to amend or renew the contract.

c. *Contract renewal.* A joint decision to pursue renewal of the contract must be made at least 60 days before the expiration date.

(1) Each contract shall be evaluated. The department shall take the results of the evaluation into consideration in making the decision on renewal. This evaluation may involve use of the Monitoring and Evaluation Review Guide, Form 470-2571, or other evaluation tools specified in the contract.

(2) Desk Audit for Civil Rights Contract Compliance, Form 470-2215, shall be completed by the provider.

d. *Contract termination.* Causes for termination during the period of the contract are:

(1) Mutual agreement of the parties involved.

(2) Demonstration that sufficient funds are unavailable to continue the services involved.

(3) Failure to make required reporting.

(4) Failure to make financial and statistical records available for review.

(5) Failure to abide by the provisions of the contract.

150.3(3) *Conditions of participation.* The provider shall meet the following standards:

a. *Licensure, approval, or accreditation.* The provider shall have any license, approval, and accreditation required by law, regulation or administrative rules, or standards of operation required by the state or the federal government before the contract can be effective. Out-of-state providers shall meet Iowa licensing standards related to treatment, professional staff to client ratio, and staff qualifications.

b. *Signed contract.* A contract can be effective only when signed by all parties required in 150.3(1)*"d."*

c. *Civil rights laws.* The providers shall be in compliance with all federal, state and local civil rights laws and regulations with respect to equal employment opportunity, or have a written work plan approved by the diversity programs unit to come into compliance. Equal Opportunity Review, Form 470-0148, shall be completed by the provider. Equal Opportunity Review Status Report, Form 470-2194, shall be completed by the diversity programs unit.

d. *Title VI compliance.* The provider shall be in compliance with Title VI of the 1964 Civil Rights Act and all other federal, state, and local laws and regulations regarding the provision of services, or have a written plan approved by the diversity programs unit to come into compliance. Equal Opportunity Review, Form 470-0148, shall be completed by the provider. Equal Opportunity Review Status Report, Form 470-2194, shall be completed by the diversity programs unit.

e. *Section 504 compliance.* The provider shall be in compliance with Section 504 of the Rehabilitation Act of 1973 and with all federal, state, and local Section 504 laws and regulations, or have a written work plan approved by the diversity programs unit to come into compliance. Equal Opportunity Review, Form 470-0148, Plan Review Accessibility Checklist, Form 470-0149, and Section 504 Transition Plan: Structural Accessibility, Form 470-0150, shall be completed by the provider. Equal Opportunity Review Status Report, Form 470-2194, shall be completed by the diversity programs unit.

f. *Affirmative action.* The provider shall be in compliance with all federal, state, and local laws and regulations regarding affirmative action, or have a written work plan approved by the diversity programs unit to come into compliance. Equal Opportunity Review, Form 470-0148, shall be completed by the provider. Equal Opportunity Review Status Report, Form 470-2194, shall be completed by the diversity programs unit.

g. *Abuse reporting.* The provider shall have a written policy and procedure approved by the service area manager or designee for reporting abuse or denial of critical care of children or dependent adults.

h. *Confidentiality.* The provider shall comply with all applicable federal and state laws and regulations on confidentiality including rules on confidentiality contained in 441—Chapter 9. The provider shall have a written policy and procedure approved by the service area manager or designee for maintaining individual client confidentiality including client record destruction.

i. *Client appeals and grievances.* Clients receiving service through a purchase of service contract have the right to appeal adverse decisions made by the department or the provider. The provider shall have a written policy and procedure approved by the service area manager or designee for handling client appeals and grievances and shall provide information to clients about their rights to appeal.

j. *Client reports.* The provider shall maintain the following client records:

(1) Provider service plan or individual program plan. Providers shall develop a written service plan or individual program plan for each client within 30 days of service initiation. The plan shall include a concise description of the situation or area which will be the focus of the service; statement of the goals to be achieved through the delivery of services; time limited and measurable objectives which will lead to the attainment of the goal to be achieved; specific service components, frequency, and the assignment of responsibility for the provision of the components; and the month and year when it is estimated the client will be able to achieve the current goals and objectives. The provider service plan shall be updated upon receipt of a new departmental case plan, but at least once every six months.

(2) Quarterly progress reports. Quarterly progress reports shall be sent to the department service worker responsible for the client. The first report shall be submitted to the department three months after service is initiated. Reports shall be submitted quarterly thereafter, unless provided for otherwise in rules for a specific service.

The progress report shall include a description of the specific service components provided, their frequency, and who provided them; the client's progress with respect to the goals and service objectives; and any recommended changes in the service plan or individual program plan. For all placement cases the report shall include interpretation of the client's reaction to placement, a summary of medical or dental services that were provided, a summary of educational or vocational progress and participation, and a summary of the involvement of the family with the client and the services.

Reports for the supervised apartment living service shall also include supporting documentation for service provision. The documentation shall list dates of client and collateral contacts, type of contact, persons contacted, and a brief explanation of the focus of each contact. Each unit of service for which payment is sought should be the subject of a written progress note.

(3) Termination of service summary. A termination of service summary shall be sent to the department service worker responsible for the client within two weeks of service termination. The summary shall include the rationale for service termination and the impact of the service components on the client in relationship to the established goals and objectives.

k. *Financial and statistical records.* Each provider of service must maintain sufficient financial and statistical records, including program and census data, to document the validity of the reports submitted to the department.

(1) The records shall be available for review at any time during normal business hours by department personnel, the purchase of service fiscal consultant, and state or federal audit personnel.

(2) These records shall be retained for a period of five years after final payment.

l. *Reports on financial and statistical records.* Reports on financial and statistical records shall be submitted as required. Failure to do so within the required time limits is grounds for termination of the contract.

m. Maintenance of client records. Records for clients served through a purchase of service contract must be retained by the provider for a period of three years after service to the client terminates.

n. Provider charges. A provider shall not charge department clients more than it receives for the same services provided to nondepartmental clients.

o. Special-purpose organizations. A provider may establish a separate, special-purpose organization to conduct certain of the provider's client-related or nonclient-related activities. For example, a development foundation assumes the provider's fund-raising activity. Often, the provider does not own the special-purpose organization (e.g., a nonprofit, nonstock-issuing corporation), and has no common governing body membership. However, a special-purpose organization is considered to be related to a provider if:

(1) The provider controls the organization through contracts or other legal documents that give the provider the authority to direct the organization's activities, management, and policies; or

(2) The provider is, for all practical purposes, the primary beneficiary of the organization's activities. The provider should be considered the special-purpose organization's primary beneficiary if one or more of the following circumstances exist:

The organization has solicited funds on the provider's behalf with provider approval, and substantially all funds so solicited were contributed with intent of benefiting the provider.

The provider has transferred some of its resources to the organization, substantially all of whose resources are held for the benefit of the provider; or

The provider has assigned certain of its functions to a special-purpose organization that is operating primarily for the benefit of the provider.

p. Certification by department of transportation.

(1) If the provider furnishes public transit service as defined in 761—910.1(324A), the provider shall annually submit to the project manager information regarding compliance with or exemption from public transit coordination requirements as found in Iowa Code chapter 324A and department of transportation rules in 761—Chapter 910. This information shall include:

1. Form 020107, Certification Application for Coordination of Public Transit Services, which the project manager shall submit to the department of transportation; and

2. A copy of an ACORD Certificate of Insurance or similar self-insurance documentation, as applicable.

(2) If a provider believes it does not furnish public transit service as defined in 761—910.1(324A) and therefore is exempt from the requirements in subparagraph (1), the provider shall submit Form 020107 with only Section 1 completed when the provider enters into a new contract.

(3) If a provider that has furnished public transit service as defined in 761—910.1(324A) ceases to do so, the provider becomes exempt from the requirements in subparagraph (1).

(4) If an exempt provider begins to furnish public transit service as defined in 761—910.1(324A), the provider shall inform the project manager within 30 days of the change and shall adhere to the procedures in subparagraph (1).

(5) Failure of the provider to cooperate in obtaining or providing the required documentation for compliance or exemption is grounds for denial or termination of the contract.

q. Services provided. Services provided, as described in Form 470-0663, Iowa Purchase of Social Services Agency Contract Face Sheet, and attachments, shall at a minimum meet the rules found in the Iowa Administrative Code for a particular service or the contract may be terminated.

r. Bonding, indemnity and insurance clauses.

(1) Rescinded IAB 2/3/93, effective 4/1/93.

(2) Indemnity. The provider agrees that it will at all times during the existence of this contract indemnify and hold harmless the department and county against any and all liability, loss, damages, costs or expenses which the provider may hereafter sustain, incur or be required to pay:

1. By reason of any client's suffering personal injury, death or property loss or damages either while participating in or receiving from the provider the care and services to be furnished by the provider under this contract, or while on premises owned, leased, or operated by the provider, or while being

transported in any vehicle owned, operated, leased, chartered, or otherwise contracted for by the provider or any officer, agency, or employee thereof.

2. By reason of any client's causing injury to or damage to another person or property during any time when the provider or any officer, agency or employee thereof has undertaken or is furnishing the care and service called for under this contract.

(3) Insurance. The provider agrees that in order to protect itself as well as the department and county under the indemnity agreement above, it will at all times during the term of the contract have and keep in force a liability insurance policy, verification of which shall accompany Form 470-0663, Iowa Purchase of Social Services Agency Contract Face Sheet. The provider agrees that all employees, volunteers, or any other person, other than employees of the department acting within the scope of their employment in the department, authorized to transport clients in privately owned vehicles, have liability insurance in force.

s. Renegotiation clause. In the event there is a revision of federal or state laws or regulations and this contract no longer conforms to those laws or regulations, both parties will review the contract and renegotiate those items necessary to conform with the new federal or state laws or regulations.

t. Performance measures. The department may require performance measures.

150.3(4) *Establishment of rates.* The Financial and Statistical Report for Purchase of Service Contracts, Form 470-0664, is the basis for establishing the rates to be paid to all providers under an Iowa Purchase of Social Services Agency Contract, Form 470-0628, except as provided below.

a. Injectable contraceptive unit. Rescinded IAB 8/1/07, effective 9/5/07.

b. Out-of-state providers.

(1) Rescinded IAB 9/1/93, effective 11/1/93.

(2) Out-of-state providers of other services shall have rates established using the applicable portions of the Financial and Statistical Report for Purchase of Service Contracts, Form 470-0664.

c. Family-centered flexible supportive services. Rescinded IAB 5/6/09, effective 7/1/09.

150.3(5) *Financial and statistical report.* The Financial and Statistical Report for Purchase of Service Contracts, Form 470-0664, shall be completed by those providers as required in 150.3(4). The reports shall be based on the following rules.

a. Accounting procedures. Financial information shall be based on the agency's financial records. When the records are not kept on an accrual basis of accounting, the provider shall make the adjustments necessary to convert the information to an accrual basis for reporting. Providers who are multiple program agencies shall submit a cost allocation schedule prepared in accordance with recognized methods and procedures.

(1) Direct program expense shall include all direct client contact personnel involved in a program including the time of a supervisor of a program, or the apportioned share of the supervisor's time when the supervisor supervises more than one program.

(2) Expenses other than salary and fringe benefits shall be charged as direct program expenses when the expenses are identifiable to a program. They may also be charged as direct program expenses when a method of distribution acceptable to the department is maintained on a consistent basis.

(3) Occupancy expenses shall be allocated to programs on a space utilization formula. The space utilization formula may be used for salaries and fringes of building maintenance and janitorial type personnel.

(4) All expenses which relate jointly to two or more programs shall be allocated to program service costs by utilizing a cost allocation method which fairly distributes costs to the related programs. Any expenses which relate directly to a particular program shall be reflected as such. All maintenance costs shall be charged directly or allocated proportionately to the related programs affected.

(5) Indirect program service costs shall be distributed over all applicable services.

(6) Expenses such as supplies, conferences, and similar expenses that cannot be directly related to a program shall be charged to indirect program service costs.

(7) A multiservice agency shall establish a method acceptable to the department of distributing indirect program service costs.

(8) Income received from fund-raising efforts or donations shall be reported as revenue on the financial and statistical report and used to offset fund-raising costs. Fund-raising costs remaining after the offset shall be an unallowable cost.

All contributions shall be accompanied by a schedule showing the contribution and anticipated designation by the agency. No private moneys contributed to the agency shall be included by the department in its reimbursement rate determination unless these moneys are contributed for services provided to specific individuals for whom the reimbursement rate is established by the department.

If a shelter care provider's actual and allowable costs for a child's shelter care placement exceed the amount the department is authorized to pay and the provider is reimbursed by the child's county of legal settlement for the difference between actual and allowable costs and the amount reimbursed by the department, the amount paid by the county shall not be included by the department in its reimbursement rate determination, as long as the amount paid is not greater than the provider's actual and allowable costs, or the statewide average of actual and allowable costs in May of the preceding year for juvenile shelter care homes, whichever is less.

(9) When an agency has a certified public accounting firm perform an audit of its financial statements, the resulting audit report shall follow one of the uniform audit report formats recommended by the American Institute of Certified Public Accountants. These formats are specified in the industry audit guide series, "Audits of Voluntary Health and Welfare Organizations," prepared by the Committee on Voluntary Health and Welfare Organizations, American Institute of Certified Public Accountants, New York, 1974. A copy of the certified audit report shall be submitted to the department within 60 days of receipt.

(10) All expenses reported on Form 470-0664 shall be supported by an agency's general ledger and documentation on file in the agency's office.

b. Failure to maintain records. Failure to maintain records adequate to support the Financial and Statistical Report for Purchase of Service Contracts, Form 470-0664, may result in termination of the contract. These records include, but are not limited to:

(1) Reviewable, legible census reports.
(2) Payroll information.
(3) Capital asset schedules.
(4) All canceled checks, deposit slips, invoices (paid and unpaid).
(5) Audit reports (if any).
(6) Board of directors' minutes.

c. Submission of reports. The financial and statistical report shall be submitted to the department no later than three months after the close of the provider's established fiscal year. At least one week must be allowed prior to this deadline for the project manager to review the report and transmit it to the bureau of purchased services in central office. Failure to submit the report in time without written approval from the chief of the bureau of purchased services may reduce payment to 75 percent of the current rate. Failure to submit the report within six months of the end of the fiscal year shall be cause for terminating the contract.

d. Rate modification. Modification of rates shall be made when required by changes in licensing requirements, changes in the law, or amendments to the contract. Requests for modification of a rate may be made when changes are because of program expansion or modification and have the approval of the service area where services are provided. Even if there is a modification of the rate, the modified rate is still subject to any maximum established in any law or rule.

e. Payment of new rate. New rates shall be effective for services provided beginning the first day of the second calendar month after receipt by the bureau of purchased services of a report sufficient to establish rates or, by mutual agreement, new rates shall be effective the first day of the month following completion of the fiscal review. Failure to submit a report sufficient to establish a rate will result in the effective date's being delayed. At least one week must be allowed prior to the deadline in paragraph *"c"* above for the project manager to review the report and transmit it to central office.

f. Exceptions to costs. Exceptions to costs identified by the bureau of purchased services or its fiscal consultant will be communicated to the provider in writing.

g. Accrual basis. Providers not using the accrual basis of accounting shall adjust amounts to the accrual basis when the financial and statistical report is completed. Records of cash receipts and disbursements shall be adjusted to reflect accruals of income and expenses.

h. Census data. Documentation of units of service provided which identifies the individual client shall be available on a daily basis and summarized on a monthly report. The documentation and reports shall be retained by the provider for review at the time the expenditure report is prepared and reviewed by the department's fiscal consultant.

i. Opinion of accountant. The department may require that an opinion of a certified public accountant or public accountant accompany the report when adjustments made to prior reports indicate noncompliance with reporting instructions.

j. Revenues. When the Financial and Statistical Report is completed, revenues shall be reported as recorded in the general books and records adjusted for accruals. Expense recoveries shall be reflected as revenues.

k. Capital asset use allowance (depreciation) schedule. The Capital Asset Use Allowance Schedule shall be prepared using the guidelines for provider reimbursement in the Medicare and Medicaid Guide, December 1981.

l. The following expenses shall not be allowed:

(1) Fees paid directors and nonworking officers' salaries.

(2) Bad debts.

(3) Entertainment expenses.

(4) Memberships in recreational clubs, paid for by an agency (country clubs, dinner clubs, health clubs, or similar places) which are primarily for the benefit of the employees of the agency.

(5) Legal assistance on behalf of clients.

(6) Costs eligible for reimbursement through the medical assistance program.

(7) Food and lodging expenses for personnel incurred in the city or immediate area surrounding the personnel's residence or office of employment, except when the specific expense is required by the agency and documentation is maintained for audit purposes. Food and lodging expenses incurred as part of programmed activities on behalf of clients, their parents, guardians, or consultants are allowable expenses when documentation is available for audit purposes.

(8) Business conferences and conventions. Meeting costs of an agency which are not required in licensure.

(9) Awards and grants to recognize board members and community citizens for achievement. Awards and grants to clients as part of treatment program are reimbursable.

(10) Survey costs when required certification is not attained.

(11) Federal and state income taxes.

m. Limited service—without a ceiling. The following expenses are limited for service without a ceiling established by administrative rule or law for that service. This includes services with maximum rates, with the exception of shelter care.

(1) Moving and recruitment are allowed as a reimbursable cost only to the extent allowed for state employees. Expenses incurred for placing advertising for purposes of locating qualified individuals for staff positions are allowed for reimbursement purposes.

(2) and (3) Rescinded IAB 5/18/88, effective May 1, 1988.

(4) Costs for participation in educational conferences are limited to 3 percent of the agency's actual salary costs, less excluded or limited salary costs as recorded on the financial and statistical report.

(5) Costs of reference publications and subscriptions for program-related materials are limited to $500 per year.

(6) Memberships in professional service organizations are allowed to the extent they do not exceed one-half of 1 percent of the total salary costs less excluded salary costs.

(7) In-state travel costs for mileage and per diem expenses are allowable to the extent they do not exceed the maximum mileage and per diem rates for state employees for travel in the state.

(8) Reimbursement for air travel shall not exceed the lesser of the minimum commercial rate or the rate allowed for mileage in subparagraph (7) above.

(9) The maximum reimbursable salary for the agency administrator or executive director charged to purchase of service is $40,000 annually.

(10) Annual meeting costs of an agency which are required in licensure are allowed to the extent required by licensure.

n. Limited service—with a ceiling. The following expenses are limited for services with a ceiling established by administrative rule or law for that service. This includes shelter care.

(1) The maximum reimbursable compensation for the agency administrator or executive director charged to purchase of service annually is $40,000.

(2) Annual meeting costs of an agency which are required for licensure are allowed to the extent required by licensure.

o. Establishment of ceiling and reimbursement rate.

(1) The maximum allowable rate ceiling applicable to each service is found in the rules for that particular service.

(2) When a ceiling exists, the reimbursement rate shall be established by determining on a per unit basis the allowable cost plus the current cost adjustment subject to the maximum allowable cost ceiling.

p. Rate limits. Interruptions in service programs will not affect the rate. If an agency assumes the delivery of service from another agency, the rate shall remain the same as for the former agency.

(1) The combined service and maintenance reimbursement rate paid to a shelter care provider shall be based on the financial and statistical report submitted to the department. For the fiscal year beginning July 1, 2008, the maximum reimbursement rate shall be $92.36 per day, based on a 365-day year. If the department reimburses the provider at less than the maximum rate, the department shall adjust the provider's reimbursement rate to the provider's actual and allowable cost plus the inflation factor or to the maximum reimbursement rate, whichever is less.

(2) Effective for the period from January 1, 2010, to June 30, 2010, the reimbursement rates for services provided under a purchase of social service agency contract for supervised apartment living shall be decreased by 5 percent of the rates in effect on December 1, 2009.

(3) The initial reimbursement rate for any new service shall be based upon actual and allowable costs. A new service does not include a new building or location or other changes in method of service delivery for a service currently provided under the contract.

1. For shelter care, if the provider is currently offering shelter care under social services contract, the only time the provider shall be considered to be offering a new service is if the provider adds a service other than shelter care.

2. For supervised apartment living, the only time a provider shall be considered to be offering a new service is when the agency adds a cluster site or a scattered site for the first time. If, for example, the agency has a supervised apartment living cluster site, the addition of a new site does not constitute a new service.

3. If the department defines, in administrative rule, a new service as a social service that may be purchased, this shall constitute a new service for purposes of establishment of a rate. Once the rate for the new service is established for a provider, the rate will be subject to any limitations established by administrative rule or law.

(4) If a social service provider loses a source of income used to determine the reimbursement rate for the provider, the provider's reimbursement rate may be adjusted to reflect the loss of income, provided that the lost income was used to support actual and allowable costs of a service purchased under a purchase of service contract.

q. Related party costs. Direct and indirect costs applicable to services, facilities, equipment, and supplies furnished to the provider by organizations related to the provider are includable in the allowable cost of the provider at the cost to the related organization. All costs allowable at the provider level are also allowable at the related organization level, unless these related organization costs are duplicative of provider costs already subject to reimbursement.

(1) Allowable costs shall be all actual direct and indirect costs applying to any service or item interchanged between related parties, such as capital use allowance (depreciation), interest on borrowed money, insurance, taxes, and maintenance costs.

(2) When the related party's costs are used as the basis for allowable rental or supply costs, the related party shall supply documentation of these costs to the provider. The provider shall complete a schedule displaying amount paid to related parties, related party cost, and total amount allowable. The resulting costs shall be allocated according to policies in 150.3(5)*"a"*(3) to (7).

Financial and statistical records shall be maintained by the related party under the provisions in 150.3(3)*"k."*

(3) Tests for relatedness shall be those specified in rule 441—150.1(234) and 150.3(3)*"o."* The department or the purchase of service fiscal consultant shall have access to the records of the provider and landlord or supplier to determine if relatedness exists. Applicable records may include financial and accounting records, board minutes, articles of incorporation, and list of board members.

r. *Day care increase.* Rescinded IAB 7/7/93, effective 7/1/93.

s. *Interest on unpaid invoices.* Any invoice that remains unpaid after 60 days following the receipt of a valid claim is subject to the payment of interest. The rate of interest is 1 percent per month beyond the 60-day period, on a simple interest basis. A separate claim for the interest is to be generated by the agency. If the original claim was paid with both federal and state funds, only that portion of the original claim paid with state funds will be subject to interest charges.

t. *Interest as an allowable cost.* Necessary and proper interest on both current and capital indebtedness is an allowable cost.

(1) "Interest" is the cost incurred for the use of borrowed funds. Interest on current indebtedness is the cost incurred for funds borrowed for a relatively short term. Interest on capital indebtedness is the cost incurred for funds borrowed for capital purposes.

(2) "Necessary" requires that the interest be incurred on a loan made to satisfy a financial need of the provider, be incurred on a loan made for a purpose reasonably required to operate a program, and be reduced by investment income except where the income is from gifts and grants whether restricted or unrestricted, and which are held separate and not commingled with other funds.

(3) "Proper" requires that interest be incurred at a rate not in excess of what a prudent borrower would have had to pay in the money market on the date the loan was made, and be paid to a lender not related through control or ownership to the borrowing organization.

u. *Rate formula.* Paragraph 150.3(5)*"p"* notwithstanding, when rates are determined based on cost of providing the service involved, they will be calculated according to the following mathematical formula:

$$\frac{\text{Net allowable expenditures}}{\text{Effective utilization level}} \times \text{Reimbursement factor} = \text{Base Rate}$$

(1) Net allowable expenditures are those expenditures attributable to service to clients which are allowable as set forth in subrule 150.3(5), paragraphs *"a"* to *"t."*

(2) Effective utilization level shall be 80 percent or actual (whichever is greater) of the licensed or staffed capacity (whichever is less) of the program.

(3) Inflation factor is the percentage which will be applied to develop payment rates consistent with current policy and funding of the department. The inflation factor is intended to overcome the time lag between the time period for which costs were reported and the time period during which the rates will be in effect. The inflation factor shall be the amount by which the Consumer Price Index for all urban consumers increased during the preceding calendar year ending December 31.

(4) Base rate is the rate which is developed independent of any limits which are in effect. Actual rates paid are subject to applicable limits or maximums.

v. Rescinded IAB 5/13/92, effective 4/16/92.

150.3(6) *Client eligibility and referral.*

a. Program eligibility. To receive services through the purchase of service system, clients shall be determined eligible and be formally referred by the department.

(1) The department shall not make payment for services provided before the client's application, eligibility determination, and referral. See *"b"* below for an exception to this requirement.

(2) Except as provided in paragraph *"c,"* the department shall use the following forms to authorize services:

1. Form 470-0622, Referral of Client for Purchase of Social Services.
2. Form 470-0719, Placement Agreement: Child Placing or Child Caring Agency (Provider).

b. When a court orders foster care and the department has no responsibility for supervision or placement of the client, the department will pay the rate established by these rules for maintenance and service provided by the facility.

c. Family-centered services. For family-centered services, the provisions in rule 441—172.3(234) relating to approval, authorization, and referral shall apply.

150.3(7) *Client fees.* The provider shall agree not to require any fee for service from departmental clients unless a fee is required by the department and is consistent with federal regulation and state policy. Rules governing client fees are found in 441—130.4(234).

The provider shall collect fees due from clients. The provider shall maintain records of fees collected, and these records shall be available for audit by the department or its representative. When a client does not pay the fee, the provider shall demonstrate that a reasonable effort has been made to collect the fee. Reasonable effort to collect means an original billing and two follow-up notices of nonpayment. When the second notice of nonpayment is sent, the provider shall send a copy of the notice to the department worker.

150.3(8) *Billing procedures.* At the end of each month the provider agency shall prepare Form 470-0020, Purchase of Service Provider Invoice, for contractual services provided by the agency during the month.

Separate invoices shall be prepared for each county from which clients were referred, each service, and each funding source involved in payment. Complete invoices shall be sent to the departmental county office responsible for the client for approval and forwarding for payment.

More frequent billings may be permitted on an exception basis with the written approval of the service area and the chief of the bureau of purchased services.

a. Time limit for submitting vouchers, invoices, or claims. The time limit for submission of original vouchers, invoices, or claims shall be three months from the date of service.

b. Resubmittals of rejected claims. Valid claims which were originally submitted within the time limit specified in paragraph *"a"* but were rejected because of an error shall be resubmitted without regard to time frames.

150.3(9) *Reviews of departmental actions.* A provider who is adversely affected by a departmental decision may request a review. A review request may cause the action to be stopped pending the outcome of the review, except in cases where it can be documented that to do so would be detrimental to the health and welfare of clients. The procedure for review is:

a. The provider shall send a written request for review to the project manager responsible for the contract within ten days of receipt of the decision in question. This request shall document the specific area in question and the remedy desired. The project manager shall provide a written response within ten days.

b. When dissatisfied with the response, the provider shall submit to the service area manager within ten days the original request, the response received, and any additional information desired. The service area manager shall study the concerns and the action taken, and render a decision in writing within 14 days. A meeting with the provider may be held to clarify the situation.

c. If still dissatisfied, the provider may within ten days request a review by the chief of the bureau of purchased services. The request for review should include copies of material from paragraphs *"a"* and *"b"* above. The bureau chief shall review the issues and positions of the parties involved and provide a written decision within 14 days. A meeting may be held with the provider, project manager, and service area manager or designee.

d. The provider may appeal this decision within ten days to the director of the department, who will issue the final department decision within 14 days.

150.3(10) *Review of financial and statistical reports.* Authorized representatives of the department or state or federal audit personnel shall have the right to review the general financial records of a provider.

The purpose of the review is to determine if expenses reported to the department have been handled as required under 150.3(5). Representatives shall provide proper identification and shall use generally accepted auditing principles. The reviews may include an on-site visit to the provider, the provider's central accounting office, the offices of the provider's agents, a combination of these, or, by mutual decision, to other locations.

150.3(11) Rescinded, effective 3/1/87.

This rule is intended to implement Iowa Code section 234.6.

[**ARC 7741B**, IAB 5/6/09, effective 7/1/09; **ARC 8447B**, IAB 1/13/10, effective 1/1/10; **ARC 8651B**, IAB 4/7/10, effective 5/12/10]

441—150.4(234) Iowa purchase of social services contract—individual providers.

150.4(1) *Individual child day care provider agreement.* Rules governing individual child day care provider agreements may be found in 441—Chapter 170.

150.4(2) *Individual in-home health-related provider agreement.* Rules governing individual in-home health-related provider agreements may be found in 441—Chapter 177.

441—150.5(234) Iowa purchase of administrative support.

150.5(1) *Initiation of contract proposal.*

a. *Right to request a contract.* All potential contractors have a right to request a contract.

b. *Initial contact.*

(1) Volunteer contract. The initial contact for a volunteer contract may be between the potential contractor and the service area manager of the service area in which the individual or the contractor agency's headquarters is located or the contract may be between the potential contractor and the director of the state volunteer program in the central office of the department. If so, the director will communicate with the service area.

(2) General use administrative support contract. The initial contact for a general use administrative support contract may be between the potential contractor and the service area manager of the service area in which the individual or contractor organization's headquarters is located or the contract may be between the potential contractor and the chief of the bureau of purchased services, who will communicate with the service area.

c. *Contract proposal development.* When the service area manager determines that a contract is to be developed, a project manager will be assigned who will assist in contract development and processing. The project manager will assist the contractor in completing the contract proposal and fiscal information appropriate to the contract. This includes documentation that the conditions of participation required below are met.

d. *Contract proposal approval or rejection.* Before a contract can be effective it shall be signed by the following persons within the time frames provided:

(1) Volunteer contract.

Individual contractor or authorized representative of the contractor agency.

Service area manager within one week from receipt.

Director of the state volunteer program within 30 days from receipt.

(2) General use administrative support contract.

Individual contractor or authorized representative of the contractor agency.

Service area manager within one week from receipt.

Chief of the bureau of purchased services within two weeks from receipt.

Administrator of the division of fiscal management within two weeks from receipt.

The contractor shall be notified of delays in the process or of rejection of the proposal. This notification along with an explanation shall be in writing. The applicant has a right to have the decision reviewed by the director of the state volunteer program, or chief of the bureau of purchased services.

e. *Criteria for rejection.* The following criteria may cause a proposed contract to be rejected.

(1) The proposed activity is not needed by the department.

(2) No funds are available for the activity being proposed.

(3) The proposed contract does not meet applicable rules, regulations, or guidelines.

f. *Contract effective date.* If the agreed-upon contract conditions have been met, the effective date of the contract is the first day of an agreed-upon month following signature by the director of the state volunteer program, or the chief of the bureau of purchased services.

150.5(2) *Contract administration.*

a. *Contract management.* During the contract period, the assigned project manager shall be the liaison between the department and the contractor. The project manager shall be contacted on all interpretations and problems related to the contract and shall follow issues through to their resolution. The project manager shall also monitor performance under the contract and will provide or arrange for technical assistance to improve the contractor's performance, if needed.

b. *Contract amendments.* The contract shall be amended only upon agreement of both parties. Amendments which affect the cost of providing the volunteer services must include reestablishment of amounts to be paid.

c. *Contract renewal.* A joint decision to pursue renewal of the contract must be made at least 60 days prior to the expiration date. Each contract shall be evaluated. The results of the evaluation shall be taken into consideration in the decision on renewal. This evaluation may involve use of evaluation tools specified in the contract.

d. *Contract termination.* Causes for termination during the period of the contract are:

(1) Mutual agreement of the parties involved.

(2) Demonstration that sufficient funds are unavailable to continue the service(s) involved.

(3) Failure to make reports required by the contract.

(4) Failure to make financial, statistical, and program records available.

(5) Failure to abide by the provisions of the contract.

150.5(3) *Conditions of participation.* The contractor shall meet the following standards:

a. *Licensure, approval, or accreditation.* The contractor shall have any license, approval, and third-party accreditation required by law, regulation, or administrative rules, or shall meet standards of operation required by state or federal regulation. This requirement must be met before the contract can be effective.

b. *Signed contract.* A contract can be effective only when signed by all parties required in 150.5(1)*"d."*

c. *Civil rights laws.* The contractors shall be in compliance with all federal, state, and local civil rights laws and regulations with respect to equal employment opportunity, or have a written work plan approved by the diversity programs unit to come into compliance.

d. *Title VI compliance.* The contractors shall be in compliance with Title VI of the 1964 Civil Rights Act and all other federal, state, and local laws and regulations regarding the provision of services, or have a written plan approved by the diversity programs unit to come into compliance.

e. *Section 504 compliance.* The contractors shall be in compliance with Section 504 of the Rehabilitation Act of 1973 and with all federal, state, and local Section 504 laws and regulations, or have a written work plan approved by the diversity programs unit to come into compliance.

f. *Affirmative action.* The contractors shall be in compliance with all federal, state, and local laws and regulations regarding affirmative action, or have a written work plan approved by the diversity programs unit to come into compliance.

g. *Abuse reporting.* The contractor shall have an approved policy and procedure for reporting abuse or denial of critical care of children or dependent adults.

h. *Confidentiality.* The contractor shall comply with all applicable federal and state laws and regulations on confidentiality.

i. *Financial and statistical records.* Each contractor of service shall maintain sufficient financial and statistical records, including program and census data, to document the validity of the reports submitted to the department.

(1) The records shall be available for review at any time during normal business hours by department personnel, the purchase of service fiscal consultant, or state or federal audit personnel.

(2) These records shall be retained for a period of five years after final payment.

j. *Certification by department of transportation.* Each contractor who supplies transportation services shall submit Form 020107, Certification Application for Coordination of Public Transit Services, and a copy of "Certificate of Insurance" (an ACORD form or similar or self-insurance documentation) to the applicable project manager annually showing information regarding compliance with, or exemption from, public transit coordination requirements as found in Iowa Code chapter 324A and department of transportation rules 761—Chapter 910.

Failure to provide the required documentation for compliance or exemption is grounds for denial or termination of the contract.

150.5(4) *Establishing amounts to be paid.* The amounts to be paid under purchase of administrative support contracts are actual approved expenses as negotiated in the contract. Approved items of cost are based on submission of a proposed budget listing those items necessary for provision of the volunteer coordination or technical assistance to be delivered. At the termination of the contract a statement of actual expenses incurred shall be submitted by the contractor.

150.5(5) *Billing procedures.* At the end of each month, or as otherwise provided in the contract, the contractor shall prepare a claim on Form GAX, General Accounting Expenditure, for expenses for which reimbursement is permitted in the contract. The claim shall be sent to the office of the department that administers the contract for approval and forwarding for payment.

a. *Time limit for submitting claims.* The time limit for submission of original claims shall be within 90 days of the provision of service.

b. *Resubmittals of rejected claims.* Valid claims which were originally submitted within this time limit but were rejected because of an error must be resubmitted, but without regard to time frames.

150.5(6) *Reviews of department actions.* A contractor who is adversely affected by a department decision may request a review. A review request may cause the action to be stopped pending the outcome of the review process, except in cases where it can be documented that to do so would be detrimental to the health and welfare of clients. The procedure for review is:

a. Within ten days of receipt of the decision in question the contractor shall send a written request for review to the project manager responsible for the contract. This request shall document the specific area in question and the remedy desired. A written response from the project manager shall be provided within ten days.

b. When dissatisfied with the response, the contractor shall submit the original request, the response received, and any additional information desired to the service area manager within ten days. The service area manager shall study the concerns, the action taken and render a decision in writing within 14 days. A meeting with the contractor may be held to clarify the situation.

c. If still dissatisfied, the contractor may within ten days request a review by the chief of the bureau of purchased services. The request for review should include copies of material from paragraphs *"a"* and *"b"* above. The bureau chief shall review the issues and positions of the parties involved and provide a written decision within 14 days. A meeting with the contractor, project manager, and service area manager or designee may be held.

d. The contractor may appeal this decision within ten days to the director of the department, who will issue the final department decision within 14 days.

150.5(7) *Reviews.* Authorized representatives of the department or state or federal audit personnel have the right to review the general financial records of a contractor. The purpose of the review is to determine if expenses reported to the department have been handled as required under 150.5(4). Representatives shall provide proper identification and shall use generally accepted auditing principles. The reviews may be on the basis of an on-site visit to the contractor, the contractor's central accounting office, the offices of the contractor's agents, a combination of these, or, by mutual decision, to other locations.

This rule is intended to implement Iowa Code sections 234.6 and 324A.5, subsection 3, paragraph *"c."*

441—150.6(234) County board of supervisors participation contract. Rescinded IAB 7/8/92, effective 7/1/92.

441—150.7(234) Iowa donation of funds contract. Rescinded IAB 12/3/08, effective 2/1/09.

441—150.8(234) Provider advisory committee. Rescinded IAB 12/3/08, effective 2/1/09.

441—150.9(234) Public access to contracts. Subject to applicable federal and state laws and regulations on confidentiality including 441—Chapter 9, all material submitted to the department of human services pursuant to this chapter shall be considered public information.

These rules are intended to implement Iowa Code section 234.6 and 2001 Iowa Acts, House File 732, section 31, subsection 6, and Senate File 537, section 1, subsection 1, paragraph *"d."*

441—150.10 to **150.20** Reserved.

DIVISION II
PURCHASE OF SOCIAL SERVICES CONTRACTING ON BEHALF OF COUNTIES FOR LOCAL PURCHASE SERVICES FOR ADULTS WITH MENTAL ILLNESS, MENTAL RETARDATION, AND DEVELOPMENTAL DISABILITIES
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CHAPTER 152
FOSTER GROUP CARE CONTRACTING

PREAMBLE

This chapter sets forth the contracting process used for providers of foster group care services, including standards for rate-setting, payment mechanisms, and provider monitoring, audits, and sanctions. The term of the contract is limited to no more than six years pursuant to 11—Chapters 106 and 107. The rules also establish provider qualifications, service authorization procedures, documentation requirements, and service termination and appeal procedures associated with foster group care services. Refer to 441—Chapter 156 for additional program requirements.

441—152.1(234) Definitions.

"Affiliates" means persons having an overt or covert relationship such that any one of them directly or indirectly controls or has the power to control another.

"Authorized representative," within the context of rule 441—152.9(234), means that person appointed to carry out audit procedures, including an assigned auditor, fiscal consultant, or agent contracted for a specific audit or audit procedure.

"Child" means a person under 18 years of age or a person 18 or 19 years of age who meets the criteria in Iowa Code section 234.1.

"Claim" means each record the department receives that tells the amount of requested payment and the service rendered by a provider to a child and family.

"Client" means a child who has been found to be eligible for foster group care services through the Iowa department of human services.

"Confidence level" means the probability that an overpayment or underpayment rate determined from a random sample of charges is less than or equal to the rate that exists in the universe from which the sample was drawn.

"Contract" means a formal written agreement between the Iowa department of human services and a provider of foster group care services.

"Contract monitor" means a department employee who is assigned to assist in developing, monitoring, and evaluating a contract and to provide related technical assistance.

"Department" means the Iowa department of human services.

"Extrapolation" means that the total dollars of overpayment or underpayment will be estimated by using sample data meeting the confidence level requirement.

"Family," for purposes of child welfare service delivery, shall include the following:

1. The natural or adoptive parents, stepparents, and children who reside in the same household.
2. A child who lives with an adult related to the child within the fourth degree of consanguinity and the adult relatives within the fourth degree of consanguinity in the child's household who are responsible for the child's supervision. Relatives within the fourth degree of consanguinity include: full or half siblings, aunts, uncles, great-aunts, great-uncles, nieces, great-nieces, nephews, great-nephews, grandparents, great-grandparents, great-great-grandparents, and first cousins.
3. A child who lives alone or who resides with a person or persons not legally responsible for the child's support.

"Fiscal record" means a tangible and legible history that documents the criteria established for financial and statistical records as set forth in subrule 152.2(7).

"Grant" means an award of funds to develop specific programs or achieve specific outcomes.

"Host area" means:

1. The department service area where the provider's corporate office is located, or
2. The service area designated by the chief of the bureau of purchased services when the provider's corporate office is out of state.

"Juvenile court officer" means a person appointed as a juvenile court officer or chief juvenile court officer under Iowa Code chapter 602.

"Level of care" means a type of foster group care service that is differentiated by the ratio of staff to children. There are three levels of foster group care services:

1. Community-level group care (service code D1), which requires a minimum staff-to-client ratio of 1 to 8 during prime programming time.
2. Comprehensive-level group care (service code D2), which requires a minimum staff-to-client ratio of 1 to 5 during prime programming time.
3. Enhanced comprehensive-level group care (service code D3), which requires a minimum staff-to-client ratio during prime programming time as follows:

- 1 staff person for facilities serving up to 4 children.
- 2 staff persons for facilities serving 5 to 7 children.
- 3 staff persons for facilities serving 8 to 10 children.
- 4 staff persons for facilities serving 11 to 13 children.
- 5 staff persons for facilities serving 14 to 16 children.
- 6 staff persons for facilities serving 17 to 19 children.
- 1 staff person for every 3 children for facilities serving 20 or more children.

"Nonprime programming time" means any period of the day other than prime programming time and sleeping time.

"Overpayment" means any payment or portion of a payment made to a provider that is incorrect according to the laws and rules applicable to foster group care services and results in a payment greater than that to which the provider is entitled.

"Prime programming time" means any period of the day when special attention, supervision, or treatment is necessary (for example, upon awakening of the clients in the morning until their departure for school, during meals, after school, during transition between activities, evenings and bedtime, and on nonschool days such as weekends, holidays, and school vacations).

"Probation" means a specified period of conditional participation in the provision of foster group care services.

"Provider" means any natural person, company, firm, association, or other legal entity that is seeking a contract or is under contract with the department pursuant to this chapter.

"Random sample" means a systematic (or every "nth" unit) sample for which each item in the universe has an equal probability of being selected.

"Referral worker" means the department worker or juvenile court officer who refers the case to a provider and who is responsible for carrying out the follow-up activities of determining client eligibility and ensuring that the service authorization is completed.

"Service authorization" means the process of determining service necessity and the level of care and number of units of service to be provided to a child.

"Service record" means an individual, tangible, and legible file that records service-related activities set forth in subrule 152.2(6).

"Site" means a location from which services are delivered or where staff report or records are kept. In the foster group care programs, each separately licensed location is a site.

"Sleeping time" means any period of the day during which clients are normally sleeping.

"Suspension of payments" means the withholding of all payments due a provider until resolution of the matter in dispute between the provider and the department.

"Underpayment" means any payment or portion of a payment not made to a provider for services delivered to eligible recipients according to the laws and rules applicable to the foster group care services program and to which the provider is entitled.

"Unit of service" means one day.

"Universe" means all items (claims) submitted by a specific provider for payment during a specific period, from which a random sample will be drawn.

"Withholding of payments" means a reduction or adjustment of the amounts paid to a provider on pending and subsequently submitted claims for purposes of offsetting overpayments previously made to the provider.

[**ARC 7741B**, IAB 5/6/09, effective 7/1/09]

441—152.2(234) Conditions of participation.

152.2(1) *Provider licensure.* The department shall enter into a contract with a provider for foster group care services only when the provider's facility has achieved full licensure as follows:

a. A facility providing community-level group care shall be licensed:

(1) As a community residential facility pursuant to 441—Chapter 114;

(2) As a comprehensive residential facility pursuant to 441—Chapter 115; or

(3) Under comparable standards by the state in which the facility is located.

b. A facility providing comprehensive-level group care shall be licensed:

(1) As a comprehensive residential facility pursuant to 441—Chapter 115; or

(2) Under comparable standards by the state in which the facility is located.

c. A facility providing enhanced comprehensive-level group care shall be licensed:

(1) As a comprehensive residential facility pursuant to 441—Chapter 115; or

(2) Under comparable standards by the state in which the facility is located.

152.2(2) *Provider staffing.* At a minimum, all providers shall meet the requirements for staff qualifications, training, and number of staff pursuant to 441—Chapter 114 or as identified in appendices to Form 470-3052, Foster Group Care Services Contract.

a. All foster group care programs shall provide an appropriate number of hours of prime programming time sufficient to meet the child welfare service needs of the children served in the program.

b. Staffing during prime programming time, nonprime programming time, and sleeping time shall be sufficient to meet the group care maintenance needs of the children served in the program.

152.2(3) *Services provided.* The provider shall comply with the requirements for services to be provided, as described on Form 470-3051, Foster Group Care Services Contract Face Sheet, and appendices to Form 470-3052, Foster Group Care Services Contract. These services shall at a minimum meet the requirements found in 441—Chapter 156 and in 441—Chapter 114 or 441—Chapters 114 and 115, as applicable, or the contract may be terminated.

152.2(4) *Provider charges.* A provider shall not charge departmental clients more than it receives for the same foster group care services provided to nondepartmental clients. The provider shall agree not to require any fee from departmental clients unless a fee is required by the department and is consistent with federal regulation and state policy.

152.2(5) *Compliance with the law.* The provider and its employees, agents, and subcontractors shall comply with all applicable federal, state, and local laws, rules, ordinances, regulations, and orders when performing services under the contract.

a. *Drug-free workplace.* The provider shall operate a drug-free workplace.

b. *Use of funds.* The provider shall:

(1) Agree that federally appropriated funds shall not be paid on behalf of the department or provider to any person for influencing or attempting to influence an officer or employee of any agency, a member of Congress, an officer or employee of Congress, or an employee of a member of Congress in connection with:

1. The awarding of any federal contract,
2. The making of any federal grant,
3. The making of any federal loan,
4. The entering into of any cooperative agreement, or
5. The extension, continuation, renewal, amendment, or modification of any federal contract, grant, loan or cooperative agreement.

(2) Ensure that no funds received or expended will be used in any way to promote or oppose unionization.

152.2(6) *Maintenance of service records.* A provider shall maintain complete and legible records as required in this subrule. A provider's client service records and case files for foster group care services shall comply with the requirements of this subrule and with the record-keeping requirements related to licensure pursuant to 441—Chapter 114.

a. The provider shall establish and maintain confidential, individual service records for each client receiving foster group care services. The service records must adequately support the provision of child welfare services and group care maintenance as defined in rule 441—156.1(234). The service record shall include, at a minimum, those items identified in rule 441—114.11(237) and the following:

(1) Additional reports, if requested by the referral worker;

(2) Form 470-3055, Referral and Authorization for Child Welfare Services;

(3) Daily documentation of billed per diem services as defined in paragraph *"b"*; and

(4) Notes indicating the child's general progress in regard to the child's care plan, entered no less than every seven calendar days.

b. Daily documentation of billed per diem services shall include:

(1) The child's first and last name;

(2) The month, day, and year service was provided;

(3) The first and last names of the persons who provided the service;

(4) A clear description of the specific service rendered, including interventions, actions, and activities performed which support the provision of child welfare services; and

(5) Any problem areas or unusual behavior for the child.

c. If individual case files include service records for services other than foster group care services, the provider has the responsibility to maintain the client records in compliance with all applicable rules.

d. The provider shall retain service records for clients receiving foster group care services for a period of not less than five years following the date of final payment or completion of any required audit or review, whichever is later. If any litigation, claim, negotiation, audit, review, or other action involving the records has been started before the expiration of the five-year period, the records must be retained until the later of:

(1) The completion of the action and resolution of all issues which arise from it, or

(2) The end of the regular five-year period.

e. Failure to maintain records or failure to make records available to the department or to its authorized representatives upon request may result in a notice of violation and recoupment of payments, pursuant to rules 441—152.9(234) and 441—152.10(234).

152.2(7) *Maintenance of financial and statistical records.* The provider shall maintain sufficient financial and statistical records, including program and census data, to document the validity of the reports submitted to the department. The records shall be available for review at any time during normal business hours by department personnel, the department's fiscal consultant, and state or federal audit personnel.

a. At a minimum, financial and statistical records shall include all revenue and expenses supported by a provider's general ledger and documentation on file in the provider's office. These records include, but are not limited to:

(1) Payroll information.

(2) Capital asset schedules.

(3) All canceled checks, deposit slips, and invoices (paid and unpaid).

(4) Audit reports (if any).

(5) The board of directors' minutes (if applicable).

(6) Loan agreements and other contracts.

(7) Reviewable, legible census reports and documentation of units of service provided to departmental clients that identify the individual client and are kept on a daily basis and summarized in a monthly report.

(8) For nondepartmental clients, sufficient documentation of utilization to establish a complete unit of service count.

b. The provider shall maintain the following documentation for each program.

(1) A list of all staff and supervisors providing foster group care services and their qualifications.

(2) The number of staff hired and terminated in the year to date.

c. The documentation prepared by the provider shall be retained for use when any financial report is prepared and for review by the department's fiscal consultant. Financial records must be retained for five years from the date of report submission or final payment for services.

d. Independent audits. When a provider has an audit conducted, a firm not related to the provider shall conduct the audit. The provider shall submit a copy of the independent audit report to the department within 30 days of receipt of the report. The bureau of purchased services shall maintain the report and provide a copy of the report to the fiscal consultant.

152.2(8) *Special-purpose organizations.* A provider may establish a separate, special-purpose organization to conduct certain client-related or non-client-related activities on behalf of the provider. (For example, a provider may establish a development foundation to assume the provider's fund-raising activity.) Even if the provider does not own the special-purpose organization (e.g., a nonprofit, non-stock-issuing corporation) and has no common governing body membership, a separate special-purpose organization shall be considered a related party for purposes of this chapter when one of the following applies:

a. The provider controls the organization through contracts or other legal documents that give the provider the authority to direct the organization's activities, management, and policies.

b. For all practical purposes, the provider is the primary beneficiary of the organization's activities. The provider shall be considered the special-purpose organization's primary beneficiary if one or more of the following circumstances exist:

(1) The organization has solicited funds on the provider's behalf with provider approval, and substantially all funds so solicited were contributed with the intent of benefiting the provider.

(2) The provider has transferred some of its resources to the organization, substantially all of whose resources are held for the benefit of the provider.

(3) The provider has assigned certain of its functions to a special-purpose organization that is operating primarily for the benefit of the provider.

152.2(9) *Certification by department of transportation.*

a. If the provider furnishes public transit service as defined in rule 761—910.1(324A), the provider shall annually submit to the contract monitor information regarding compliance with or exemption from public transit coordination requirements as found in Iowa Code chapter 324A and department of transportation rules in 761—Chapter 910. This information shall include:

(1) Form 020107, Certification Application for Coordination of Public Transit Services, which the contract monitor shall submit to the department of transportation; and

(2) A copy of an ACORD Certificate of Insurance or similar self-insurance documentation, as applicable.

b. If a provider believes it does not furnish public transit service as defined in rule 761—910.1(324A) and, therefore, is exempt from the requirements in paragraph *"a,"* the provider shall submit Form 020107 with only Section 1 completed when the provider enters into a new contract.

c. If a provider that has furnished public transit service as defined in rule 761—910.1(324A) ceases to do so, the provider becomes exempt from the requirements in paragraph *"a."*

d. If an exempt provider begins to furnish public transit service as defined in rule 761—910.1(324A), the provider shall inform the contract monitor within 30 days of the change and shall adhere to the procedures in paragraph *"a."*

e. Failure of the provider to cooperate in obtaining or providing the required documentation of compliance or exemption is grounds for denial or termination of the contract.

152.2(10) *Copyright and patents.* The activities and results of contract activity may be published subject to confidentiality requirements.

[**ARC 7741B**, IAB 5/6/09, effective 7/1/09]

441—152.3(234) Determination of rates. Rates for foster group care services effective on or after November 1, 2006, shall be based on the historical payment rate negotiated between the provider and the department and shall be calculated based on rule 441—156.9(234).

152.3(1) *Negotiation of rates.* Rates for foster group care services effective on or after November 1, 2006, must be established in accordance with this subrule, except as provided in subrule 152.3(4).

a. All historical rate negotiations made under the former rehabilitative treatment and supportive services program on or after February 1, 1998, remain true and valid.

b. The scope of negotiations is limited solely to the rate to be paid for each service.

c. No other items, such as, but not limited to, changes in staff qualifications, service definition, required components, allowable costs or any licensing or other contractual requirements, shall be the subject of negotiations or be used as a basis for changing rates.

d. The service area manager of the host area is responsible for the negotiation of rates for each provider whose contract for foster group care services is administered by the host area, regardless of where the services are provided. Only the service area manager of the host area may approve the rates negotiated for a provider, except as provided in subrule 152.3(4).

(1) The service area manager of the host area shall take into consideration the other service areas served by a provider when negotiating a rate for a service provided in multiple service areas.

(2) When a service is provided only in a nonhost area, the two service area managers shall determine which one will negotiate the rate for that service.

e. The service area manager of the host area and the provider are mutually responsible for initiating the rate negotiation process. Negotiations may be conducted in a manner acceptable to both parties, but shall be conducted face to face upon the request of either party.

f. At the initiation of the rate negotiation process, the provider must disclose all relevant subcontractual and related-party relationships involved in the provision of foster group care services.

g. Negotiated rates shall not exceed any rate ceiling established or authorized by the legislature.

h. Once a negotiated rate is established, it shall not be changed or renegotiated, except in the following circumstances:

(1) Rates may be changed when funds are appropriated for an across-the-board increase.

(2) Rates may be changed by mandated across-the-board decreases. Effective for the period from January 1, 2010, to June 30, 2010, the negotiated reimbursement rates for foster group care shall be decreased by 5 percent of rates in effect on December 31, 2009.

152.3(2) *New service.* When a prospective provider contracts to provide a foster group care service or an existing provider adds a new foster group care service on or after November 1, 2006, the rate for the new service shall be established based on a payment rate negotiated with the provider.

a. The starting point for negotiated rates shall be the weighted average for each service as of July 1, 1997, as previously established in accordance with 441—subrule 185.109(1), in effect at that time, and further calculated based on rule 441—156.9(234). These rates shall become the established weighted average rates for each service code as described in 441—Chapter 156 and in the appendices of the foster group care contract.

(1) The rate for community-level group care child welfare service is $8.43 per unit of service.

(2) The rate for community-level group care maintenance is $50.16 per unit of service.

(3) The rate for comprehensive-level group care child welfare service is $10.13 per unit of service.

(4) The rate for comprehensive-level group care maintenance is $60.31 per unit of service.

(5) The rate for enhanced comprehensive-level group care child welfare service is $13.36 per unit of service.

(6) The rate for enhanced comprehensive-level group care maintenance is $79.55 per unit of service.

b. In the event the department and a new provider or an existing provider adding a new foster group care service are unable to reach agreement on a rate for a service within 60 days of initiating rate negotiations, a rate resolution process may be used. If no rate is agreed upon within 60 days of initiation of a rate resolution process, no rate shall be established and the services in question shall not be part of any approved contract for foster group care services.

152.3(3) *Interruptions in a program.*

a. The rate for a new provider shall remain the same as the rate established for the former provider if:

(1) A provider assumes the delivery of a program from a related-party provider, or

(2) The difference between the former provider and the new provider is a change in name or a change in the legal form of ownership (i.e., a change from partnership to corporation).

b. If a provider ceases to contract for and provide a foster group care service on or before October 31, 2006, and before the calculation of new rates according to rule 441—156.9(234), the rate in effect when the contract ceased shall be used to calculate the new rates to be used as the starting point in negotiations.

c. If a provider ceases to contract for and provide a foster group care service after a rate has been established in accordance with rule 441—156.9(234) and then decides to again contract for and provide the foster group care service, the rate shall be established at the rate in effect when the service was interrupted.

152.3(4) *Exception to rate policy.* When a provider not located in Iowa has been granted an exception to these rules based upon another state's requirement that its providers be paid the same rate they are paid for clients from that state, the exception shall continue in effect as written for the life of the contract.

152.3(5) *Across-the-board cuts.* Payment under the contract may be subject to across-the-board cuts pursuant to Iowa Code section 8.31.

[**ARC 7741B**, IAB 5/6/09, effective 7/1/09; **ARC 8449B**, IAB 1/13/10, effective 1/1/10; **ARC 8652B**, IAB 4/7/10, effective 5/12/10]

441—152.4(234) Initiation of contract proposal. All potential providers have a right to request a contract.

152.4(1) *Initial contact.* The initial contact shall be between the potential provider and the bureau of purchased services.

a. At the beginning of the contract development process, the bureau shall give the potential provider:

(1) Information about the contracting process; and

(2) Instructions on how to access the foster group care services provider handbook electronically.

b. The provider shall sign Form 470-3057, Verification of Receipt, at the end of the contract development process to verify receipt of information on how to access the handbook.

152.4(2) *Contract proposal development.* When the bureau of purchased services determines that a new contract is to be developed, a contract monitor shall be assigned to assist in contract development and processing. The contract monitor shall assist the applicant in the completion of the contract proposal and required fiscal information. The contract proposal shall include all of the following:

a. Form 470-3051, Foster Group Care Services Contract Face Sheet.

b. Form 470-3404, Foster Group Care Services Negotiated Rate Establishment Amendment. This form need not be completed until the completion of the rate negotiation process, but the contract proposal will not be acted upon until the form is completed and attached to the contract proposal.

c. Form 470-3052, Foster Group Care Services Contract, or Form 470-3053, Amendment to Foster Group Care Services Contract.

152.4(3) *Contract proposal approval.* The department shall review all complete proposed contracts for compliance with state and federal requirements.

a. The applicant shall submit four copies of the contract proposal to the assigned contract monitor 60 calendar days in advance of the desired effective date of the contract.

b. Submission within the time frame does not ensure the effective date of the contract. The department shall give the applicant notice and explanation in writing of any delay in the approval process.

c. The contract monitor shall forward four signed copies of the contract proposal to the bureau of purchased services within four weeks of receipt.

d. Before the contract can be effective, it shall be approved and signed by the following persons:

(1) An authorized representative of the provider.

(2) The service area manager, who shall make a decision within one week of receipt.

(3) The director of the department or the director's designee, who shall make a decision within 15 days of receipt.

152.4(4) *Rejection of contract proposal.* The department shall give the applicant notice and explanation in writing of the reasons for rejection of the contract proposal within ten working days of the decision. The following criteria may cause a proposed contract or proposed contract amendment to be rejected:

a. The proposed contract does not meet applicable rules, regulations, or guidelines.

b. The applicant has falsified any information required as a condition of participation.

c. Licenses submitted as a condition of participation in the contract process have never been approved or have been revoked or suspended.

d. The provider fails to provide notification within seven days of any changes that may significantly affect the licenses submitted as a condition of contracting.

e. The department and the provider fail to reach agreement on negotiated rates.

[**ARC 7741B**, IAB 5/6/09, effective 7/1/09]

441—152.5(234) Contract. All providers shall enter into a contract with the department using Form 470-3052, Foster Group Care Services Contract.

152.5(1) *Contract effective date.* When the agreed-upon contract conditions have been met, the effective date of a new contract, a renewed contract, or an amendment to add a new service code to the contract is the day following signature of the director of the department or the director's designee, unless the provider and the department agree to a later specified date.

a. The contract shall be effective only after the provider is licensed to provide foster group care services as described in subrule 152.2(1).

b. The contract shall be effective only when signed by all parties as required by paragraph 152.4(3)*"d."*

152.5(2) *Liability for payment.* The department shall not be liable for payment for any programs or services before:

a. The contract effective date, or

b. The effective date of the rate for the program or service.

152.5(3) *Term of contract.* Pursuant to the provisions of 11—Chapters 106 and 107, the term of the contract is limited to no more than six years from the effective date of the contract.

[**ARC 7741B**, IAB 5/6/09, effective 7/1/09]

441—152.6(234) Client eligibility and referral.

152.6(1) *Determination of eligibility.* The department shall determine a child's eligibility for foster group care services. The department shall not make payment for foster group care services provided before the child's eligibility determination and service authorization.

152.6(2) *Court order.* If a child and family have been referred to the department and the department has not authorized foster group care services, but the services have been ordered by the juvenile court, the department shall make payment subject to availability of authorized funds.

152.6(3) *Service authorization.* Any change in the level of care or increase in the number of units or duration of foster group care services shall be authorized by the department.

[**ARC 7741B**, IAB 5/6/09, effective 7/1/09]

441—152.7(234) Billing procedures. At the end of each month, the provider shall prepare Form 470-0020, Purchase of Service Provider Invoice, for contractual services provided during the month for which the provider has documentation of the billed per diem services as described in subrule 152.2(6). Separate invoices shall be prepared for each county from which clients were referred. Each invoice shall contain claims for only one month of service. A separate invoice is required for each separate month of service if the service spans more than one month.

152.7(1) *Submission of invoices.* Complete invoices shall be sent to the department local office responsible for the client for approval and forwarding for payment. The time limit for submission of original invoices shall be 90 days from the date of service, except at the end of the state fiscal year when claims for services through June 30 shall be submitted by August 10.

152.7(2) *Resubmittal of rejected claims.* Valid claims that were originally submitted within the time limit specified in subrule 152.7(1) but were rejected because of an error shall be resubmitted as soon as corrections are made.

152.7(3) *Payment.* The invoices shall be subject to audit and adjustment by the department. Within 60 days of the date of receipt of a valid invoice, the department shall make payment in full of all claims concerning foster group care services rendered to clients.

[**ARC 7741B**, IAB 5/6/09, effective 7/1/09]

441—152.8(234) Contract management. During the contract period, the assigned contract monitor designated in the contract shall be the contract liaison between the department and the provider.

152.8(1) The provider shall contact the contract monitor about all interpretations and problems relating to the contract, and the contract monitor shall follow the issues through to their resolution.

152.8(2) The contract monitor shall also monitor performance under the contract and shall provide or arrange for technical assistance to improve the provider's performance if needed. Form 470-0670, Report of On-Site Visit, shall be used to monitor performance under the contract.

152.8(3) The contract monitor shall make at least one on-site visit to each provider during the term of the provider's contract. The on-site visit shall be coordinated with on-site visits scheduled to fulfill requirements for provider reviews, licensing, or other on-site visits required by the department. Site visits to out-of-state providers shall be made at the discretion of the service area responsible for administration of the contract.

[**ARC 7741B**, IAB 5/6/09, effective 7/1/09]

441—152.9(234) Provider reviews. The department may review any provider at its discretion at any time. Records generated and maintained by the department or its fiscal agent may be used by reviewers and in all proceedings of the department.

152.9(1) *Review of provider records.* The department shall have the authority to conduct a scheduled or an unannounced site visit to evaluate the adequacy of service records in compliance with the policies and procedures for foster group care services.

152.9(2) *Purpose.* Upon proper identification, authorized representatives of the department shall have the right to review the service and fiscal records of the provider to determine whether:

a. The department has accurately paid claims for services.

b. The provider has furnished the services.

c. The provider has retained service records and fiscal records, as described in subrules 152.2(6) and 152.2(7), that substantiate claims submitted for payment during the review period.

d. Expenses reported to the department have been handled as required under subrule 152.2(8).

152.9(3) *Method.* The department shall select the appropriate method of conducting a review and shall protect the confidential nature of the records being reviewed. The provider may be required to furnish records to the department. The provider may select the method of delivering any requested records to the department. Review procedures may include, but are not limited to, the following:

a. Comparing service and fiscal records with each claim.

b. Interviewing clients and employees of providers.

152.9(4) *Sampling.* The department's procedures for reviewing a provider's service records may include the use of random sampling and extrapolation. When these procedures are used, all sampling will be performed within acceptable statistical methods, yielding not less than a 95 percent confidence level.

a. *Findings.* The review findings generated through the review procedure shall constitute prima facie evidence in all department proceedings of the number and amount of requests for payment as submitted by the provider.

b. *Extrapolation.* Findings of the sample will be extrapolated to the universe for the review period. The total of the payments determined to be in error in the review sample shall be divided by the total payments in the reviewed sample to calculate the percentage of dollars paid in error. This percentage shall then be multiplied by the total payments in the review universe to determine the extrapolated overpayment.

c. *Disagreement with findings.* When the provider disagrees with the department's review findings and the findings have been generated through sampling and extrapolation, the provider may present evidence to show that the sample was invalid. The burden of proof of compliance rests with the provider. The evidence may include a 100 percent review of the universe of provider records used by the department in the drawing of the department's sample. This review shall:

(1) Be arranged and paid for by the provider.

(2) Be conducted by a certified public accountant.

(3) Demonstrate that bills and records not reviewed in the department's sample complied with program regulations and requirements.

(4) Be submitted to the department with all supporting documentation.

152.9(5) *Actions based on review findings.*

a. The department shall report the results of a review of provider records to concerned parties consistent with the provisions of 441—Chapter 9.

b. When an overpayment is found, the department may do one or more of the following:

(1) Request repayment in writing.

(2) Impose sanctions provided for in rule 441—152.10(234).

(3) Investigate and refer the matter to an agency empowered to prosecute.

[**ARC 7741B**, IAB 5/6/09, effective 7/1/09]

441—152.10(234) Sanctions against providers. Failure to meet the requirements relevant to provider contracting, financial record keeping, billing and payment, and client record keeping may subject providers to sanctions.

152.10(1) *Grounds for sanction.* The department may impose sanctions against a provider for committing one or more of the following actions:

a. Failing to provide and maintain the quality of the services to children and families within established standards, including:

(1) Failing to meet standards required by state or federal law for licensure.

(2) Failing to correct deficiencies in provider operations after receiving notice of these deficiencies from the department.

(3) Engaging in a course of conduct or performing an act that is in violation of state or federal regulations or continuing that conduct following notification that it should cease.

(4) Violating any laws, regulations, or code of ethics governing the conduct of occupations or professions subject to this chapter.

(5) Receiving a formal reprimand or censure by an association of the provider's peers for unethical practices.

(6) Being suspended or terminated from participation in another governmental program such as, but not limited to, workers' compensation or Medicaid remedial services.

(7) Committing a negligent practice resulting in client death or injury.

b. Failing to disclose or make available to the department or its authorized agent records of services provided to a child and family and records of payments made for those services.

c. Engaging in deceptive billing practices, such as:

(1) Presenting or causing to be presented for payment any false or deceptive claim for services.

(2) Submitting or causing to be submitted false information for the purpose of obtaining greater compensation than that to which the provider is legally entitled.

d. Submitting or causing to be submitted false information to meet service authorization requirements.

e. Inducing, furnishing or otherwise causing the child or family to receive foster group care services that are not authorized (overutilization of services).

f. Rebating or accepting a fee or portion of a fee or a charge for referrals of a child or family.

g. Failing to repay or arrange for the repayment of identified overpayments or other erroneous payments.

152.10(2) *Notice of violation.* Should the department have information that indicates that a provider may have submitted bills or been practicing in a manner inconsistent with the program requirements, or may have received payment for which the provider may not be properly entitled, the department shall notify the provider of the discrepancies noted.

a. Notification shall set forth:

(1) The nature of the discrepancies or violations.

(2) The known dollar value of the discrepancies or violations.

(3) The method of computing the dollar value.

(4) Further actions to be taken or sanctions to be imposed by the department.

(5) Any actions required of the provider.

b. The provider shall have 15 days after the date of the notice and before the department action to show cause why the action should not be taken.

152.10(3) *Sanctions.* The following sanctions may be imposed on providers based on the grounds specified in subrule 152.10(1):

a. A term of probation for provision of foster group care services.

b. Termination from participation in the provision of foster group care services.

c. Suspension from provision of foster group care services.

d. Suspension or withholding of payments to the provider.

e. Review of 100 percent of the provider's claims before payment.

f. Referral to the appropriate state licensing board for investigation.

g. Referral of the matter to appropriate federal or state legal authorities for investigation and prosecution under applicable federal or state laws.

h. Suspension of foster group care services licensure.

i. Termination of foster group care services licensure.

152.10(4) *Imposition and extent of sanction.* The department shall determine what sanction to impose. The following factors shall be considered in determining the sanction or sanctions to be imposed:

a. Seriousness of the offense.

b. Extent of violations.

c. History of prior violations.

d. Prior imposition of sanctions.

e. Prior provision of technical assistance.

f. Pattern of failure to follow program rules.

g. Whether a lesser sanction will be sufficient to remedy the problem.

h. Actions taken or recommended by peer review groups or licensing bodies.

152.10(5) *Scope of sanction.*

a. The sanction may be applied to all known affiliates of a provider. Each decision to include an affiliate shall be made on a case-by-case basis after giving due regard to all relevant factors and circumstances. The violation, failure, or inadequacy of performance may be imputed to a person with whom the violator is affiliated when the conduct was committed in the course of official duty or was effectuated with the knowledge or approval of that person.

b. When there are grounds for sanction pursuant to subrule 152.10(1) against a provider facility, campus, or site, the department may suspend or terminate the provision of foster group care services by:

(1) The provider; or

(2) The specific facility, campus, or site; or

(3) Any individual within the provider's organization who is responsible for the violation.

c. No provider shall submit claims for payments to the department for any services provided by any facility, campus, site, or person within the organization that has been suspended or terminated from provision of foster group care services except for those services provided before the suspension or termination.

d. Suspension or termination from provision of foster group care services shall preclude the submission of claims to the department for payment for any services provided after suspension or termination, whether submitted personally or through the provider.

152.10(6) *Suspension or withholding of payments pending a final determination.* When the department has notified a provider of a violation pursuant to paragraph 152.9(5)*"b"* or subrule 152.10(2) and has demanded repayment of an identified overpayment, the department may withhold payments on pending and subsequently received claims in an amount reasonably calculated to approximate the amounts in question or may suspend payment pending a final determination. When the department intends to withhold or suspend payments, it shall notify the provider in writing.

152.10(7) *Notice of sanction.* When a provider has been sanctioned, the department shall notify, as appropriate, the applicable professional society, board of registration or licensure, and federal or state agencies of the findings made and the sanctions imposed.
[**ARC 7741B**, IAB 5/6/09, effective 7/1/09]

441—152.11(234) Appeals of departmental actions. Providers may appeal decisions of the department, other than rate determinations, according to rules in 441—Chapter 7.
[**ARC 7741B**, IAB 5/6/09, effective 7/1/09]

These rules are intended to implement Iowa Code section 234.6.

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CHAPTER 156
PAYMENTS FOR FOSTER CARE

[Prior to 7/1/83, Social Services[770] Ch 137]
[Previously appeared as Ch 137—renumbered IAB 2/29/84]
[Prior to 2/11/87, Human Services[498]]

441—156.1(234) Definitions.

"Child welfare services" means age-appropriate activities to maintain a child's connection to the child's family and community, to promote reunification or other permanent placement, and to facilitate a child's transition to adulthood.

"Cost of foster care" means the maintenance and supervision costs of foster family care, the maintenance costs and child welfare service costs of group care, and the maintenance and service costs of supervised apartment living and shelter care. The cost for foster family care supervision and for supervised apartment living services provided directly by the department caseworker shall be $250 per month. When using this average monthly charge results in unearned income or parental liability being collected in excess of the cost of foster care, the excess funds shall be placed in the child's escrow account. The cost for supervised apartment living services purchased from a private provider shall be the actual costs paid by the department.

"Department" means the Iowa department of human services.

"Director" means the director of the child support recovery unit of the department or the director's designee.

"Earned income" means income in the form of a salary, wages, tips, bonuses, commissions earned as an employee, income from job corps or profit from self-employment.

"Escrow account" means an interest bearing account in a bank or savings and loan association which is maintained by the department in the name of a particular child.

"Family foster care supervision" means the support, assistance, and oversight provided by department caseworkers to children in family foster care and directed toward achievement of the child's permanency plan goals.

"Foster care" means substitute care furnished on a 24-hour-a-day basis to an eligible child in a licensed or approved facility by a person or agency other than the child's parent or guardian but does not include care provided in a family home through an informal arrangement for a period of 20 days or less. Child foster care shall include but is not limited to the provision of food, lodging, training, education, supervision and health care.

"Foster family care" means foster care provided by a foster family licensed by the department according to 441—Chapter 113 or licensed or approved by the placing state. The care includes the provision of food, lodging, clothing, transportation, recreation, and training that is appropriate for the child's age and mental and physical capacity.

"Group care maintenance" means food, clothing, shelter, school supplies, personal incidentals, daily care, general parenting, discipline, and supervision of children to ensure their well-being and safety, and administration of maintenance items provided in a group care facility.

"Income" means earned and unearned income.

"Mental health professional" means a person who meets all of the following conditions:

1. Holds at least a master's degree in a mental health field including, but not limited to, psychology, counseling and guidance, psychiatric nursing and social work; or is a doctor of medicine or osteopathic medicine; and

2. Holds a current Iowa license when required by the Iowa professional licensure laws (such as a psychiatrist, a psychologist, a marital and family therapist, a mental health counselor, an advanced registered nurse practitioner, a psychiatric nurse, or a social worker); and

3. Has at least two years of postdegree experience supervised by a mental health professional in assessing mental health problems, mental illness, and service needs and in providing mental health services.

"Mental retardation professional" means a psychologist, physician, registered nurse, educator, social worker, physical or occupational therapist, speech therapist or audiologist who meets the

educational requirements for the profession, as required in the state of Iowa, and has one year of experience working with persons with mental retardation.

"Parent" means the biological or adoptive parent of the child.

"Parental liability" means a parent's liability for the support of a child during the period of foster care placement. Liability shall be determined pursuant to 441—Chapter 99, Division I.

"Physician" means a licensed medical or osteopathic doctor as defined in rule 441—77.1(249A).

"Service area manager" means the department employee or designee responsible for managing department offices within a department service area and for implementing policies and procedures of the department.

"Special needs child" means a child with needs for emotional care, behavioral care, or physical and personal care which require additional skill, knowledge, or responsibility on the part of the foster parents, as measured by Form 470-4401, Foster Child Behavioral Assessment. See subrule 156.6(4).

"Unearned income" means any income which is not earned income and includes supplemental security income (SSI) and other funds available to a child residing in a foster care placement.

This rule is intended to implement Iowa Code section 234.39.

[**ARC 7606B**, IAB 3/11/09, effective 5/1/09; **ARC 7741B**, IAB 5/6/09, effective 7/1/09; **ARC 8010B**, IAB 7/29/09, effective 10/1/09]

441—156.2(234) Foster care recovery. The department shall recover the cost of foster care provided by the department pursuant to the rules in this chapter and the rules in 441—Chapter 99, Division I, which establishes policies and procedures for the computation and collection of parental liability.

156.2(1) Funds shall be applied to the cost of foster care in the following order and each source exhausted before utilizing the next funding source:

a. Unearned income of the child.

b. Parental liability of the noncustodial parent.

c. Parental liability of custodial parent(s).

156.2(2) The department shall serve as payee to receive the child's unearned income. When a parent or guardian is not available or is unwilling to do so, the department shall be responsible for applying for benefits on behalf of a child placed in the care of the department. Until the department becomes payee, the payee shall forward benefits to the department. For voluntary foster care placements of children aged 18 and over, the child is the payee for the unearned income. The child shall forward these benefits, up to the actual cost of foster care, to the department.

156.2(3) The custodial parent shall assign child support payments to the department.

156.2(4) Unearned income of a child and parental liability of the noncustodial parent shall be placed in an account from whence it shall be applied toward the cost of the child's current foster care and the remainder placed in an escrow account.

156.2(5) When a child has funds in escrow these funds may be used by the department to meet the current needs of the child not covered by the foster care payments and not prohibited by the source of the funds.

156.2(6) When the child leaves foster care, funds in escrow shall be paid to the custodial parent(s) or guardian or to the child when the child has attained the age of majority, unless a guardian has been appointed.

156.2(7) When a child who has unearned income returns home after the first day of a month, the remaining portion of the unearned income (based on the number of days in the particular month) shall be made available to the child and the child's parents, guardian or custodian, if the child is eligible for the unearned income while in the home of a parent, guardian or custodian.

This rule is intended to implement Iowa Code section 234.39.

441—156.3(252C) Computation and assessment of parental liability. Rescinded IAB 3/13/96, effective 5/1/96.

441—156.4(252C) Redetermination of liability. Rescinded IAB 3/13/96, effective 5/1/96.

441—156.5(252C) Voluntary payment. Rescinded IAB 3/13/96, effective 5/1/96.

441—156.6(234) Rate of maintenance payment for foster family care.

156.6(1) *Basic rate.* A monthly payment for care in a foster family home licensed in Iowa shall be made to the foster family based on the following schedule effective January 1, 2010, to June 30, 2010:

Age of child	Daily rate
0 through 5	$15.54
6 through 11	$16.16
12 through 15	$17.69
16 or over	$17.93

156.6(2) *Out-of-state rate.* A monthly payment for care in a foster family home licensed or approved in another state shall be made to the foster family based on the rate schedule in effect in Iowa, except that the service area manager or designee may authorize a payment to the foster family at the rate in effect in the other state if the child's family lives in that state and the goal is to reunite the child with the family.

156.6(3) *Mother and child in foster care.* When the child in foster care is a mother whose young child is in placement with her, the rate paid to the foster family shall be based on the daily rate for the mother according to the rate schedule in subrules 156.6(1) and 156.6(4) and for the child according to the rate schedule in subrule 156.6(1). The foster parents shall provide a portion of the young child's rate to the mother to meet the partial maintenance needs of the young child as defined in the case permanency plan.

156.6(4) *Difficulty of care payment.*

a. For placements made before January 1, 2007, when foster parents provide care to a special needs child, the foster family shall be paid the basic maintenance rate plus $5 per day for extra expenses associated with the child's special needs. This rate shall continue for the duration of the placement.

b. When a foster family provides care to a sibling group of three or more children, an additional payment of $1 per day per child may be authorized for each nonspecial needs child in the sibling group.

c. When the foster family's responsibilities in the case permanency plan include providing transportation related to family or preplacement visits outside the community in which the foster family lives, the department worker may authorize an additional maintenance payment of $1 per day. Expenses over the monthly amount may be reimbursed with prior approval by the worker. Eligible expenses shall include the actual cost of the most reasonable passenger fare or gas.

d. Effective January 1, 2007, when a foster family provides care to a child who was receiving behavioral management services for children in therapeutic foster care in that placement as of October 31, 2006, the foster family shall be paid the basic maintenance rate plus $15 per day for that child. This rate shall continue for the duration of the placement.

e. Effective January 1, 2007, when a service area manager determines that as of October 31, 2006, a foster family was providing care for a child comparable to behavioral management services for children in therapeutic foster care, except that the placement is supervised by the department and the child's treatment plan is supervised by a physician, mental health professional, or mental retardation professional, the foster family shall be paid the basic maintenance rate plus $15 per day for that child. This rate shall continue for the duration of the placement.

f. For placements made on or after January 1, 2007, the supervisor may approve an additional maintenance payment above the basic rate in subrule 156.6(1) to meet the child's special needs as identified by the child's score on Form 470-4401, Foster Child Behavioral Assessment. The placement worker shall complete Form 470-4401 within 30 days of the child's initial entry into foster care.

(1) Additional maintenance payments made under this paragraph shall begin no earlier than the first day of the month following the month in which Form 470-4401 is completed and shall be awarded as follows:

1. Behavioral needs rated at level 1 qualify for a payment of $4.75 per day.
2. Behavioral needs rated at level 2 qualify for a payment of $9.50 per day.
3. Behavioral needs rated at level 3 qualify for a payment of $14.25 per day.

(2) The department shall review the child's need for this difficulty of care maintenance payment using Form 470-4401:

1. Whenever the child's behavior changes significantly;
2. When the child's placement changes;
3. After termination of parental rights, in preparation for negotiating an adoption subsidy or pre-subsidy payment; and
4. Before a court hearing on guardianship subsidy.

g. All maintenance payments, including difficulty of care payments, shall be documented on Form 470-0716, Foster Family Placement Contract.

h. Rescinded IAB 1/3/07, effective 1/1/07.

156.6(5) *Payment method.* All foster family maintenance payments shall be made directly to the foster family.

156.6(6) *Return of overpayments.* When a foster family has received payments in excess of those allowed under this chapter, the department caseworker shall ask the foster family to return the overpayment. If the foster family is returning the overpayment to the department, the caseworker will note the monthly amount the foster family agrees to pay in the family's case file. The amount returned shall not be less than $50 per month.

This rule is intended to implement Iowa Code section 234.38.

[**ARC 8010B**, IAB 7/29/09, effective 10/1/09; **ARC 8451B**, IAB 1/13/10, effective 1/1/10; **ARC 8653B**, IAB 4/7/10, effective 5/12/10]

441—156.7(234) Purchase of family foster care services. Rescinded IAB 5/6/09, effective 7/1/09.

441—156.8(234) Additional payments.

156.8(1) *Clothing allowance.* When, in the judgment of the worker, clothing is needed at the time the child is removed from the child's home and placed in foster care, an allowance may be authorized, not to exceed $237.50, to purchase clothing.

a. Once during each calendar year that the child remains in foster care, the department worker may authorize another clothing allowance, not to exceed $190 for family foster care and $100 for all other levels when:

(1) The child needs clothing to replace lost clothing or because of growth or weight change, and

(2) The child does not have escrow funds to cover the cost.

b. When clothing is purchased by the foster family, the foster family shall submit receipts to the worker within 30 days of purchase for auditing purposes, using Form 470-1952, Foster Care Clothing Allowance.

156.8(2) *Supervised apartment living.* When a youth is initially placed in supervised apartment living, the service area manager or designee may authorize an allowance not to exceed $400 if the youth does not have sufficient resources to cover initial costs.

156.8(3) *Medical care.* When a child in foster care needs medical care or examinations which are not covered by the Medicaid program and no other source of payment is available, the cost may be paid from foster care funds with the approval of the service area manager or designee. Eligible costs shall include emergency room care, medical treatment by out-of-state providers who refuse to participate in the Iowa Medicaid program, and excessive expenses for nonprescription drugs or supplies. Requests for payment for out-of-state medical treatment and for nonprescription drugs or supplies shall be approved prior to the care being provided or the drugs or supplies purchased. Claims shall be submitted to the department on Form GAX, General Accounting Expenditure, within 90 days after the service is provided. The rate of payment shall be the same as allowed under the Iowa Medicaid program.

156.8(4) *Transportation for medical care.* When a child in foster family care has expenses for transportation to receive medical care which cannot be covered by the Medicaid program, the expenses may be paid from foster care funds, with the approval of the service area manager. The claim for all the expenses shall be submitted to the department on Form GAX, General Accounting Expenditure, within 90 days after the trip. This payment shall not duplicate or supplement payment through the Medicaid

program. The expenses may include the actual cost of meals, parking, child care, lodging, passenger fare, or mileage at the rate granted state employees.

156.8(5) *Funeral expense.* When a child under the guardianship of the department dies, the department will pay funeral expenses not covered by the child's resources, insurance or other death benefits, the child's legal parents, or the child's county of legal settlement, not to exceed $650.

The total cost of the funeral and the goods and services included in the total cost shall be the same as defined in rule 441—56.3(239,249).

The claim shall be submitted by the funeral director to the department on Form GAX, General Accounting Expenditure, and shall be approved by the service area manager. Claims shall be submitted within 90 days after the child's death.

156.8(6) *School fees.* Payment for required school fees of a child in foster family care or supervised apartment living that exceed $5 may be authorized by the department worker in an amount not to exceed $50 per calendar year if the child does not have sufficient escrow funds to cover the cost. Required school fees shall include:

a. Fees required for participation in school or extracurricular activities; and

b. Fees related to enrolling a child in preschool when a mental health professional or a mental retardation professional has recommended school attendance.

156.8(7) *Respite care.* The service area manager or designee may authorize respite for a child in family foster care for up to 24 days per calendar year per placement. Respite shall be provided by a licensed foster family. The payment rate to the respite foster family shall be the rate authorized under rule 441—156.6(234) to meet the needs of the child.

156.8(8) *Tangible goods, child care, and ancillary services.* To the extent that a foster child's escrow funds are not available, the service area manager or designee may authorize reimbursement to foster parents for the following:

a. Tangible goods for a special needs child including, but not limited to, building modifications, medical equipment not covered by Medicaid, specialized educational materials not covered by educational funds, and communication devices not covered by Medicaid.

b. Child care services when the foster parents are working, the child is not in school, and the provision of child care is identified in the child's case permanency plan.

(1) Child care services shall be provided by a licensed foster parent or a licensed or registered child care provider when available.

(2) When foster parents elect to become child care providers, they shall be registered pursuant to 441—Chapter 110.

c. Ancillary services needed by the foster parent to meet the needs of a special needs child including, but not limited to, specialized classes when directed by the case permanency plan.

d. Ancillary services needed by the special needs child including, but not limited to, recreation fees, in-home tutoring and specialized classes not covered by education funds.

e. Requests for tangible goods, child care, and ancillary services shall be submitted to the service area manager for approval on Form 470-3056, Request for Tangible Goods, Child Care, and Ancillary Services. Payment rates for tangible goods and ancillary services shall be comparable to prevailing community standards. Payment rates for child care shall be established pursuant to 441—subrule 170.4(7).

f. Prior payment authorization shall be issued by the service area manager before tangible goods, child care, and ancillary services are purchased by or for foster parents.

[**ARC 7606B**, IAB 3/11/09, effective 5/1/09; **ARC 8010B**, IAB 7/29/09, effective 10/1/09; **ARC 8451B**, IAB 1/13/10, effective 1/1/10; **ARC 8653B**, IAB 4/7/10, effective 5/12/10]

441—156.9(234) Rate of payment for foster group care.

156.9(1) *In-state reimbursement.* Effective November 1, 2006, public and private foster group care facilities licensed or approved in the state of Iowa shall be paid for group care maintenance and child welfare services in accordance with the rate-setting methodology in this subrule.

a. A provider of group care services shall maintain at least the minimum staff-to-child ratio during prime programming time as established in the contract. Staff shall meet minimum qualifications as established in 441—Chapters 114 and 115. The actual number and qualifications of the staff will vary depending on the needs of the children.

b. Additional payment for group care maintenance may be authorized if a facility provides care for a mother and her young child according to subrule 156.9(4).

c. Reimbursement rates shall be adjusted based on the provider's rate in effect on October 31, 2006, to reflect an estimate that group care providers will provide an average of one hour per day of group remedial services and one hour per week of individual remedial services. The reimbursement rate shall be calculated as follows:

(1) Step 1. Annualize the provider's combined daily reimbursement rate for maintenance and service in effect on October 31, 2006, by multiplying that combined rate by 365 days.

(2) Step 2. Annualize the provider's remedial services reimbursement rate for one hour per day of remedial services code 96153 (health and behavioral interventions - group), as established by the Iowa Medicaid enterprise, by multiplying that rate by 365 days.

(3) Step 3. Annualize the provider's remedial services reimbursement rate for one hour per week of remedial services code 96152 (health and behavioral interventions - individual), as established by the Iowa Medicaid enterprise, by multiplying that rate by 52 weeks.

(4) Step 4. Add the amounts determined in Steps 2 and 3.

(5) Step 5. Subtract the amount determined in Step 4 from the amount determined in Step 1.

(6) Step 6. Divide the amount determined in Step 5 by 365 to compute the new combined maintenance and child welfare service per diem rate.

(7) Step 7. Determine the maintenance portion of the per diem rate by multiplying the new combined per diem rate determined in Step 6 by 85.62 percent.

(8) Step 8. Determine the child welfare service portion of the per diem rate by multiplying the new combined per diem rate determined in Step 6 by 14.38 percent.

EXAMPLE: Provider A has the following rates as of October 31, 2006:

- A combined daily maintenance and service rate of $121.45;
- A Medicaid rate for service code 96153 of $5.10 per 15 minutes, or $20.40 per hour;
- A Medicaid rate for service code 96152 of $19.92 per 15 minutes, or $79.68 per hour.

Step 1. $121.45 × 365 days = $44,329.25
Step 2. $20.40 × 365 days = $7,446.00
Step 3. $79.68 × 52 weeks = $4,143.36
Step 4. $7,446.00 + $4,143.36 = $11,589.36
Step 5. $44,329.25 - $11,589.36 = $32,739.89
Step 6. $32,739.89 ÷ 365 days = $89.70
Step 7. $89.70 × 0.8562 = $76.80 maintenance rate
Step 8. $89.70 × 0.1438 = $12.90 child welfare service rate

Provider A's rates are $76.80 for maintenance and $12.90 for child welfare services.

d. If the Iowa Medicaid enterprise has not made a determination by October 31, 2006, on the need for remedial services for a child who is in group care placement as of that date, the department service area manager may approve a payment from state funds for the estimated daily reimbursement rate for remedial services that was used in the calculation of the provider's reimbursement rate under paragraph 156.9(1)*"c."* The service area manager shall document the reason for the delay in the decision on the child's need for remedial services.

(1) The service area manager may approve such payment only until the time that the Iowa Medicaid enterprise is anticipated to issue the decision regarding the child's need for remedial services. The service area manager shall not authorize payment from state funds if the Iowa Medicaid enterprise has determined that the child does not need remedial services.

(2) The payment that the service area manager may authorize shall be based on a reimbursement rate calculated as follows:

Step 1. Annualize the provider's reimbursement rate for one hour per day of remedial services code 96153 (health and behavioral interventions - group), as established by the Iowa Medicaid enterprise, by multiplying that rate by 365 days.

Step 2. Annualize the provider's remedial services reimbursement rate for one hour per week of remedial services code 96152 (health and behavioral interventions - individual), as established by the Iowa Medicaid enterprise, by multiplying that rate by 52 weeks.

Step 3. Add the amounts determined in Steps 1 and 2.

Step 4. Determine the provider's estimated daily rate for reimbursement of remedial services by dividing the amount in Step 3 by 365 days.

EXAMPLE: Provider B has the following rates as of October 31, 2006:

- A Medicaid rate for service code 96153 of $5.10 per 15 minutes, or $20.40 per hour;
- A Medicaid rate for service code 96152 of $19.92 per 15 minutes, or $79.68 per hour.

Step 1. $20.40 × 365 days = $7,446.00

Step 2. $79.68 × 52 weeks = $4,143.36

Step 3. $7,446.00 + $4,143.36 = $11,589.36

Step 4. $11,589.36 ÷ 365 days = $31.75 estimated daily rate for remedial services

156.9(2) *Out-of-state group care payment rate.* The payment rate for maintenance and child welfare services provided by public or private agency group care licensed or approved in another state shall be established using the same rate-setting methodology as that in subrule 156.9(1), unless the director determines that appropriate care is not available within the state pursuant to the following criteria and procedures.

a. *Criteria.* When determining whether appropriate care is available within the state, the director shall consider each of the following:

(1) Whether the child's treatment needs are exceptional.

(2) Whether appropriate in-state alternatives are available.

(3) Whether an appropriate in-state alternative could be developed by using juvenile court-ordered service fund or wrap-around funds.

(4) Whether the placement and additional payment are expected to be time-limited with anticipated outcomes identified.

(5) If the placement has been approved by the service area manager or chief juvenile court officer.

b. *Procedure.* The service area manager or chief juvenile court officer shall submit the request for director's exception to the Bureau of Policy Analysis, Department of Human Services, Fifth Floor, Hoover State Office Building, Des Moines, Iowa 50319-0114. This request shall be made in advance of placing the child and should allow a minimum of two weeks for a response. The request shall contain documentation addressing the criteria for director's approval listed in 156.9(2)*"a."*

c. *Appeals.* The decision of the director regarding approval of an exception to the rate determination in rule 441—152.3(234) is not appealable.

156.9(3) *Supplemental payments for in-state facilities.* Rescinded IAB 9/1/93, effective 8/12/93.

156.9(4) *Mother-young child rate.* When a group foster care facility provides foster care for a mother and her young child, the maintenance rate for the mother shall include an additional amount to cover the actual and allowable maintenance needs of the young child. No additional amount shall be allowed for service needs of the child.

a. The rate shall be determined according to the policies in rule 441—152.3(234) and added to the maintenance rate for the mother. The young child portion of the maintenance rate shall be limited to the costs associated with food, clothing, shelter, personal incidentals, and supervision for each young child and shall not exceed the maintenance rate for the mother. Costs for day care shall not be included in the maintenance rate.

b. Rescinded IAB 6/8/94, effective 6/1/94.

c. Unless the court has transferred custody from the mother, the mother shall have primary responsibility for providing supervision and parenting for the young child. The facility shall provide services to the mother to assist her to meet her parenting responsibilities and shall monitor her care of the young child.

d. The facility shall provide services to the mother to assist her to:

(1) Obtain a high school diploma or general education equivalent (GED).

(2) Develop preemployment skills.

(3) Establish paternity for her young child whenever appropriate.

(4) Obtain child support for the young child whenever paternity is established.

e. The agency shall maintain information in the mother's file on:

(1) The involvement of the mother's parents or of other adults.

(2) The involvement of the father of the minor's child, including steps taken to establish paternity, if appropriate.

(3) A decision of the minor to keep and raise her young child.

(4) Plan for the minor's completion of high school or a GED program.

(5) The parenting skills of the minor parent.

(6) Child care and transportation plans for education, training or employment.

(7) Ongoing health care of the mother and child.

(8) Other services as needed to address personal or family problems or to facilitate the personal growth and development toward economic self-sufficiency of the minor parent and young child.

f. The agency shall designate $35 of the young child rate as an allowance to the mother to meet the maintenance needs of her young child, as defined in her case permanency plan.

This rule is intended to implement Iowa Code sections 234.6 and 234.38.

[**ARC 7741B**, IAB 5/6/09, effective 7/1/09]

441—156.10(234) Payment for reserve bed days.

156.10(1) *Group care facilities.* The department shall provide payment for group care maintenance and child welfare services according to the following policies.

a. *Family visits.* Reserve bed payment shall be made for days a child is absent from the facility for family visits when the absence is in accord with the following:

(1) The visits shall be consistent with the child's case permanency plan.

(2) The facility shall notify the worker of each visit and its planned length prior to the visit.

(3) The intent of the department and the facility shall be for the child to return to the facility after the visit.

(4) Staff from the facility shall be available to provide support to the child and family during the visit.

(5) Payment shall be canceled and payments returned if the facility refuses to accept the child back.

(6) If the department and the facility agree that the return would not be in the child's best interest, payment shall be canceled effective the day after the joint decision not to return the child.

(7) Payment shall be canceled effective the day after a decision is made by the court or parent in a voluntary placement not to return the child.

(8) Payment shall not exceed 14 consecutive days, except upon prior written approval of the service area manager. In no case shall payment exceed 30 consecutive days.

(9) The provider shall document the use of reserve bed days in the daily log and report the number of reserve bed days claimed in the quarterly report.

b. *Hospitalization.* Reserve bed payment shall be made for days a child is absent from the facility for hospitalization when the absence is in accord with the following:

(1) The facility shall contact the worker at least 48 hours in advance of a planned hospitalization and within 24 hours after an unplanned hospitalization.

(2) The intent of the department and the facility shall be for the child to return to the facility after the hospitalization.

(3) Staff from the facility shall be available to provide support to the child and family during the hospitalization.

(4) Payment shall be canceled and payments returned if the facility refuses to accept the child back.

(5) If the department and the facility agree that the return would not be in the child's best interest, payment shall be canceled effective the day after the joint decision not to return the child.

(6) Payment shall be canceled effective the day after a decision is made by the court or parent in a voluntary placement not to return the child.

(7) Payment shall not exceed 14 consecutive days, except upon prior written approval of the service area manager. In no case shall payment exceed 30 consecutive days.

(8) The provider shall document the use of reserve bed days in the daily log and report the number of reserve bed days claimed in the quarterly report.

c. Runaways. Reserve bed payment shall be made for days a child is absent from the facility after the child has run away when the absence is in accord with the following:

(1) The facility shall notify the worker within 24 hours after the child runs away.

(2) The intent of the department and the facility shall be for the child to return to the facility once the child is found.

(3) Payment shall be canceled and payments returned if the facility refuses to accept the child back.

(4) If the department and the facility agree that the return would not be in the child's best interest, payment shall be canceled effective the day after the joint decision not to return the child.

(5) Payment shall be canceled effective the day after a decision is made by the court or parent in a voluntary placement not to return the child.

(6) Payment shall not exceed 14 consecutive days, except upon prior written approval of the service area manager. In no case shall payment exceed 30 consecutive days.

(7) The provider shall document the use of reserve bed days in the daily log and report the number of reserve bed days claimed in the quarterly report.

d. Preplacement visits. Reserve bed payment shall be made when a child is making a planned preplacement visit to another foster care placement or an adoptive placement when the absence is in accord with the following:

(1) The visits shall be consistent with the child's case permanency plan.

(2) The intent of the department and the facility shall be for the child to return to the facility.

(3) Staff from the facility shall be available to provide support to the child and provider during the visit.

(4) Payment shall be canceled and payment returned if the facility refuses to accept the child back.

(5) Payment shall not exceed two consecutive days.

(6) The provider shall document the use of reserve bed days in the daily log and report the number of reserve bed days claimed in the quarterly report.

156.10(2) *Foster family care.*

a. Family visits. Reserve bed payment shall be made for days a foster child is absent from the foster family home for family visits when the absence is in accord with the following:

(1) The visits shall be consistent with the child's case permanency plan.

(2) The intent of the department and the foster family shall be for the child to return to the foster family home after the visit.

(3) Payment shall be canceled and payments returned if the foster family refuses to accept the child back.

(4) If the department and the foster family agree that the return would not be in the child's best interest, payment shall be canceled effective the day after the joint decision not to return the child.

(5) Payment shall be canceled effective the day after a decision is made by the court or parent in a voluntary placement not to return the child.

(6) Payment shall not exceed 14 consecutive days, except upon prior written approval of the service area manager. In no case shall payment exceed 30 consecutive days.

b. Hospitalization. Reserve bed payment shall be made for days a foster child is absent from the foster family home for hospitalization when the absence is in accord with the following:

(1) The intent of the department and the foster family shall be for the child to return to the foster family home after the hospitalization.

(2) Payment shall be canceled and payments returned if the foster family refuses to accept the child back.

(3) If the department and the foster family agree that the return would not be in the child's best interest, payment shall be canceled effective the day after the joint decision not to return the child.

(4) Payment shall be canceled effective the day after a decision is made by the court or parent in a voluntary placement not to return the child.

(5) Payment shall not exceed 14 consecutive days, except upon prior written approval of the service area manager. In no case shall payment exceed 30 consecutive days.

c. Runaways. Reserve bed payment shall be made for days a foster child is absent from the foster family home after the child has run away when the absence is in accord with the following:

(1) The foster family shall notify the worker within 24 hours after the child runs away.

(2) The intent of the department and the foster family shall be for the child to return to the foster family home once the child is found.

(3) Payment shall be canceled and payments returned if the foster family refuses to accept the child back.

(4) If the department and the foster family agree that the return would not be in the child's best interest, payment shall be canceled effective the day after the joint decision not to return the child.

(5) Payment shall be canceled effective the day after a decision is made by the court or parent in a voluntary placement not to return the child.

(6) Payment shall not exceed 14 consecutive days, except upon prior written approval of the service area manager. In no case shall payment exceed 30 consecutive days.

d. Preplacement visits. Reserve bed payment shall be made when a foster child is making a planned preplacement visit to another foster care placement or an adoptive placement when the absence is in accord with the following:

(1) The visits shall be consistent with the child's case permanency plan.

(2) The intent of the department and the foster family home shall be for the child to return to the foster family home.

(3) Payment shall be canceled and payment returned if the foster family home refuses to accept the child back.

(4) Payment shall not exceed two consecutive days.

156.10(3) *Shelter care facilities.*

a. Hospitalization. Reserve bed payment shall be made for days a child is absent from the facility for hospitalization when the absence is in accord with the following:

(1) The facility shall contact the worker at least 48 hours in advance of a planned hospitalization and within 24 hours after an unplanned hospitalization.

(2) The intent of the department and the facility shall be for the child to return to the facility after the hospitalization.

(3) Staff from the facility shall be available to provide support to the child and family during the hospitalization.

(4) Payment shall be canceled and payments returned if the facility refuses to accept the child back.

(5) If the department and the facility agree that the return would not be in the child's best interest, payment shall be canceled effective the day after the joint decision not to return the child.

(6) Payment shall be canceled effective the day after a decision is made by the court or parent in a voluntary placement not to return the child.

(7) Payment shall not exceed 14 consecutive days, except upon prior written approval of the service area manager. In no case shall payment exceed 30 consecutive days.

(8) The provider shall document the use of reserve bed days in the daily log and report the number of reserve bed days claimed in the quarterly report.

b. Preplacement visits. Reserve bed payment shall be made when a child is making a planned preplacement visit to another foster care placement or an adoptive placement when the absence is in accord with the following:

(1) The visits shall be consistent with the child's case permanency plan.

(2) The intent of the department and the facility shall be for the child to return to the facility.

(3) Staff from the facility shall be available to provide support to the child and provider during the visit.

(4) Payment shall be canceled and payment returned if the facility refuses to accept the child back.

(5) Payment shall not exceed two consecutive days.

(6) The provider shall document the use of reserve bed days in the daily log and report the number of reserve bed days claimed in the quarterly report.

This rule is intended to implement Iowa Code sections 234.6 and 234.35.

[**ARC 8010B**, IAB 7/29/09, effective 10/1/09]

441—156.11(234) Emergency care.

156.11(1) and **156.11(2)** Rescinded IAB 3/11/09, effective 5/1/09.

156.11(3) Shelter care payment. Public and private juvenile shelter care facilities approved or licensed in Iowa shall be paid according to the rate-setting methodology in 441—paragraph 150.3(5)*"p."*

a. Facilities shall bill for actual units of service provided in accordance with 441—subrule 150.3(8). In addition, facilities may be guaranteed a minimum level of payment to the extent determined by the department through a request-for-proposal process.

(1) Guaranteed payment shall be calculated monthly.

(2) The guaranteed level of payment shall be calculated by multiplying the number of beds for which payment is guaranteed by the number of days in the month.

(3) When the actual unit billings for a facility do not equal the guaranteed level of payment for the month, the facility may submit a supplemental billing for the deficiency.

(4) The amount of the supplemental billing shall be determined by multiplying the facility's unit cost for shelter care by the number of units below the guaranteed level for the month for which the facility was not reimbursed.

b. The total reimbursement to the agency shall not exceed the agency's allowable costs as defined in 441—subrule 150.3(5). Agencies shall refund any payments which have been made in excess of the agencies' allowable costs.

c. Shelter contracts for the state fiscal year beginning July 1, 2007, shall provide for the statewide availability of a daily average of 273 guaranteed emergency juvenile shelter care beds during the fiscal year.

This rule is intended to implement Iowa Code section 234.35.

[**ARC 7606B**, IAB 3/11/09, effective 5/1/09]

441—156.12(234) Supervised apartment living.

156.12(1) *Maintenance.* When a youth at least aged 16 but under the age of 20 is living in a supervised apartment living situation, the maximum monthly maintenance payment for the youth shall be $573.90. This payment may be paid to the youth or another payee, other than a department employee, for the youth's care.

156.12(2) *Service.* When services for a youth in supervised apartment living are purchased, the service components and number of hours purchased shall be specified by the service worker in the youth's case permanency plan.

This rule is intended to implement Iowa Code section 234.35.

[**ARC 8451B**, IAB 1/13/10, effective 1/1/10; **ARC 8653B**, IAB 4/7/10, effective 5/12/10]

441—156.13(234) Excessive rates. Rescinded IAB 6/9/93, effective 8/1/93.

441—156.14(234,252C) Voluntary placements. When placement is made on a voluntary basis, the parent or guardian shall complete and sign Form 470-0715, Voluntary Placement Agreement.

441—156.15(234) Child's earnings. Earned income of a child who is not in a supervised apartment living arrangement and who is a full-time student or engaged in an educational or training program shall be reported to the department and its use shall be a part of a plan for service, but the income shall not

be used towards the cost of the child's care as established by the department. When the earned income of children in supervised apartment living arrangements or of other children exceeds the foster care standard, the income in excess of the standard shall be applied to meet the cost of the child's care. When the income of the child exceeds twice the cost of maintenance, the child shall be discontinued from foster care.

441—156.16(234) Trust funds and investments.

156.16(1) When the child is a beneficiary of a trust and the proceeds therefrom are not currently available, or are not sufficient to meet the child's needs, the worker shall assist the child in having a petition presented to the court requesting release of funds to help meet current requirements. When the child and responsible adult cooperate in necessary action to obtain a ruling of the court, income shall not be considered available until the decision of the court has been rendered and implemented. When the child and responsible adult do not cooperate in the action necessary to obtain a ruling of the court, the trust fund or investments shall be considered as available to meet the child's needs immediately. When the child or responsible adult does not cooperate within 90 days in making the income available the maintenance payment shall be terminated.

156.16(2) The Iowa department of human services shall be payee for income from any trust funds or investments unless limited by the trust.

156.16(3) Savings accounts from any income and proceeds from the liquidation of securities shall be placed in the child's account maintained by the department and any amount in excess of $1,500 shall be applied towards cost of the child's maintenance.

This rule is intended to implement Iowa Code section 234.39.

441—156.17(234) Preadoptive homes. Payment for a foster child placed in a preadoptive home shall be limited to the amount negotiated pursuant to rule 441—201.5(600) and shall not exceed the foster care maintenance amount paid in family foster care.

This rule is intended to implement Iowa Code section 234.38.

[**ARC 8010B**, IAB 7/29/09, effective 10/1/09]

441—156.18(237) Foster parent training expenses. Rescinded IAB 7/29/09, effective 10/1/09.

441—156.19(237) Rate of payment for care in a residential care facility. When a child is receiving group care maintenance and child welfare services in a licensed residential care facility and is not eligible for supplemental security income or state supplementary assistance, the department will pay for the group care maintenance and child welfare services in accordance with subrule 156.9(1). When a child receives group care maintenance and child welfare services in a licensed residential care facility and is eligible for supplemental security income or state supplementary assistance, the department will pay for child welfare services in accordance with subrule 156.9(1).

This rule is intended to implement Iowa Code section 237.1(3)*"e."*

441—156.20(234) Eligibility for foster care payment.

156.20(1) *Client eligibility.* Foster care payment shall be limited to the following populations.

a. Youth under the age of 18 shall be eligible based on legal status, subject to certain limitations.

(1) Legal status. The youth's placement shall be based on one of the following legal statuses:

1. The court has ordered foster care placement pursuant to Iowa Code section 232.52, subsection 2, paragraph *"d,"* Iowa Code section 232.102, subsection 1, Iowa Code section 232.117, or Iowa Code section 232.182, subsection 5.

2. The child is placed in shelter care pursuant to Iowa Code section 232.20, subsection 1, or Iowa Code section 232.21.

3. The department has agreed to provide foster care pursuant to rule 441—202.3(234).

(2) Limitations. Department payment for group care shall be limited to placements which have been authorized by the department and which conform to the service area group care plan developed

pursuant to rule 441—202.17(232). Payment for an out-of-state group care placement shall be limited to placements approved pursuant to 441—subrule 202.8(2).

b. Youth aged 18 and older who meet the definition of child in rule 441—202.1(234) shall be eligible based on age, a voluntary placement agreement pursuant to 441—subrule 202.3(3), and type of placement.

(1) Except as provided in subparagraph 156.20(1)*"b"*(3), payment for a child who is 18 years of age shall be limited to family foster care or supervised apartment living.

(2) Except as provided in subparagraph 156.20(1)*"b"*(3), payment for a child who is 19 years of age shall be limited to supervised apartment living.

(3) Exceptions. An exception to subparagraphs (1) and (2) shall be granted for all unaccompanied refugee minors. The service area manager or designee shall grant an exception for other children when the child meets all of the following criteria. The child's eligibility for the exception shall be documented in the case record.

1. The child does not have mental retardation. Funding for services for persons with mental retardation is the responsibility of the county or state pursuant to Iowa Code section 222.60.

2. The child is at imminent risk of becoming homeless or of failing to graduate from high school or obtain a general equivalency diploma. "At imminent risk of becoming homeless" shall mean that a less restrictive living arrangement is not available.

3. The placement is in the child's best interests.

4. Funds are available in the service area's allocation. When the service area manager has approved payment for foster care pursuant to this subparagraph, funds which may be necessary to provide payment for the time period of the exception, not to exceed the current fiscal year, shall be considered encumbered and no longer available. Each service area's funding allocation shall be based on the service area's portion of the total number of children in foster care on March 31 preceding the beginning of the fiscal year, who would no longer be eligible for foster care during the fiscal year due to age, excluding unaccompanied refugee minors.

c. A young mother shall be eligible for the extra payment for her young child living with her in care as set forth in subrule 156.6(4), paragraph *"a,"* and subrule 156.9(4) if all of the following apply:

(1) The mother is placed in foster care.

(2) The mother's custodian determines, as documented in the mother's case permanency plan, that it is in her best interest and the best interest of the young child that the child remain with her.

(3) A placement is available.

(4) The mother agrees to refund to the department any child support payments she receives on behalf of the child and to allow the department to be made payee for any other unearned income for the child.

156.20(2) *Provider eligibility for payment.*

a. Providers of shelter care services and supervised apartment living services shall have a purchase of service contract under 441—Chapter 150 in force.

b. Providers of group care services shall have a foster group care services contract under 441—Chapter 152 in force.

This rule is intended to implement Iowa Code sections 232.143, 234.35 and 234.38.

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CHAPTER 159
CHILD CARE RESOURCE AND REFERRAL SERVICES

PREAMBLE

These rules define the process for awarding grants for the delivery of child care resource and referral services.

441—159.1(237A) Definitions.

"Applicant" means an agency that applies for a contract as a regional child care resource and referral agency.

"Child care facility" means a child care center, preschool, or child development home.

"Child care resource and referral agency" means a community-based nonprofit incorporated agency or public agency that is under a contract with the department to provide resource and referral services as defined in subrule 159.3(1).

"Director" means the director of the department of human services.

"Region" means the service area of the child care resource and referral agency as determined in the contract with the department.

[**ARC 8654B**, IAB 4/7/10, effective 6/1/10]

441—159.2(237A) Availability of funds. In any year in which funds are available for child care resource and referral services, the department shall award grants for child care resource and referral services pursuant to a request for proposals.

159.2(1) The total amount of grant moneys awarded shall be contingent upon the funds available.

159.2(2) Grants shall be issued on a regional basis. The department shall determine the amount of grant money available for each region based upon the factors set forth in the request for proposals.

[**ARC 8654B**, IAB 4/7/10, effective 6/1/10]

441—159.3(237A) Participation requirements.

159.3(1) *Resource and referral services.* Grants will be awarded to community-based nonprofit incorporated agencies and public agencies that have the capacity to provide all of the following types of services:

a. *Parent services.*

(1) The agency shall assist families in selecting quality child care and shall provide referrals to child care facilities.

(2) The agency may provide referrals to child care homes and may provide specialized referral services to employers.

b. *Provider services.* The agency shall:

(1) Assist child care providers in adopting developmentally appropriate programs and sustainable business practices to provide quality child care services through the delivery of consultation, training, and other resources and materials.

(2) Support the development of new child care facilities and the expansion of existing child care facilities in response to identified needs.

(3) Encourage participation of eligible child care facilities in the federal Child and Adult Care Food Program (CACFP).

c. *Community services.* The agency shall:

(1) Provide information to the public regarding the availability and quality of child care services within the agency's region.

(2) Coordinate with other public and private entities and services within the region. Activities shall include coordinating with community-level efforts to improve the consistency and quality of data collection, consultation and other supports to child care homes and child development homes, particularly the efforts of home consultants funded by a community empowerment area board.

d. *Other.* The agency shall offer such other services as set forth in the request for proposals issued by the department.

159.3(2) *Matching funds.* The agency must provide a financial match of the grant award as set forth in the request for proposals. Eligible match includes in-kind contributions, private donations and public funding.
[**ARC 8654B**, IAB 4/7/10, effective 6/1/10]

441—159.4(237A) Request for proposals for project grants. The department shall announce the request for proposals through public notice.

159.4(1) *Proposal submittal.* All applicants shall submit proposals to Iowa Department of Human Services, Bureau of Child Care, Hoover State Office Building, Fifth Floor, 1305 E. Walnut, Des Moines, Iowa 50319-0114.

159.4(2) *Proposal requirements.* To be eligible for review, a proposal shall:

a. Be received by the due date specified in the request for proposals;

b. Be in the form prescribed by the department in the request for proposals; and

c. Meet the requirements set forth in the request for proposals.
[**ARC 8654B**, IAB 4/7/10, effective 6/1/10]

441—159.5(237A) Selection of proposals. The selection criteria for the grants shall be set forth in the request for proposals.

159.5(1) The director shall make the final decision regarding grants awarded to applicants. Only one grant shall be awarded in each specified region to the agency that best meets the criteria set forth in the request for proposals.

159.5(2) The department reserves the right to award grants for less than the amount of appropriated funds if there is an insufficient number of acceptable proposals submitted to adequately achieve the purpose of child care resource and referral services statewide.
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These rules are intended to implement Iowa Code section 237A.26.

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CHAPTER 187
AFTERCARE SERVICES AND SUPPORTS

PREAMBLE

These rules define and structure the aftercare services program, which assists youth leaving foster care in their successful transition to adulthood. The aftercare program, including the preparation for adult living (PAL) component, helps former foster care youth to continue preparing for the challenges and opportunities presented by adulthood while receiving services and supports. The program also offers financial benefits to eligible youth up to the age of 21. All services and supports are voluntary.

DIVISION I
AFTERCARE SERVICES

441—187.1(234) Purpose. The purpose of aftercare services is to provide services and supports to youth aged 18, 19 or 20 who were formerly in foster care. The primary goal of the program is for participants to achieve self-sufficiency and to recognize and accept their personal responsibility for the transition from adolescence to adulthood.

441—187.2(234) Eligibility. To be eligible for aftercare services, a youth must meet the following requirements:

187.2(1) *Residence.* The youth must reside in Iowa.

187.2(2) *Age.* The youth must be at least 18 years of age but less than 21 years of age.

187.2(3) *Foster care experience.*

a. The youth must leave foster care either:

(1) On or after the youth's eighteenth birthday; or

(2) Between the ages of 17 ½ and 18 after being in foster care continuously for at least six months.

b. For purposes of this division, "foster care" is defined as 24-hour substitute care for a child who is placed away from the child's parents or guardians and for whom the department or juvenile court services has placement and care responsibility through either court order or voluntary agreement.

c. A placement may meet the definition of foster care regardless of whether:

(1) The placement is licensed and the state or a local agency makes payments for the child's care;

(2) Adoption subsidy payments are being made before the finalization of adoption; or

(3) There is federal matching of any payments made.

d. Foster care may include, but is not limited to, placement in:

(1) A foster family home;

(2) A foster home of relatives;

(3) A group home;

(4) An emergency shelter;

(5) A preadoptive home;

(6) A residential facility; or

(7) The home of an unlicensed relative or suitable person.

e. Foster care does not include placement in:

(1) A detention facility;

(2) A forestry camp;

(3) A training school; or

(4) Any other facility operated primarily for the detention of children who are determined to be delinquent.

187.2(4) *Responsibility.* The youth must:

a. Actively take part in developing and participating in a self-sufficiency plan; and

b. Indicate recognition and acceptance of personal responsibility in the transition toward self-sufficiency.

441—187.3(234) Services and supports provided. The aftercare program shall provide the following services and supports to eligible youth:

187.3(1) *Individual self-sufficiency plan.* Each youth shall have an individual self-sufficiency plan based on an assessment of the youth's strengths and needs. The plan shall identify:

a. The youth's goals for achieving self-sufficiency;

b. The target date for reaching the goals; and

c. The tasks, responsible parties, time frames, and desired outcomes needed to reach the goals.

187.3(2) *Life skills services.* The program shall provide life skills services to enable youth to maintain a safe, healthy, and stable home.

187.3(3) *Vendor payments.* The program shall make vendor payments to meet direct expenses of the participant that are necessary in order to meet goals of the participant's self-sufficiency plan.

a. *Need.* To receive a vendor payment, the youth must demonstrate that there are no other means to meet these needs. Youth receiving a PAL stipend are not eligible for a vendor payment.

b. *Scope.* Vendor payments may include but are not limited to:

(1) Life skills training;

(2) Transportation assistance;

(3) Employment and education assistance;

(4) Clothing; and

(5) Room and board.

c. *Maximum payment.* The amount available for a 12-month period of service shall not exceed $1200 per youth.

187.3(4) *Follow-up.* The program shall maintain individual face-to-face contact with the youth at a frequency as defined in the youth's self-sufficiency plan to ensure that the youth is meeting the goals of the plan.

187.3(5) *Ongoing assessment.* Ongoing assessment activities shall be directed toward:

a. Monitoring the progress being made in the youth's ability to achieve self-sufficiency; and

b. Coordination and evaluation of the services and supports being provided to reach the self-sufficiency goal.

187.3(6) *Case management.* Case management activities shall include, but not be limited to:

a. Community involvement services to enable the youth to access community resources; and

b. Development of support systems, including services to assist the youth in establishing or reestablishing relationships with significant adults.

441—187.4(234) Termination. Aftercare services and supports shall be terminated when any of the following conditions apply:

187.4(1) The youth fails to follow self-sufficiency plan components and expectations as determined by the program administrator.

187.4(2) The youth voluntarily withdraws from aftercare services.

187.4(3) The youth is no longer residing in Iowa.

187.4(4) The youth reaches 21 years of age.

187.4(5) There are insufficient funds to continue the services.

441—187.5(234) Waiting list. The program administrator or designee shall create a waiting list when all funds for the aftercare services program are committed for the fiscal year. Names shall be entered on the waiting list on a first-come, first-served basis once the youth is determined eligible.

441—187.6(234) Administration. The department may contract with another state agency or a private organization to perform the administrative and case management functions necessary to administer this program.

187.6(1) The contractor and any subcontractors shall meet the standards in 441—subrule 150.5(3) and paragraph 150.3(3)*"i."*

187.6(2) Agencies providing services or supports shall meet the standards in rules 441—108.2(238) through 441—108.6(238).

441—187.7 to **187.9** Reserved.

These rules are intended to implement Iowa Code section 234.6 and Public Law 106-169, the Foster Care Independence Act of 1999.

DIVISION II
PREPARATION FOR ADULT LIVING (PAL) PROGRAM

441—187.10(234) Purpose. The purpose of the PAL program is to provide financial support to eligible youth who are receiving aftercare services. Youth receiving a PAL stipend are not eligible to receive aftercare vendor payments.

441—187.11(234) Eligibility. A monthly stipend may be provided to a youth receiving aftercare services who left foster care after May 1, 2006, and who meets all of the following criteria:

187.11(1) *Ineligibility for foster care.* The youth must be ineligible for voluntary foster care placement under 441—Chapter 202.

187.11(2) *Foster care experience.* The youth must:

a. Leave foster care paid for by the state under Iowa Code section 234.35 on or after the youth's eighteenth birthday; and

b. Have been in foster care paid for by the state under Iowa Code section 234.35 in at least 6 of the last 12 months before the youth left foster care.

187.11(3) *Living arrangement.* The youth must have a living arrangement other than a parent's home, which may include a former foster family, an apartment, a college dormitory, or another approved arrangement. The program administrator or designee is responsible for approving the living arrangement.

187.11(4) *Activity.* The youth must be engaged in or actively pursuing full-time activity comprised of one or more of the following:

a. Enrollment in a postsecondary educational training program or work training;

b. Employment for an average of 25 hours or more per week; or

c. School or program attendance leading to a high school diploma or GED.

187.11(5) *Financial need.* Initial and ongoing eligibility shall be based on the youth's income and need as determined according to rule 441—187.12(234).

441—187.12(234) Payment. The program administrator or designee shall issue payment to each participant according to the following guidelines:

187.12(1) *Need.* The amount of the PAL stipend shall be based on the needs of the youth as documented in the youth's self-sufficiency plan. Eligibility and the stipend amount shall be based on the best estimate of the youth's income, as determined at least quarterly.

a. All earned and unearned income received by the youth during the 30 days before the determination shall be used to project future income. If the 30-day period is not indicative of future income, income from a longer period or verification of anticipated income from the income source may be used to project future income.

b. The youth shall timely report the beginning or ending of earned or unearned income. A report shall be considered timely when made within ten days from the receipt of income or the date income ended.

c. When the youth timely reports a change in income, prospective eligibility and stipend amount for the following month shall be determined based on the change.

d. Recoupment shall be made for any overpayment due to failure to timely report a change in income.

e. Recoupment shall not be made when a youth timely reports a change in income and the change is timely acted upon, but the timely notice policy in rule 441—7.7(17A) requires that the action be delayed until the second calendar month following the month of change.

187.12(2) *Amount of monthly stipend.* The maximum monthly stipend shall be $574.

a. The stipend shall be prorated based on the date of entry.

b. Effect of income.

(1) When the monthly unearned income of the youth exceeds the maximum monthly stipend, the youth is not eligible for a stipend.

(2) When the net earnings of the youth exceed the maximum monthly stipend, the stipend shall be reduced the following month by 50 cents for every dollar earned over the maximum monthly stipend.

187.12(3) *Payee.* The PAL stipend may be paid to the youth, the foster family, or another payee other than a department employee. The payee shall be agreed upon by the parties involved and specified in the self-sufficiency plan under 187.3(1).

187.12(4) *Start-up allowance.* When a youth is approved for the PAL program, the program administrator or designee may authorize a one-time start-up allowance in addition to the monthly stipend. The start-up allowance:

a. Is intended to assist in covering the initial costs of establishing the youth's living arrangement, such as rental and utility deposits, purchase of food, and purchase of necessary household items.

b. Shall be based on the youth's income and need as determined according to subrule 187.12(1).

c. Shall not exceed the maximum monthly stipend amount.

[**ARC 8451B**, IAB 1/13/10, effective 1/1/10; **ARC 8653B**, IAB 4/7/10, effective 5/12/10]

441—187.13(234) Termination of stipend. The PAL stipend shall be terminated when any of the following conditions apply:

187.13(1) The youth reaches the age of 21.

187.13(2) The youth fails to meet work or education eligibility requirements for 30 consecutive days without good cause as determined by the program administrator or designee.

187.13(3) The youth fails to follow self-sufficiency plan components and expectations as determined by the program administrator or designee.

187.13(4) The youth fails to maintain satisfactory progress as defined by the education or training program in which the youth is enrolled. A youth who is not making satisfactory progress may stay in the PAL program by choosing the work option.

187.13(5) The youth chooses to live in a nonapproved setting.

187.13(6) The youth no longer resides in Iowa.

187.13(7) The youth lives with a parent.

187.13(8) There are insufficient funds to continue the stipend.

441—187.14(234) Waiting list. The program administrator or designee shall create a waiting list when all funds for the PAL program are committed for the fiscal year. Names shall be entered on the waiting list on a first-come, first-served basis once the youth is determined eligible.

441—187.15(234) Administration. The department may contract with another state agency or a private organization to perform the administrative functions necessary to administer the PAL program.

187.15(1) The contractor and any subcontractors shall meet the standards in 441—subrule 150.5(3) and paragraph 150.3(3)*"i."*

187.15(2) Agencies providing support or services shall meet the standards in rules 441—108.2(238) through 441—108.6(238).

These rules are intended to implement Iowa Code section 234.46.

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CHAPTER 201
SUBSIDIZED ADOPTIONS

[Prior to 7/1/83, Social Services(770), Ch 138]
[Previously appeared as Ch 138—renumbered IAB 2/29/84]
[Prior to 2/11/87, Human Services(498)]

441—201.1(600) Administration. The Iowa department of human services, through the administrator of the division of child and family services, shall administer the subsidized adoption program, in conformance with the legal requirements for adoption as defined in Iowa Code chapter 600.

441—201.2(600) Definitions.

"Child" means a person who has not attained age 18, or a person with a physical or mental disability who has not attained age 21.

"Escrow account" means an interest-bearing account in a bank or savings and loan association which is maintained by the department in the name of a particular child.

"Maintenance subsidy" means a monthly payment to assist in covering the cost of room, board, clothing, and spending money. The child will also be eligible for medical assistance pursuant to 441—Chapter 75.

"Mental health professional" means the same as defined in rule 441—24.1(225C).

"Mental retardation professional" means a person who has at least one year of experience working directly with persons with mental retardation or other developmental disabilities and who is one of the following:

1. A doctor of medicine or osteopathy.
2. A registered nurse.
3. A person who holds at least a bachelor's degree in a human services field including, but not limited to: social work, sociology, special education, rehabilitation counseling, and psychology.

"Nonrecurring expenses" means reasonable and necessary adoption fees, court costs, attorney fees and other expenses which are directly related to the legal adoption of a child with special needs. These shall be limited to attorney fees, court filing fees and other court costs.

"Physician" means a licensed medical or osteopathic doctor as defined in rule 441—77.1(249A).

"Presubsidy" means payment for maintenance or special services for a special needs child who is placed in an adoptive home but whose adoption is not finalized.

"Special services subsidy" means payment to a provider or the parent for medical, dental, therapeutic, or other services, equipment or appliances required by a child because of a handicapping condition.

441—201.3(600) Conditions of eligibility or ineligibility.

201.3(1) The child is eligible for subsidy when the department or a private agency has documented that it has been unable to place the child in an appropriate adoptive home without a subsidy and the child is determined to be a child with "special needs" based on one or more of the following reasons:

a. The child has a medically diagnosed disability which substantially limits one or more major life activities, requires professional treatment, assistance in self-care, or the purchase of special equipment.

b. The child has been determined by a qualified mental retardation professional to be mentally retarded.

c. Effective April 20, 2004, or later, the child has been determined by a qualified professional to be at high risk of developing a qualifying medical, mental, or emotional condition as defined in this subrule. A child in this group is eligible for subsidy of nonrecurring expenses only.

d. The child has been diagnosed by a qualified mental health professional to have a psychiatric condition which impairs the child's mental, intellectual, or social functioning, and for which the child requires professional services.

e. The child has been diagnosed by a qualified mental health professional to have a behavioral or emotional disorder characterized by situationally inappropriate behavior which deviates substantially

from behavior appropriate to the child's age or significantly interferes with the child's intellectual, social and personal adjustment.

f. The child is aged eight or over and Caucasian.

g. The child is aged two or older and is a member of a minority race or ethnic group or the child's biological parents are of different races.

h. The child is a member of a sibling group of three or more who are placed in the same adoptive home.

201.3(2) A child who enters the United States from another country on the basis of a visa classifying the child as an orphan, in accordance with the Immigration and Naturalization Act, for the purpose of adoption by a specific United States family is not eligible for subsidized adoption maintenance payments, medical assistance, or special services except for nonrecurring expenses. A child entering the country for adoption may be eligible for subsidy for nonrecurring expenses, not to exceed $500, in the following situations:

a. Rescinded IAB 8/11/99, effective 10/1/99.

b. The child from another country who meets the criteria in subrule 201.3(1) and whose adoption is finalized after June 14, 1989, must file an application on Form 470-0744, Application for Adoption Subsidy, and complete Form 470-0749, Adoption Subsidy Agreement, before or at the time of a final decree of adoption. The claim for reimbursement must be filed on Form GAX, General Accounting Expenditure, within two years of the date of the adoption decree and must include receipts.

c. If the adoptive placement disrupts prior to finalization or if the parental rights of the adoptive parents are terminated after the adoption is finalized and the department is named guardian of the child, the child may be eligible for subsidy in another adoptive placement.

201.3(3) Maintenance and child care subsidies for children who were determined to be eligible before January 1, 2004, shall continue unless one of the conditions for termination defined in 441—201.7(600) is present. The child care subsidy payment shall not exceed the applicable reimbursement rate under the child care assistance program as specified in 441—subrule 170.4(7).

201.3(4) The determination of whether a child meets eligibility requirements is made by the Iowa department of human services. An adverse determination may be appealed according to rules in 441—Chapter 7.

201.3(5) The department shall review the subsidy agreement when the child reaches the age of 17½ to determine whether the child is eligible to receive a subsidy through the age of 21 due to the child's physical or mental disability.

a. The disability shall be diagnosed by a physician, a qualified mental health professional, or a qualified mental retardation professional.

b. The diagnosis shall be current within one year of the child's eighteenth birthday.

441—201.4(600) Application. Application for presubsidy or subsidy shall be made on Form 470-0744, Application for Subsidy, at the time of the adoptive placement of the child, or at any time in the adoptive process before finalization of the adoption.

201.4(1) The prospective adoptive family residing in Iowa who has been studied and approved for adoptive placement or a family residing outside of the state of Iowa studied and approved by a governmental child-placing agency or a licensed child-placing agency in that state, may apply for subsidy for an eligible Iowa child.

201.4(2) Withdrawal of the application for the subsidy shall be reported to the department immediately.

201.4(3) The effective date for the Adoption Subsidy Agreement will be the date the agreement is signed by all parties, which may be the date the child is placed in the adoptive home or any date up to and including the date the adoption is finalized. The agreement shall state the amount of the presubsidy or subsidy, and the frequency and duration of payments.

201.4(4) An application for subsidy cannot be taken after the child is adopted except when there are facts relevant to a child's eligibility that were not presented before the finalizing of the adoption.

a. Upon receiving verification that the child was eligible before the child's adoption, the department may conduct an administrative review of the facts and may determine the child an eligible special needs child. Eligibility will be effective after Form 470-0744, Application for Subsidy, is completed and Form 470-0749, Adoption Subsidy Agreement, is signed by all parties.

b. Requests for determining a child an eligible special needs child after the adoption is finalized shall be forwarded with verification of eligibility to the division of child and family services, adoption program. The division shall conduct an administrative review of eligibility factors and render a written decision regarding the child's eligibility as a special needs child within 30 days of receipt of request and verification materials unless additional verification is requested. If additional verification is requested, a decision shall be reached within 30 days of receipt of additional verification materials.

441—201.5(600) Negotiation of amount of presubsidy or subsidy.

201.5(1) The amount of presubsidy or subsidy shall be negotiated between the department and the adoptive parents and shall be based upon the needs of the child and the circumstances of the family.

a. Each time negotiations are completed, the Adoption Subsidy Agreement, Form 470-0749, shall be completed.

b. Form 470-0762, Agreement to Future Adoption Subsidy, shall be completed and retained in an inactive case record for future reference when:

(1) A child is eligible for subsidy but the child or family does not currently need assistance; or

(2) The child is at risk of being determined a child with special needs according to paragraph 201.3(1)*"a," "b," "d,"* or *"e"* in the future.

201.5(2) Other services available to the family free of charge to meet the needs of the child, such as other federal, state, and local governmental and private assistance programs, shall be explored and used before the expenditure of subsidy funds.

a. and *b.* Rescinded IAB 5/11/05, effective 5/1/05.

c. Unearned income of the child shall be verified by documentation provided to the department worker by the family from the source of the income.

201.5(3) to **201.5(5)** Rescinded IAB 5/3/89, effective 7/1/89.

201.5(6) A maintenance subsidy may be no less than $10 per month.

201.5(7) An adoptive family may request a review of the subsidy agreement when there is a change in the family's circumstances or the needs of the child.

201.5(8) Maintenance subsidy shall continue under the same rules if the adoptive family moves outside of the state of Iowa.

201.5(9) The maximum monthly maintenance payment for a child in subsidized adoption shall be made pursuant to the foster family care maintenance rates according to the age and special needs of the child as found at 441—subrule 156.6(1) and 441—paragraph 156.6(4)*"f."*

441—201.6(600) Types of subsidy.

201.6(1) *Special services only.*

a. Reimbursement to the adoptive family or direct payment made to a provider is suspended from January 1, 2010, to June 30, 2010, for any special services negotiated in that period except for nonrecurring expenses as defined in subparagraph (7).

(1) Outpatient counseling or therapy services. Reimbursement for outpatient individual or family services may be provided from a non-Medicaid provider only with approval from the service area manager or designee and when one of the following applies:

1. The services are not available from a Medicaid provider within a reasonable distance from the family.

2. The child and the family were already receiving therapy or counseling from a non-Medicaid provider and it would not be in the child's best interest to disrupt the services.

3. Available Medicaid providers lack experience in working with foster, adoptive, or blended families.

Reimbursement to non-Medicaid providers shall be limited to the Medicaid rate.

(2) Expenses for transportation, lodging, or per diem related to preplacement visits, not to exceed $2000 per family.

(3) Medical services not covered by the Medicaid program shall be limited to an additional premium amount due to the child's special needs to include the child in the family's health insurance coverage group. An adoption subsidy payment shall not supplement the Medicaid payment rate to a Medicaid provider or a non-Medicaid provider.

(4) Child care, if the family has entered into a presubsidy or subsidy agreement on or before June 30, 2004, that contains a provision for child care reimbursement. Child care subsidy payments shall not exceed the maximum rates established in 441—paragraph 170.4(7)*"a"* for the child's age and type of care, unless the department grants a waiver under rule 441—1.8(17A,217). Child care services are available through the child care assistance program to families that meet the requirements of 441—Chapter 170.

(5) Medical transportation not covered by Medicaid and the family's lodging and meals, if necessary, when the child is receiving specialized care or the child and family are required to stay overnight as part of a treatment plan.

(6) Supplies and equipment as required by the child's special needs and unavailable through other resources. When a sibling group of three or more are placed together, a one-time-only payment can be made, not to exceed $500 per child. When home modifications have been authorized to accommodate a child's special needs and the family later sells the house, the family shall repay the department an amount equal to the increase in the equity value of the home attributable to the modifications.

(7) Nonrecurring expenses. Payment for nonrecurring expenses is generally limited to a total of $500 per child for attorney fees, court costs and other related legal expenses. Nonrecurring expenses may be paid when the adoptive family has negotiated an Adoption Subsidy Agreement, Form 470-0747, or an Agreement to Future Adoption Subsidy, Form 470-0762.

(8) Funeral benefits at the amount allowed for a foster child in accordance with 441—subrule 156.8(5).

b. The need for special services shall be established by a report in the child's record from the private or public agency which had guardianship of the child, and substantiating information from specialists as defined in rule 441—201.2(600).

c. Any single special service and any special service delivered over a 12-month period costing $500 or more shall have prior approval from the central office adoption program manager prior to expending program funds.

d. For all Medicaid covered services the department shall reimburse at the same rate and duration as Medicaid as set forth in rule 441—79.1(249A).

201.6(2) *Maintenance only.* A monthly payment to assist with room, board, clothing and spending money may be provided, as determined under rule 441—201.5(600). The child will also be eligible for medical assistance pursuant to 441—Chapter 75.

201.6(3) *Maintenance and special services.* For special needs children, a special services subsidy may also be included when a maintenance subsidy is provided.

[**ARC 8451B**, IAB 1/13/10, effective 1/1/10; **ARC 8653B**, IAB 4/7/10, effective 5/12/10]

441—201.7(600) Termination of subsidy. Subsidy will terminate when any of the following occur:

201.7(1) The adoptive child no longer meets the definition of child in rule 441—201.1(600).

201.7(2) The child marries.

201.7(3) The adoptive parents are no longer using the maintenance payments to support the child.

201.7(4) Death of the child, or death of the parents of the child (one in a single-parent family and both in a two-parent family).

201.7(5) Upon conclusion of the terms of the agreement.

201.7(6) Upon request of the adoptive parents.

201.7(7) The adoptive parents are no longer legally responsible for the child.

201.7(8) Rescinded IAB 3/12/08, effective 4/16/08.

441—201.8(600) Reinstatement of subsidy. Reinstatement of subsidy will be made when the subsidy was terminated because of reasons in 201.7(3), 201.7(6), or 201.7(7) and the reason for termination no longer exists.

441—201.9(600) New application. New applications will be taken at any time, but processed only so long as funds are available. Maintenance and special services already approved will continue.

441—201.10(600) Medical assistance based on residency. Special needs children eligible for any type of subsidy are entitled to medical assistance as defined in 441—Chapter 75. The funding source for medical assistance is based on the following criteria:

201.10(1) IV-E-eligible children:

a. IV-E-eligible children residing in Iowa from Iowa and from other states shall receive medical assistance from Iowa.

b. IV-E-eligible children from Iowa residing in another state shall receive medical assistance from the family's state of residence, even though medical assistance available in the family's state of residence may vary from Iowa's medical assistance.

201.10(2) Non-IV-E-eligible children:

a. Non-IV-E-eligible children from Iowa residing in Iowa shall be covered by Iowa's medical assistance.

b. Non-IV-E-eligible children from Iowa residing in another state shall be covered by Iowa's medical assistance unless eligible for benefits from the other state pursuant to a program funded under Title XIX of the federal Social Security Act.

c. Non-IV-E-eligible children from another state residing in Iowa shall be covered by Iowa's medical assistance if all of the following conditions are met:

(1) The child is under the age of 21.

(2) The child is residing in Iowa in a private home with the child's adoptive parent or parents.

(3) Another state is currently paying an adoption subsidy for the child pursuant to an adoption assistance agreement in effect for the chid with that state.

(4) The state paying the adoption subsidy is a member of the interstate compact on adoption and medical assistance (ICAMA).

(5) The state paying the adoption subsidy provides medical assistance benefits pursuant to a program funded under Title XIX of the Social Security Act, under the optional group at Section 1902(a)(10)(A)(ii)(VIII) of the Act, to children residing in that state (at least until age 18) for whom there is a state adoption assistance agreement in effect with the state of Iowa other than under Title IV-E of the Social Security Act.

201.10(3) When an Iowa child receives medical assistance from another state, Iowa shall discontinue paying any medical costs the month following the move unless additional time is necessary for a timely notice of decision to be provided to the family. An exception shall be made when the initial Iowa subsidy agreement provides for services not covered by the other states.

441—201.11(600) Presubsidy recovery. The department shall recover the cost of presubsidy maintenance and special services provided by the department as follows:

201.11(1) Funds shall be applied to the cost of presubsidy maintenance and special services from the unearned income of the child.

201.11(2) The department shall serve as payee to receive the child's unearned income. The income shall be placed in an account from whence it shall be applied toward the cost of the child's current care and the remainder placed in an escrow account.

201.11(3) When a child has funds in escrow these funds may be used by the department to meet the current needs of the child not covered by the presubsidy payments and not prohibited by the source of the funds.

201.11(4) When the child leaves presubsidy care, funds in the escrow shall be paid to the adoptive parents, or to the child if the child has attained the age of majority.

These rules are intended to implement Iowa Code sections 600.17 to 600.23.

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Rescinded IAB 4/7/10, effective 5/12/10; see 481—Ch 90

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CHAPTER 90
PUBLIC ASSISTANCE DEBT RECOVERY UNIT

[Prior to 4/7/10, see 481—Ch 71]

PREAMBLE

These rules define the department's policies regarding the recovery of public assistance debts. See also Iowa Administrative Code 441—Chapter 11, "Collection of Public Assistance Debts."

481—90.1(10A) Definitions. For the purposes of this chapter, the following definitions apply:

"Active case" means a household that is receiving public assistance.

"Allotment reduction" means an amount withheld from a financial or food assistance benefit. More specifically, "grant reduction" refers to the family investment program (FIP) and to refugee cash assistance (RCA), and "benefit reduction" refers to the food assistance (FA) program.

"Debt" means the dollar amount of public assistance, by program, received by or on behalf of a person or provider in excess of that allowed by law, rules, or regulations for any given month(s); or the dollar amount of public assistance unlawfully transferred or obtained in violation of program rules; or the dollar amount of unpaid IowaCare personal financial responsibility obligations.

"Debtor" means any person who has been determined by DHS or by the department to be responsible for the repayment of a particular public assistance debt.

"Department" means the department of inspections and appeals.

"DHS" means the department of human services.

"Economic assistance fraud bureau" means the economic assistance fraud bureau of the department of inspections and appeals.

"FA" means the food assistance program as defined in rule 441—65.1(234).

"FIP" means the family investment program described in 441—Chapters 40 to 46.

"Notice of debt" means a notice that informs the debtor that a debt in a public assistance program has occurred. The notice identifies the debt amount, the dates on which the debt was incurred, the cause of the debt, and the options the debtor has to repay the debt. (See 441—Chapter 11.)

"Offsetting" means the repayment of a debt by setoff of a state warrant or setoff of state income tax refunds or federal tax refunds and federal payments.

"Public assistance" means any program that DHS administers that confers a financial, medical, or food assistance benefit.

"RCA" means refugee cash assistance described in 441—Chapter 60.

"Recovery" means the repayment of a debt by direct cash payment from the debtor, by allotment reduction, by offsetting, or by garnishment of wages or assets.

"Repayment agreement" means an agreement entered into voluntarily between the department and the debtor for the repayment of a debt. Agreements are made on Form 470-0495, Agreement to Pay a Debt, or on a notice of debt listed in 441—subrule 11.2(2). The repayment agreement, whether Form 470-0495 or a notice of debt, tells the amount and program(s) overpaid and gives the debtor a choice of repayment methods. Failure to return the repayment agreement may result in further collection actions.

"Title XIX divestiture" means a debt against a person who receives transferred assets from a Medicaid applicant or recipient within five years prior to an application for medical assistance if the applicant is approved for medical assistance (Medicaid) or a transfer impacting the recovery or payment of a medical assistance (Medicaid) debt.

[**ARC 8656B**, IAB 4/7/10, effective 5/12/10]

481—90.2(10A) Recovery process. The recovery process begins when data is successfully entered on the DHS overpayment recovery system and a notice of debt is issued to the debtor. The data specifies which public assistance program(s) is owed a debt.

[**ARC 8656B**, IAB 4/7/10, effective 5/12/10]

481—90.3(10A) Records. The recovery unit maintains an account for each debt that has occurred for a debtor. The account is filed under the debtor's name and includes information maintained pursuant to rule 441—11.2(217).
[**ARC 8656B**, IAB 4/7/10, effective 5/12/10]

481—90.4(10A) Review. The recovery unit reviews the record and additional information provided in the DHS overpayment recovery system to determine whether a referral for suspected fraud will be made to the economic assistance fraud bureau. The referral criteria include client errors that are over $1,000 per claim.
[**ARC 8656B**, IAB 4/7/10, effective 5/12/10]

481—90.5(10A) Debt repayment. A notice of debt or Form 470-0495, Agreement to Pay a Debt, is used to initiate payments of a debt. The minimum rate of payment is determined by each program (unless set by a court order) and is negotiated by the debtor and recovery unit. All recoveries are transmitted to the DHS cashier. Payments are made directly in cash by the debtor except as otherwise provided in this rule. The amount of allotment reduction for an agency error shall be different from the amount of allotment reduction for a client error.

90.5(1) *Active cases—PROMISE JOBS program.* For payment reduction for the PROMISE JOBS program, the debtor must provide written permission to effectuate a FIP reduction.

90.5(2) *Active cases—FIP, RCA, FA.* Allotment reduction shall be used, except that cash payment pursuant to a repayment agreement may be used when the repayment amount exceeds the amount that may be collected by allotment reduction. For the food assistance program, debt repayment may also be made in accordance with subrule 90.5(3).

90.5(3) *Food assistance program with electronic benefit balances.* Food assistance payments may be made by returning electronic benefits to pay the debt.
[**ARC 8656B**, IAB 4/7/10, effective 5/12/10]

481—90.6(10A) Further collection action. If complete repayment has not been received by the methods described in rule 481—90.5(10A), further collection action may be taken. This action includes, but is not limited to, the following:

90.6(1) *For all debts.*

a. Debts of $5,000 or less, small claims court action.

b. Debts of more than $5,000, referral to the attorney general for district court action.

c. State income tax refund offset in accordance with 441—Chapter 11 and Iowa Code section 8A.504.

d. The filing of a claim in a debtor's estate or bankruptcy proceedings.

e. Garnishment of wages or assets.

f. Setoff of a state warrant.

g. Distress warrants.

h. Liens.

90.6(2) *For food assistance debts.* In addition to the above actions, federal offsets (taxes, federal payments) may be used for the collection of food assistance debts in accordance with rule 441—11.5(234).
[**ARC 8656B**, IAB 4/7/10, effective 5/12/10]

481—90.7(10A) Appeal rights. If a notice of debt or other notice of adverse action is received by the debtor and the debtor wishes to contest the debt, an appeal is submitted to the recovery unit or to DHS. If an appeal is submitted, the recovery process is suspended until conclusion of the appeal process outlined in 481—Chapter 10 and 441—Chapter 7.
[**ARC 8656B**, IAB 4/7/10, effective 5/12/10]

481—90.8(10A) Data processing systems matches. The recovery unit compares information with other data processing systems to identify the location, resources, or income of a debtor. Part or all of a data

processing system is used. The recovery unit uses, but is not limited to using, the data processing systems of the following entities:

1. Social Security Administration,
2. Department of workforce development,
3. Department of revenue,
4. Department of administrative services,
5. Department of transportation (driver's license and motor vehicle registration), and
6. Department of human services.

[**ARC 8656B**, IAB 4/7/10, effective 5/12/10]

481—90.9(10A) Confidentiality. The confidentiality of records is in accordance with 441—Chapter 9, "Public Records and Fair Information Practices."

[**ARC 8656B**, IAB 4/7/10, effective 5/12/10]

These rules are intended to implement Iowa Code sections 10A.108 and 10A.402.

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ENVIRONMENTAL PROTECTION COMMISSION[567]

Former Water, Air and Waste Management[900], renamed by 1986 Iowa Acts, chapter 1245, Environmental Protection Commission under the "umbrella" of the Department of Natural Resources.

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CHAPTER 15
CROSS-MEDIA ELECTRONIC REPORTING

567—15.1(455B,554D) Purpose. This rule implements the cross-media electronic reporting rule (also known as CROMERR) as defined by 40 CFR Part 3.

15.1(1) *Applicability.* The provisions of this subrule shall apply to persons and signatories who submit electronic reports or other documents to satisfy requirements of Title 40 of the Code of Federal Regulations for authorized programs for which the department is accepting specified electronic documents and other media used for electronic reporting, except for the following:

a. Documents submitted via facsimile;

b. Electronic documents submitted via magnetic or optical media such as diskette, compact disc, digital video disc, or tape;

c. Electronic documents submitted through an electronic document receiving system pursuant to a non-federal state-only program; or

d. Data transfers between the department and the U.S. Environmental Protection Agency, local governments, or tribes as part of an authorized program or administrative arrangement.

15.1(2) *Definitions.* For the purpose of this rule, the following terms shall have the meanings indicated below:

"Authorized program" means a federal program that the U.S. Environmental Protection Agency (EPA) has delegated to, authorized, or approved the department, on behalf of the state of Iowa, to administer, or a program that the EPA has delegated to, authorized, or approved the department to administer in lieu of a federal program, under provisions of 40 CFR and for which the delegation, authorization or approval has not been withdrawn or expired.

"Copy of record" means a true and correct copy of an electronic document received by an electronic document receiving system, which can be viewed in a human-readable format that clearly and accurately associates all the information provided in the electronic document with descriptions or labeling of the information. A "copy of record" includes:

1. Any electronic signature contained in or logically associated with the document;
2. The date and time of receipt; and
3. Any other information used to record the meaning of the document or the circumstances of its receipt.

"Electronic document" means any information that is submitted to one of the department's electronic document receiving systems in digital form to satisfy requirements of an authorized program and may include data, text, sounds, codes, computer programs, software, or databases.

"Electronic document receiving system" means the apparatus, procedures, software, or records established and used by the department to receive electronic documents in lieu of paper.

"Electronic signature" means any information in digital form attached to or logically associated with a record submitted to one of the department's electronic document receiving systems and executed or adopted by a person with the intent of expressing the same meaning as would a handwritten signature if affixed to an equivalent paper document with the same content.

"Electronic signature agreement" means a written agreement prepared by the department and signed by an individual with respect to an electronic signature device that the individual will use to create the individual's electronic signature.

"Electronic signature device" means a code or other mechanism, assigned to an individual who is uniquely entitled to use it and that is then used to create the individual's electronic signature.

"Federal program" means any program administered by EPA under any provision of 40 CFR.

"Handwritten signature" means the scripted name or legal mark of an individual made by that individual with the present intention to authenticate a signature in a permanent form.

"Signatory" means an individual authorized to sign and who signs a document submitted to one of the department's electronic document receiving systems pursuant to an electronic signature agreement.

"State program" means any program other than an authorized program that is implemented by the department under the laws of the state of Iowa.

"Valid electronic signature" means an electronic signature on an electronic document created by using an electronic signature device that the identified signatory is uniquely entitled to use for signing the electronic document, provided the device has not been compromised and provided the signatory is an individual authorized to sign the document by virtue of legal status or relationship to the entity on whose behalf the signature is created.

15.1(3) *Use of electronic document receiving systems.*

a. Announcement on public Web site. When the director has announced on the department's public Web site that the department is accepting specified electronic documents in lieu of paper to satisfy requirements under each authorized program, individuals who submit such electronic documents must use the department's CROMERR-compliant electronic document receiving systems.

b. Submittals requiring signature. Any electronic document submitted to the department must bear a valid electronic signature of a signatory, if that signatory would be required under the authorized program to sign the paper document for which the electronic document substitutes.

c. Submittals not requiring signature. If no signature is required under the authorized program, individuals may submit electronic documents in lieu of paper to satisfy requirements of such programs through the department's CROMERR-compliant electronic document receiving system without an electronic signature or an electronic signature agreement.

15.1(4) *Electronic signature agreement.*

a. Agreement to be executed. In the case of an electronic document that must bear the electronic signature of a signatory under an authorized program, each signatory must execute an electronic signature agreement.

b. Form and content of agreement. All agreements shall be in writing and filed with the electronic document receiving system administrator via a mail delivery service or by hand delivery. The agreement shall include the information and follow the format as defined by the department. The agreement form may be downloaded and printed for signing during the signatory's registration process.

c. Verification. The identity and authority of each individual submitting an electronic signature agreement shall be verified by the state of Iowa. After the state of Iowa has satisfactorily completed the verification, the department shall notify the individual electronically that the electronic signature device has been activated and access to the database has been granted.

d. Certification. Each submission authorized by an electronic signature shall contain the following statement: "I certify under penalty of law that I have had the opportunity to review, in human-readable format, the content of the electronic document to which I here certify and attest, and I further certify under penalty of law that, based on the information and belief formed after reasonable inquiry, the statements and information contained in this submission are true, accurate, and complete. I understand that making any false statement, representation, or certification of this submission may result in criminal penalties."

15.1(5) *Valid electronic signature.*

a. Signatory. An authorized signatory may not allow another individual to use the electronic signature device unique to the authorized signatory's electronic signature.

b. Unique signature device. When the electronic signature device is used to create an individual's electronic signature, the code or mechanism must be unique to that individual at the time the signature is created and the individual must be uniquely entitled to use it. The signatory shall:

(1) Protect the electronic signature device from compromise; and

(2) Report to the department, within one business day of discovery, any evidence that the security of the device has been compromised.

15.1(6) *Effect of electronic signature.*

a. Electronic signature establishes intent. The presence of an electronic signature on an electronic document submitted to the department establishes that the signatory intended to sign the electronic document and to submit it to the department to fulfill the purpose of the electronic document.

b. Electronic signature legally binding. Where an electronic document submitted to satisfy a reporting requirement of an authorized program bears an electronic signature, the electronic signature legally binds, obligates, and makes the signatory responsible to the same extent as the signatory's handwritten signature on a paper document submitted to satisfy the same reporting requirement. If an

applicable law or rule requires a handwritten signature on a document, an electronic signature satisfies that requirement.

15.1(7) *Enforcement.*

a. Penalties and other remedies. If the submitter or signatory fails to comply with a reporting requirement by failing to comply with the provisions of this chapter, the electronic signature agreement, or other applicable reporting requirements, the submitter or signatory is subject to any appropriate civil or criminal penalties or other remedies under Iowa law.

b. Electronic document as evidence. Nothing in this chapter or the authorized program limits the use of an electronic document, copy of record, or other information derived from an electronic document as evidence in enforcement proceedings.

[**ARC 8678B**, IAB 4/7/10, effective 5/12/10]

This rule is intended to implement Iowa Code section 455B.105 and chapter 554D.

[Filed ARC 8678B (Notice ARC 8467B, IAB 1/13/10), IAB 4/7/10, effective 5/12/10]

CHAPTERS 16 to 19
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CHAPTER 122
CATHODE RAY TUBE DEVICE RECYCLING

567—122.1(455B,455D) Purpose. These rules are intended to satisfy the requirements of Iowa Code sections 455D.6(7) and 455B.304(1). The purpose of this chapter is to implement rules for the recycling of discarded CRTs and the disassembly and removal of toxic parts from discarded CRTs in a manner that is safe for human health and the environment.

567—122.2(455B,455D) Applicability and compliance.

122.2(1) This chapter applies to facilities that perform CRT recycling functions, including but not limited to the collection, refurbishing, demanufacturing, and processing of discarded CRTs.

122.2(2) This chapter does not apply to facilities solely engaged in CRT reuse activities. This chapter does not apply to businesses solely engaged in CRT service and repair. This chapter does not apply to batteries, circuit boards, CRTs, mercury-containing components, or PCB capacitors removed during the maintenance or service of equipment containing such items.

122.2(3) These rules do not pertain to appliance demanufacturing. For rules pertaining to appliance demanufacturing, see 567—Chapter 118.

122.2(4) The issuance of a permit by the department in no way relieves the applicant of the responsibility of complying with all other local, state, or federal statutes, ordinances, and rules or other requirements applicable to the construction and operation of a CRT recycling facility.

[**ARC 8679B**, IAB 4/7/10, effective 7/1/10]

567—122.3(455B,455D) Definitions. In addition to the definitions set out in Iowa Code section 455B.301, which shall be considered to be incorporated by reference in these rules, the following definitions shall apply:

"Battery" means a device consisting of one or more electrically connected electrochemical cells, which is designed to receive, store, and deliver electric energy.

"Broken CRT" means a CRT that has had the glass broken or the vacuum released. "Broken CRT" does not include a CRT that is intact but not functional.

"Capacitor" means a device for accumulating and holding a charge of electricity that consists of conducting surfaces separated by a dielectric fluid. For the purposes of this chapter, "capacitor" does not include dry-cell capacitors.

"Cathode ray tube" and its abbreviation *"CRT"* mean a vacuum tube composed primarily of leaded glass and used to convert an electrical signal into a visual image.

"CFR" means Code of Federal Regulations.

"Circuit board" means a board in a computer or electronic good that holds integrated circuits and other electronic components.

"CRT collection" means any activity by a CRT recycling facility or CRT collection facility involving the collection of discarded CRTs.

"CRT collection facility" means a site where ongoing CRT collection is the only CRT recycling activity performed.

"CRT demanufacturing" means any activity involving the disassembly of discarded CRTs.

"CRT device" means any device that contains a CRT. Examples of a CRT device include, but are not limited to, computer monitors, televisions, some cash registers, and oscilloscopes.

"CRT fluff" means the residual waste from the shredding of discarded CRTs.

"CRT glass" means any glass generated from CRTs.

"CRT processing" means any activity that processes discarded CRTs into raw materials.

"CRT recycling" means any process by which discarded CRTs or electronic materials that would otherwise become waste are collected, processed and returned to use in the form of raw materials or products. CRT recycling includes, but is not limited to, CRT demanufacturing, CRT processing, and CRT refurbishing.

"CRT recycling facility" means a site where CRT recycling takes place.

"CRT refurbishing" means any activity that repairs and rebuilds discarded CRTs, so that they may be used for their original intended purpose.

"CRT reuse" means any activity involving the donation or sale of discarded CRTs for their original intended purpose provided that the CRT devices are in good working order and do not require refurbishment.

"CRT reuse facility" means a facility where CRT reuse occurs and the only CRTs accepted are those in good working order, and the CRTs are sold or donated without being refurbished.

"Discarded" means no longer to be used for the original intended purpose and means the letting go or throwing away of materials that have become useless or superfluous though often not intrinsically valueless. CRTs that are returned to the original owner are not "discarded."

"Discarded CRT" means a cathode ray tube or CRT device that has been discarded.

"DOT-approved container" means those containers approved by the U.S. Department of Transportation for shipping hazardous materials in the United States.

"Hazardous condition" means any situation involving the actual, imminent or probable release of a hazardous substance onto the land, into a water of the state, or into the atmosphere which, because of the quantity, strength or toxicity of the hazardous substance, its mobility in the environment and its persistence in the environment, creates an immediate or potential danger to the public health or safety, or to the environment.

"Mercury-containing components" means devices, other than batteries, containing a regulated amount of mercury.

"PCB" or *"PCBs"* means polychlorinated biphenyl, which is a chemical substance that is limited to the biphenyl molecule that has been chlorinated to varying degrees, or any combination of such substances.

[**ARC 8679B**, IAB 4/7/10, effective 7/1/10]

567—122.4(455B,455D) CRT recycling permits.

122.4(1) *Permit required.* A CRT recycling facility shall not be constructed or operated without a permit from the department.

122.4(2) *CRT recycling permit exemption.* If a CRT recycling facility is located at a permitted sanitary disposal project, it shall not require its own permit; instead, the CRT recycling activities shall be amended into the host facility's permit.

122.4(3) *Construction and operation.* CRT recycling facilities shall be constructed and operated according to the plans and specifications approved by the department and the conditions of the permit. The approved plans and specifications shall constitute a condition of the permit.

122.4(4) *Transfer of title and permit.* If title to a CRT recycling facility is transferred, then the department shall transfer the permit within 60 days if the department has found that the following requirements have been met:

a. The title transferee has applied in writing to the department to request a transfer of the permit within 30 days of the transfer of title.

b. The permitted facility is in compliance with Iowa Code chapters 455B and 455D, these rules and the conditions of the permit.

122.4(5) *Permit conditions.* Any permit may be issued subject to conditions specified in writing by the department that are necessary to ensure that the facility is constructed and operated in compliance with Iowa Code chapters 455B and 455D and these rules.

122.4(6) *Effect of revocation.* If a permit held by any public or private agency is revoked by the director, then no new permit shall be issued to that agency for that CRT recycling facility for a period of one year from the date of revocation. Such revocation shall not prohibit the issuance of a permit for the facility to another public or private agency.

122.4(7) *Inspection prior to commencing new operation.* The department shall be notified when the construction of a new facility has been completed. No discarded CRTs shall be accepted by the facility until it has been inspected and approved by the department or until 30 days have passed from the date of permit issuance and no inspection has been performed by the department.

122.4(8) *Duration and renewal of permits.* A permit shall be issued and may be renewed for a period of five years, unless otherwise authorized by the department.

122.4(9) *Request and approval of permit renewal.* A request for permit renewal shall be in writing and shall be filed at least 90 days before the expiration of the current permit by submitting Form 50 (542-1542) to the department. The department may request that additional information be submitted for review to make a permit renewal decision. The department shall renew the permit if, after a review and inspection of the facility and its compliance history, the department finds that the facility is in compliance with Iowa Code chapters 455B and 455D, these rules and the conditions of the permit, and is making a good-faith effort to maintain compliance. If the facility is found not to be in compliance with Iowa Code chapters 455B and 455D, these rules, and the conditions of the permit or if a good-faith effort to maintain compliance is not being made, the facility shall be brought into compliance or placed on a compliance schedule approved by the department before the permit is renewed.

122.4(10) *Request for permit modification.* A request for permit modification shall be submitted in writing to the department with supporting documentation and materials. The department may request that additional information be submitted for review to make a permit modification decision.

[**ARC 8679B**, IAB 4/7/10, effective 7/1/10]

567—122.5(455B,455D) Registration for CRT collection facilities. A CRT collection facility shall register with the department using Form 542-0060.

[**ARC 8679B**, IAB 4/7/10, effective 7/1/10]

567—122.6(455B,455D) CRT collection and storage requirements for registered collection points.

122.6(1) CRT storage at a registered collection site shall be limited to 48 Gaylord boxes or the equivalent containing no more than 2,000 CRTs.

122.6(2) A CRT shall not be stored at a registered collection point for more than one year.

122.6(3) All CRTs shall be stored in a building, shipping container, or enclosed vehicle that provides protection from the elements.

122.6(4) Access to the CRT storage area shall be secured during nonbusiness hours.

122.6(5) The CRT storage area shall be free of other solid waste, other than in designated storage areas, except for incidental amounts of solid waste that are not discarded CRTs.

122.6(6) Containers or packages shall be labeled and transported in compliance with state and federal Department of Transportation (DOT) rules.

122.6(7) Any container holding CRTs shall be clearly labeled with the contents of the container and the date the first CRT was placed in the container.

122.6(8) The CRT collection facility shall maintain the following records on site for a minimum of three years.

a. The total amount of CRTs received in a calendar year.

b. The total amount of CRTs shipped for recycling or reuse in a calendar year.

c. All shipping papers, manifests, and bills of lading for CRTs shipped from the facility.

122.6(9) The registrant must annually provide information to all employees who handle or have responsibility for managing discarded CRTs. The information shall describe proper handling, safety, and emergency procedures appropriate for discarded CRTs. A training log shall be maintained on site by the registrant and shall contain the following information:

a. A copy of the information provided to the employees;

b. The names of the employees who received the information; and

c. The date the training was provided to the employee.

[**ARC 8679B**, IAB 4/7/10, effective 7/1/10]

567—122.7(455B,455D) Record-keeping requirements for CRT collection facilities. All CRT collection facilities shall maintain the following records, on a calendar-year basis, for three years:

122.7(1) The name and address of the facility receiving a shipment that left the CRT collection facility, and contact information for that facility.

122.7(2) The type of service the receiving facility will provide to the CRT collection facility.

122.7(3) A description of the shipment contents.

122.7(4) All bills of lading.

122.7(5) All hazardous waste manifests.

[**ARC 8679B**, IAB 4/7/10, effective 7/1/10]

567—122.8(455B,455D) CRT recycling facility permit application requirements.

122.8(1) A CRT recycling facility permit applicant shall submit the following permit application information to the department:

a. The name, address, and telephone number of:

(1) The owner of the site where the project will be located.

(2) The permit applicant.

(3) The individual responsible for the operation of the project.

(4) The professional engineer (P.E.) licensed in the state of Iowa and retained for the design of the facility, if any.

(5) The agency to be served by the project, if any.

(6) The responsible official of the agency to be served, if any.

b. A legal description of the site, and any collection sites if separate from the main facility.

c. A map or aerial photograph locating the boundaries of the site and identifying:

(1) North and other principal compass points.

(2) Zoning and land use within 250 feet of the property boundary.

(3) Homes and buildings within 250 feet of the property boundary.

(4) Section lines or other legal boundaries.

(5) The 100-year flood plain pursuant to rule 567—122.9(455B,455D).

d. Proof of the applicant's ownership of the site or legal entitlement to use the site for CRT recycling.

e. Documentation that the facility meets local zoning requirements.

f. Days and hours of operation of the site.

g. The service area of the facility.

h. The type, source, and number or weight of discarded CRTs expected to be handled each year.

i. A description of the CRT recycling process to be used, such as collection, demanufacturing, processing, reuse, refurbishing, or a combination thereof.

j. Site plans detailing how the site will comply with rule 567—122.10(455B,455D), including floor plans of buildings where discarded CRTs will be handled and the location within each building for specific recycling activities.

k. A plan of operations detailing how the site will comply with rules 567—122.11(455B,455D) to 567—122.19(455B,455D).

l. An emergency response and remedial action plan (ERRAP) pursuant to rule 567—122.20(455B,455D).

m. A reporting plan detailing how the site will comply with rule 567—122.22(455B,455D).

n. A closure plan detailing how the site will comply with rule 567—122.24(455B,455D).

122.8(2) If the department finds the permit application information to be incomplete, it shall notify the applicant of that fact and of the specific deficiencies. If the deficiencies are not corrected within 30 days, the department shall return the application materials to the applicant. The applicant may reapply without prejudice.

[**ARC 8679B**, IAB 4/7/10, effective 7/1/10]

567—122.9(455B,455D) Site requirements for CRT recycling facilities. A CRT recycling facility shall not be located within a 100-year flood plain.

[**ARC 8679B**, IAB 4/7/10, effective 7/1/10]

567—122.10(455B,455D) Design requirements for CRT recycling facilities. A CRT recycling facility shall be designed and constructed to meet the following requirements:

122.10(1) CRT recycling facilities shall be enclosed by walls, a roof, and a floor satisfactory to:

a. Prevent litter from exiting the building.

b. Keep precipitation out of the building.

122.10(2) A CRT recycling facility shall maintain a separation between stormwater and liquids generated inside the building.

122.10(3) Discarded CRTs shall be demanufactured and processed in an area where hazardous materials can be contained.

122.10(4) A sign shall be posted at the primary entrance to the facility. The sign shall be a minimum of 8½ × 11 inches and visible from the outside of the building at approximately eye level. The lettering shall be a minimum of 1-inch high and state the following information:

a. Name and permit number of facility.

b. Telephone number of emergency contact person(s).

122.10(5) A CRT recycling facility may store discarded CRTs and materials derived from discarded CRTs outdoors if the following conditions are met:

a. The facility has a stormwater permit, if applicable.

b. The material is not harboring or attracting vectors.

c. Litter is contained within the storage area or unit.

d. The discarded CRTs and materials derived from discarded CRTs are not broken CRTs or CRT glass.

[**ARC 8679B**, IAB 4/7/10, effective 7/1/10]

567—122.11(455B,455D) Operational requirements for permitted CRT recycling facilities.

122.11(1) *Collection requirements for CRTs.* All discarded CRTs coming into the CRT recycling facility shall be collected in a manner that complies with the following requirements:

a. Collection activities for discarded CRTs shall occur in an area and through a process that minimizes the risk of hazardous conditions.

b. Discarded CRTs shall be collected and contained in a manner that is structurally adequate to prevent breakage and spillage under normal operating conditions, and that is compatible with the contents.

c. CRT glass and CRTs that show evidence of breakage, leakage, or damage that could cause the release of lead or other hazardous constituents into the environment shall be collected in enclosed and separate containers from other discarded CRTs.

122.11(2) *Transportation requirements for CRTs.* All discarded CRTs leaving the CRT recycling facility shall be transported in a manner that complies with the following requirements:

a. Discarded CRTs shall be transported in a contained manner that is structurally adequate to prevent breakage and spillage under normal operating conditions, and that is compatible with the contents.

b. Containers or packages shall be labeled. Labeling shall specify the contents (e.g., CRTs, nonintact CRTs), point of origin, destination, and shipment date.

c. CRT glass and CRTs that show evidence of breakage, leakage, or damage that could cause the release of lead or other hazardous constituents into the environment shall be transported in enclosed and separate containers from other discarded CRTs.

d. Discarded CRTs shall be transported in compliance with state and federal Department of Transportation (DOT) regulations.

122.11(3) *General operating requirements.* All CRT recycling facilities shall comply with the following requirements:

a. CRT refurbishing, CRT demanufacturing, and CRT processing shall be done in a specifically designated location within a facility.

b. Working conditions shall be in compliance with state and federal worker safety requirements.

[**ARC 8679B**, IAB 4/7/10, effective 7/1/10]

567—122.12(455B,455D) Further requirements for batteries for CRT recycling facilities.

122.12(1) CRT recycling facilities shall manage waste batteries derived from discarded CRTs in a manner that prevents release of any hazardous material into the environment.

122.12(2) Any battery that shows evidence of leakage, spillage, or damage that could cause a release of hazardous material into the environment must be contained in a container that is compatible with the contents of the battery.

122.12(3) All batteries must be managed in accordance with all state and federal regulations.
[**ARC 8679B**, IAB 4/7/10, effective 7/1/10]

567—122.13(455B,455D) Further requirements for circuit boards for CRT recycling facilities. Spent circuit boards are regulated as scrap metal when recycled and stored in containers sufficient to prevent a release into the environment and the circuit board contains only minor battery or mercury switching components. If minor batteries and mercury switching components are removed, the minor batteries or mercury switching components may be universal waste under 40 CFR Part 273 or a hazardous waste under 40 CFR Parts 261, 262, and 263.
[**ARC 8679B**, IAB 4/7/10, effective 7/1/10]

567—122.14(455B,455D) Further requirements for CRTs for CRT recycling facilities.

122.14(1) CRT recycling facilities shall manage CRT materials in a manner that prevents the release of any hazardous material or component into the environment as follows:

a. A CRT recycling facility shall immediately clean up and contain any CRTs, CRT devices, and CRT glass that are unintentionally broken.

b. A CRT recycling facility may disassemble or crush CRTs provided the handler crushes CRTs in a controlled manner.

122.14(2) All CRTs, CRT devices, and CRT glass must be managed in accordance with all state and federal regulations.
[**ARC 8679B**, IAB 4/7/10, effective 7/1/10]

567—122.15(455B,455D) Further requirements for removal and disposal of mercury-containing components for CRT recycling facilities.

122.15(1) CRT demanufacturers and CRT processors that manage mercury-containing components may be considered hazardous waste generators. Precautions shall be taken to prevent the release of mercury.

122.15(2) All removed mercury-containing components shall be stored in a DOT-approved container and labeled with a label stating "hazardous waste–mercury" or "mercury components" in both English and the predominant language of any non-English-reading workers. Furthermore, the date when the first mercury-containing component was placed in the container shall be affixed on the container.

122.15(3) All mercury containers shall be sealed prior to shipment.

122.15(4) All mercury-containing components shall be managed at an EPA-approved mercury recycling or recovery facility.

122.15(5) Mercury-containing components must be managed in accordance with all state and federal regulations.
[**ARC 8679B**, IAB 4/7/10, effective 7/1/10]

567—122.16(455B,455D) Further requirements for removal and disposal of PCB capacitors for CRT recycling facilities.

122.16(1) CRT demanufacturers and CRT processors shall remove all capacitors not marked as non-PCB unless the manufacturer certifies in writing that no PCBs were used in the manufacture of the discarded CRT or capacitor.

122.16(2) All capacitors are assumed to contain PCBs unless proven otherwise by an approved laboratory, unless the words "No PCBs" have been imprinted on the body of the capacitor by the manufacturer, or unless the manufacturer certifies in writing that no PCBs were used in the manufacture of the discarded CRT or capacitor.

122.16(3) Capacitors that are proven not to contain PCBs may be recycled or disposed of as nonhazardous waste.

122.16(4) PCB capacitors shall be stored and transported in compliance with the Toxic Substances Control Act (TSCA; 40 CFR Part 761) and disposed of at a TSCA-permitted disposal facility. Facilities used for the storage of PCB items designated for disposal shall comply with the following requirements:

a. PCB items shall be stored in a manner that provides adequate protection from the elements and adequate secondary containment. Storage shall be over an impervious material.

b. All capacitors containing or suspected of containing PCBs shall be placed in a DOT-approved container that shows no signs of damage. The bottom of the container shall be filled to a depth of two inches with an absorbent material (e.g., oil-dry, kitty litter).

c. All DOT-approved containers shall be affixed with an EPA-approved 6-inch × 6-inch yellow label stating "PCBs" in both English and the predominant language of any non-English-reading workers (Reference: 40 CFR Part 761.45). Furthermore, the date when the first capacitor was placed in the container shall be affixed on the container.

d. All containers must be sealed prior to shipment.

e. Capacitors shall be be stored for no more than 270 days.

122.16(5) An EPA-approved PCB transporter using an EPA Uniform Hazardous Waste form may be required to transport the labeled and dated container. The demanufacturer has one year from the first date entered on the container to have the contents buried at a TSCA landfill or incinerated at a TSCA disposal facility (Reference: 40 CFR Part 761.65). The burial or incineration must be documented and the records kept by the demanufacturer for three years from the date the PCB waste was accepted by the initial transporter.

[**ARC 8679B**, IAB 4/7/10, effective 7/1/10]

567—122.17(455B,455D) Spills and releases at CRT recycling facilities.

122.17(1) Any spills from leaking or cracked capacitors shall be handled by placing the capacitor or component containing the capacitor and any contaminated rags, clothing, absorbents, and soil into a DOT-approved container for PCBs for shipment to an EPA-approved PCB waste disposal facility. Spills of PCBs that occur outside a DOT-approved container shall be cleaned up pursuant to 40 CFR Part 761.125. Detailed records of such cleanups and sampling shall be maintained pursuant to 40 CFR Part 761.180.

122.17(2) Mercury spill kits, with a mercury absorbent in the kits, shall be readily available and immediately utilized in the event of a mercury spill. Any waste from the cleanup of a mercury spill shall be managed in accordance with state and federal rules.

122.17(3) Any hazardous condition shall be immediately contained and remedied with proper equipment and procedures pursuant to 567—Chapter 131 and the emergency response and remedial action plan (ERRAP) pursuant to rule 567—122.20(455B,455D). Within six hours of the release, the department field office with jurisdiction over the spill or release location shall be notified.

[**ARC 8679B**, IAB 4/7/10, effective 7/1/10]

567—122.18(455B,455D) CRT recycling facilities that shred CRTs. CRT fluff from the shredding of discarded CRTs shall be sampled quarterly, at a minimum, and analyzed according to Test Methods for Evaluation of Solid Waste, Physical-Chemical Methods SW 846, U.S. EPA, Third Edition 1986, or other method approved by the department, for the presence of PCBs. CRT fluff from the shredding of discarded CRTs shall be sampled quarterly at a minimum and analyzed for metals according to the toxicity characteristic leaching procedure (TCLP, EPA Method 1311). The fluff shall be sampled once per day for seven consecutive working days to make a composite sample. If the total PCB amount is less than 50 parts per million (ppm) and if the TCLP results demonstrate the CRT fluff is not hazardous, then the CRT fluff may be disposed of in a municipal solid waste (MSW) sanitary landfill in Iowa.

[**ARC 8679B**, IAB 4/7/10, effective 7/1/10]

567—122.19(455B,455D) Storage requirements for CRT recycling facilities. All CRT recycling facilities shall store discarded CRTs in compliance with the following requirements:

122.19(1) Discarded CRTs and materials derived from discarded CRTs shall be stored in a manner that minimizes the risk of a release into the environment.

122.19(2) Discarded CRTs and materials derived from discarded CRTs shall not be speculatively accumulated at a permitted CRT recycling facility without the permit holder obtaining and maintaining financial assurance for the additional CRTs in accordance with rule 567—122.25(455B,455D). Speculative accumulation occurs when a facility cannot demonstrate that the amount of discarded CRTs and materials derived from discarded CRTs leaving the facility within a 12-month time period is greater than 75 percent, by weight or volume, of the discarded CRTs and materials derived from discarded CRTs received by the facility within a 12-month time period.
[**ARC 8679B**, IAB 4/7/10, effective 7/1/10]

567—122.20(455B,455D) ERRAP requirements for CRT recycling facilities. A CRT recycling facility shall develop, submit to the department for approval, and maintain on site a detailed emergency response and remedial action plan (ERRAP).

122.20(1) *Submittal requirements.* An updated ERRAP shall be included with any request for permit modification, to incorporate a facility expansion, or for significant changes in facility operation that require modification of the currently approved ERRAP.

122.20(2) *Content.* The content of ERRAP documents shall be concise and readily usable as a reference manual by facility managers and operators during emergency conditions. The ERRAP document content shall address at least the following primary issues in detail, unless project conditions render the specific issue as not applicable. To facilitate department review, the rationale for exclusion of any issues that are not determined to be applicable must be provided either in the body of the plan or as a supplement. Additional ERRAP requirements unique to the facility shall be addressed, as applicable.

a. *Facility information.*
(1) Permitted agency.
(2) DNR permit number.
(3) Responsible individual and contact information.
(4) Facility description.
(5) Site and environs map.
b. *Regulatory requirements—reference to provisions of the permit.*
c. *Emergency conditions—response activities—remedial action.*
(1) Failure of utilities.
1. Short-term (48 hours or less).
2. Long-term (over 48 hours).
(2) Weather-related event.
1. Tornado.
2. Windstorms.
3. Intense rainstorms.
4. Lightning strikes.
5. Flooding.
(3) Fire and explosions.
1. Discarded CRT materials.
2. Building and site.
3. Equipment.
4. Utilities.
5. Working area.
6. Evacuation.
(4) Regulated waste and hazardous material spills and releases.
1. Collection.
2. Transport.
3. Working area.
4. Storage.
(5) Emergency and release notifications and reporting.
1. Federal agencies.

2. State agencies.
3. County and city agencies.
4. Emergency response agencies.
5. Special populations within 2 miles.
6. Reporting requirements and forms.

(6) Emergency aid.

1. Responder contacts.
2. Medical services.
3. Contracts and agreements.

(7) Primary emergency equipment inventory.

1. Major equipment.
2. Fire hydrants and water sources.
3. Off-site equipment resources.

(8) ERRAP training requirements.

1. Training providers.
2. Employee orientation.
3. Annual training updates.
4. Training completion and record keeping.

(9) Reference tables, figures and maps.

[**ARC 8679B**, IAB 4/7/10, effective 7/1/10]

567—122.21(455B,455D) Training requirements for CRT recycling facilities.

122.21(1) *General training.* All employees of a CRT recycling facility involved in activities relevant to CRT recycling shall be trained in the following requirements and procedures as appropriate to the employees' specific job responsibilities:

a. The requirements of this chapter.

b. Standard operating procedures utilized by the CRT recycling facility, including:

(1) The proper method of loading and unloading discarded CRTs and materials derived from discarded CRTs.

(2) The proper collection, storage, and transportation requirements for discarded CRTs and materials derived from discarded CRTs.

(3) The proper disposal of discarded CRTs and materials derived from discarded CRTs.

(4) The proper management of batteries.

(5) The proper management of CRTs.

(6) The proper management of circuit boards.

(7) The proper management of mercury-containing components.

(8) The proper management of PCBs.

(9) Spill and release response procedures.

(10) Worker health and safety.

(11) Use of the department-approved ERRAP.

122.21(2) *DNR-approved training course.* Rescinded IAB 4/7/10, effective 7/1/10.

[**ARC 8679B**, IAB 4/7/10, effective 7/1/10]

567—122.22(455B,455D) Reporting requirements for CRT recycling facilities. A CRT recycling facility shall maintain a record of the number or weight of CRT devices received each calendar year and report this information to the department within 30 days of the end of that calendar year.

[**ARC 8679B**, IAB 4/7/10, effective 7/1/10]

567—122.23(455B,455D) Record-keeping requirements for CRT recycling facilities. All CRT recycling facilities shall maintain the following records, on a calendar-year basis, for three years:

122.23(1) The total aggregate weight and receipt date of each shipment of discarded CRTs received from businesses, institutions, CRT collection facilities, short-term CRT collection events, and other permitted CRT recycling facilities.

122.23(2) The name, address and contact information for shipments reported in subrule 122.23(1).

122.23(3) The total aggregate weight and date of each shipment leaving the CRT recycling facility.

122.23(4) The name and address of the facility receiving a shipment that left the CRT recycling facility, contact information for the receiving facility and a description of the shipment contents including all applicable bills of lading.

122.23(5) The type of service the receiving facility will provide to the CRT recycling facility.

122.23(6) All hazardous waste manifests.

122.23(7) Information related to the management of spills and releases pursuant to rule 567—122.17(455B,455D).

122.23(8) Information related to the management of CRT fluff pursuant to rule 567—122.18(455B,455D).

122.23(9) Information related to training requirements pursuant to subrule 122.21(1).

[**ARC 8679B**, IAB 4/7/10, effective 7/1/10]

567—122.24(455B,455D) Closure requirements for CRT recycling facilities. A CRT recycling facility shall submit to the department and department field office with jurisdiction over the facility written notice of intent to permanently close at least 60 days before closure. Closure shall be in conformance with the closure plan pursuant to paragraph 122.11(1)*"n."* Closure shall not be official until the department field office with jurisdiction over the facility has given written certification of the proper disposal of all solid waste, discarded CRTs, and materials derived from discarded CRTs at the site.

[**ARC 8679B**, IAB 4/7/10, effective 7/1/10]

567—122.25(455B,455D) Financial assurance requirements for cathode ray tube (CRT) recycling facilities. Permitted CRT recycling facilities must obtain and submit a financial assurance instrument to the department for the storage of solid waste, discarded CRTs and materials derived from discarded CRTs at the site in accordance with this rule. The financial assurance instrument shall provide monetary funds to properly dispose of solid waste, discarded CRTs and materials derived from discarded CRTs that may remain at a site due to the owner's or operator's failure to properly close the site within 30 days of permit suspension, termination, revocation, or expiration.

122.25(1) No permit without financial assurance. The department shall not issue or renew a permit to an owner or operator of a CRT recycling facility until a financial assurance instrument has been submitted to and approved by the department.

122.25(2) Proof of compliance. Proof of the establishment of the financial assurance instrument and compliance with this rule, including a current closure cost estimate, shall be submitted to the department at the time of application for a permit for a new CRT recycling facility. The owner or operator must provide continuous coverage for closure and submit proof of compliance, including an updated closure cost estimate, with each permit renewal thereafter until released from this requirement by the department.

122.25(3) Use of one financial assurance instrument for multiple permitted activities. CRT recycling facilities required to maintain financial assurance pursuant to any other provisions of 567—Chapters 100 to 123 may satisfy the requirements of this rule by the use of one financial assurance instrument if the permit holder ensures that the instrument provides financial assurance for an amount at least equal to the current cost estimates for closure of all sanitary disposal project activities covered.

122.25(4) CRT recycling facilities shall have financial assurance coverage equal to one dollar per pound of CRTs determined to be speculatively accumulated in accordance with subrule 122.19(2).

122.25(5) Acceptable financial assurance instruments. The financial assurance instrument shall be established in an amount equal to the cost estimate prepared in accordance with subrule 122.25(4)and shall not be canceled, revoked, disbursed, released, or allowed to terminate without the approval of the department. Financial assurance may be provided by cash in the form of a secured trust fund or local government dedicated fund, surety bond, letter of credit, or corporate or local government guarantee as follows:

a. Secured trust fund. The owner or operator of a CRT recycling facility or an entity serving as a guarantor may demonstrate financial assurance for closure by establishing a secured trust fund that conforms to the requirements of this paragraph.

(1) The trustee must be an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency. The fund shall be restricted for the sole purpose of funding closure activities at the facility, and a copy of the trust agreement must be submitted to the department and placed in the facility's official files.

(2) A secured trust fund shall name the department of natural resources as the entity authorized to draw funds from the trust, subject to proper notification to the trust officer of failure by the permittee to properly close the site within 30 days of permit suspension, termination, revocation, or expiration.

(3) Moneys in the fund shall not be assigned for the benefit of creditors with the exception of the state.

(4) Moneys in the fund shall not be used to pay any final judgment against a permit holder arising out of the ownership or operation of the site during its active life or after closure.

(5) The owner or operator or another person authorized to conduct closure activities may request reimbursement from the trustee for closure expenditures as they are incurred. Requests for reimbursement shall be granted by the trustee only if sufficient funds are remaining in the trust fund to cover the remaining costs of closure and if documentation of the justification for reimbursement has been submitted to the department for prior approval.

(6) If the balance of the trust fund exceeds the current cost estimate for closure at any time, the owner or operator may request withdrawal of the excess funds from the trustee so long as the withdrawal does not cause the balance to be reduced below the amount of the current cost estimate.

b. Local government dedicated fund. The owner or operator of a publicly owned CRT recycling facility or a local government serving as a guarantor may demonstrate financial assurance for closure by establishing a dedicated fund that conforms to the requirements of this paragraph.

(1) The fund shall be dedicated by state constitutional provision or local government statute, charter, ordinance, resolution or order as a restricted fund to pay for closure costs arising from the operation of the facility.

(2) A copy of the document establishing the dedicated fund must be submitted to the department and placed in the facility's official files.

(3) If the balance of the dedicated fund exceeds the current cost estimate for closure at any time, the owner or operator may withdraw excess funds so long as the withdrawal does not cause the balance to be reduced below the amount of the current cost estimate.

c. Surety bond. A surety bond must be written by a company authorized by the commissioner of insurance to do business in the state. The surety bond shall comply with the following:

(1) The bond shall be in a form approved by the commissioner of insurance and shall be payable to the department of natural resources.

(2) The bond shall be specific to a particular facility for the purpose of properly disposing of any solid waste, discarded CRTs, and materials derived from discarded CRTs associated with the collection and recycling of CRTs that may remain on site due to the owner's or operator's failure to properly close the site within 30 days of permit suspension, termination, revocation, or expiration.

(3) The owner or operator shall provide the department with a statement from the surety with each permit application renewal, noting that the bond is paid and current for the permit period for which the owner or operator has applied for renewal.

d. Letter of credit. The issuing institution must be an entity which has the authority to issue letters of credit and whose letter-of-credit operations are regulated and examined by a federal or state agency.

(1) The owner or operator must submit to the department a copy of the letter of credit and place a copy in the facility's official files.

(2) A letter from the owner or operator referring to the letter of credit by number, issuing institution, and date, and providing the name and address of the facility and the amount of funds assured, must be included with the letter of credit submitted to the department and placed in the facility's files.

(3) The letter of credit must be irrevocable and must be issued for a period of at least one year. The letter of credit must provide that the expiration date will be automatically extended for a period of at least one year unless the issuing institution has canceled the letter of credit by sending notice of cancellation by certified mail to the owner or operator and to the department 90 days in advance of cancellation. When such notice is provided, the owner or operator shall, within 60 days, provide to the department adequate proof of alternative financial assurance, notice of withdrawal of cancellation, or proof of a deposit of a sum equal to the amount of the letter of credit into a secured trust fund that meets the requirements of paragraph 122.25(5)*"a."* If the owner or operator has not complied with this subrule within the 60-day time period, the issuer of the letter of credit shall deposit a sum equal to the amount of the letter of credit into the secured trust fund established by the owner or operator. The provision of funds by the issuer of the letter of credit shall be considered an issuance of a loan to the owner or operator, and the terms of that loan shall be governed by the letter of credit or subsequent agreement between those parties.

e. Corporate guarantee. An owner or operator may meet the requirements of this rule by obtaining a written guarantee. The guarantor must be the direct or higher-tier parent corporation of the owner or operator, an owner or operator whose parent corporation is also the parent corporation of the owner or operator, or an owner or operator with a "substantial business relationship" with the owner or operator.

(1) The terms of the written guarantee must provide that within 30 days of the owner's or operator's failure to perform closure of a facility covered by the guarantee, the guarantor will:

1. Perform closure or pay a third party to perform closure as required (performance guarantee);

2. Establish a fully funded secured trust fund as specified in paragraph 122.25(5)*"a"* in the name of the owner or operator (payment guarantee); or

3. Establish an alternative financial assurance instrument in the name of the owner or operator as required by this rule.

(2) The guarantor must satisfy one of the following three conditions:

1. A current rating for its senior unsubordinated debt of AAA, AA, A, or BBB as issued by Standard & Poor's or Aaa, Aa, A, or Baa as issued by Moody's; or

2. A ratio of less than 1.5 comparing total liabilities to net worth; or

3. A ratio of greater than 0.10 comparing the sum of net income plus depreciation, depletion and amortization, minus $10 million, to total liabilities.

(3) The tangible net worth of the guarantor must be greater than the sum of the current closure cost estimate and any other environmental obligations, including other financial assurance guarantees.

(4) The guarantor must have assets amounting to at least the sum of the current closure cost estimate and any other environmental obligations, including other financial assurance guarantees.

(5) Record-keeping and reporting requirements. The guarantor must submit the following records to the department and place a copy in the facility's official files:

1. A copy of the written guarantee between the owner or operator and the guarantor.

2. A letter signed by a certified public accountant and based upon a certified audit that:

- Lists all the current cost estimates covered by a guarantee including, but not limited to, cost estimates required by subrule 122.25(4); cost estimates required for municipal solid waste management facilities pursuant to 40 CFR Part 258; cost estimates required for UIC facilities under 40 CFR Part 144, if applicable; cost estimates required for petroleum underground storage tank facilities under 40 CFR Part 280, if applicable; cost estimates required for PCB storage facilities under 40 CFR Part 761, if applicable; and cost estimates required for hazardous waste treatment, storage, and disposal facilities under 40 CFR Parts 264 and 265, if applicable; and
- Provides evidence demonstrating that the guarantor meets the conditions of subparagraphs 122.25(5)*"e"*(2), (3) and (4).

3. A copy of the independent certified public accountant's unqualified opinion of the guarantor's financial statements for the latest completed fiscal year. In order for the guarantor to be eligible to use the guarantee, the guarantor's financial statements must receive an unqualified opinion from the independent certified public accountant. An adverse opinion or disclaimer of opinion shall be cause for disallowance of this instrument. A qualified opinion related to the demonstration of financial assurance may, at the discretion of the department, be cause for disallowance. If the department does not allow use of the

corporate guarantee, the owner or operator must provide alternative financial assurance that meets the requirements of this rule.

f. *Local government guarantee.* An owner or operator may demonstrate financial assurance for closure by obtaining a written guarantee provided by a local government or jointly provided by the members of an agency established pursuant to Iowa Code chapter 28E.

(1) The terms of the written guarantee must provide that within 30 days of the owner's or operator's failure to perform closure of a facility covered by the guarantee, the guarantor will:

1. Perform closure or pay a third party to perform closure as required (performance guarantee);

2. Establish a fully funded secured trust fund as specified in paragraph 122.25(5)*"a"* in the name of the owner or operator (payment guarantee); or

3. Establish an alternative financial assurance instrument in the name of the owner or operator as required by this rule.

(2) The guarantor must satisfy one of the following requirements:

1. If the guarantor has outstanding, rated, general obligation bonds that are not secured by insurance, a letter of credit, or other collateral or guarantee, the guarantor must have a current rating of Aaa, Aa, A, or Baa, as issued by Moody's, or AAA, AA, A, or BBB, as issued by Standard & Poor's, on all such general obligation bonds; or

2. The guarantor must satisfy each of the following financial ratios based on the guarantor's most recent audited annual financial statement: a ratio of cash plus marketable securities to total expenditures greater than or equal to 0.05, and a ratio of annual debt service to total expenditures less than or equal to 0.20.

(3) The guarantor must prepare its financial statements in conformity with generally accepted accounting principles or other comprehensive basis of accounting and have its financial statements audited by an independent certified public accountant or the office of the auditor of the state of Iowa. The financial statement shall be in the form prescribed by the office of the auditor of the state of Iowa.

(4) A guarantor is not eligible to assure its obligations if:

1. The guarantor is currently in default on any outstanding general obligation bonds; or

2. The guarantor has any outstanding general obligation bonds rated lower than Baa as issued by Moody's or BBB as issued by Standard & Poor's; or

3. The guarantor operated at a deficit equal to 5 percent or more of total annual revenue in each of the past two fiscal years; or

4. The guarantor receives an adverse opinion or disclaimer of opinion from the independent certified public accountant or office of the auditor of the state of Iowa auditing its financial statement. A qualified opinion that is related to the demonstration of financial assurance may, at the discretion of the department, be cause for disallowance of this mechanism; or

5. The closure costs to be assured are greater than 43 percent of the guarantor's total annual revenue.

(5) The local government guarantor must include disclosure of the closure costs assured through the guarantee in its next annual audit report prior to the initial receipt of CRTs at the facility or prior to cancellation of an alternative financial assurance instrument, whichever is later. For the first year the guarantee is used to assure costs at a particular facility, the reference may instead be placed in the guarantor's official files until issuance of the next available annual audit report if timing does not permit the reference to be incorporated into the most recently issued annual audit report or budget. For closure costs, conformance with Governmental Accounting Standards Board Statement 18 ensures compliance with this public notice component.

(6) The local government owner or operator must submit to the department the following items:

1. A copy of the written guarantee between the owner or operator and the local government serving as guarantor for the closure costs at the facility.

2. A copy of the guarantor's most recent annual financial audit report indicating compliance with the financial ratios required by numbered paragraph 122.25(5)*"f"*(2)"2," if applicable, and the requirements of subparagraphs 122.25(5)*"f"*(3) and (4).

3. A letter signed by the local government's chief financial officer that lists all the current cost estimates covered by the guarantor, as described in subrule 122.25(4); and that provides evidence and certifies that the local government meets the conditions of subparagraphs 122.25(5)*"f"*(2), (3), (4) and (5).

122.25(6) Financial assurance cancellation and permit suspension.

a. A financial assurance instrument may be terminated by the owner or operator only if the owner or operator substitutes alternate financial assurance prior to cancellation, as specified in this rule, or if the owner or operator is no longer required to demonstrate financial responsibility in accordance with this rule.

b. A financial assurance instrument shall be continuous in nature until canceled by the financial assurance provider or until the department gives written notification to the owner, operator, and financial assurance provider that the covered site has been properly closed. The financial assurance provider shall give at least 90 days' notice in writing to the owner or operator and the department in the event of any intent to cancel the instrument.

c. Within 60 days of receipt of a written notice of cancellation of financial assurance by the financial assurance provider, the owner or operator must provide the department an alternative financial assurance instrument. If a means of continued financial assurance is not provided within that 60 days, the department shall suspend the permit.

d. The owner or operator shall perform proper closure within 30 days of the permit suspension. For the purpose of this rule, "proper closure" means completion of all items pursuant to rule 567—122.24(455B,455D) and subrule 122.25(4).

e. If the owner or operator does not properly close the site within the 30-day period allowed, the department shall file a claim with the financial assurance instrument provider to collect the amount of funds necessary to properly close the site.

f. An owner or operator who elects to terminate a permitted activity, whose renewal application has been denied, or whose permit has been suspended or revoked for cause must submit within 30 days of the termination of the permit a schedule for completing proper closure of the terminated activity. Closure completion cannot exceed 60 days from the date of termination of the permit.

g. The director may also request payment from any financial assurance provider for the purpose of completing closure when the following circumstances exist:

(1) The owner or operator is more than 15 days late in providing a schedule for closure or for meeting any date in the schedule for closure.

(2) The owner or operator declares an economic inability to comply with this rule, either by sending written notification to the director or through an action such as, but not limited to, filing for bankruptcy.

[**ARC 8679B**, IAB 4/7/10, effective 7/1/10]

These rules are intended to implement Iowa Code sections 455D.6(7) and 455B.304(1).

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[Prior to 7/29/87, Health Department[470]]

641—7.1(139A) Definitions.

"Admitting official" means the superintendent of schools or the superintendent's designated representative if a public school; if a nonpublic school or licensed child care center, the governing official of the school or child care center.

"Applicant" means any person seeking enrollment in a licensed child care center or elementary or secondary school.

"Certified medical assistant" means a person who is certified to practice as a certified medical assistant following completion of a postsecondary medical assistant program accredited by the Commission on Accreditation of Allied Health Education Programs or the Accrediting Bureau of Health Education Schools and successful completion of the certification examination and who is directed by a supervising physician, physician assistant, or nurse practitioner.

"Competent private instruction" means private instruction as defined by the department of education pursuant to Iowa Code section 299A.1.

"Department" means the Iowa department of public health.

"Electronic signature" means a confidential personalized digital key, code, or number that is used for secure electronic data transmission and that identifies and authenticates the signatory.

"Elementary school" means kindergarten if provided, and grades one through eight or grades one through six when grades seven and eight are included in a secondary school.

"Enrolled user" means a user of the registry who has completed an enrollment form that specifies the conditions under which the registry can be accessed and who has been issued an identification code and password by the department.

"Immunization registry" or *"registry"* means the database and file server maintained by the department as well as the software application that allows enrolled users to exchange immunization records.

"Institution of higher education" means a postsecondary school.

"Licensed child care center" means a facility or program licensed by the Iowa department of human services to provide child care for seven or more children or a prekindergarten or preschool, regardless of the source of funding, operated by a local school district, an accredited nonpublic school, an area education agency, or a college or university.

"Nurse" means a person licensed to practice as a nurse pursuant to Iowa Code chapter 152.

"Nurse practitioner" means a person licensed to practice as a registered nurse pursuant to Iowa Code chapter 152 and certified by a professional certifying body approved by the board of nursing.

"On-campus residence hall or dormitory" means campus housing for students that is owned or leased by the institution of higher education and located on a recognized campus site.

"Physician" means a person licensed to practice medicine and surgery or osteopathic medicine and surgery pursuant to Iowa Code chapter 148, 150, or 150A.

"Physician assistant" means a person licensed to practice as a physician assistant pursuant to Iowa Code chapter 148C.

"Postsecondary school" means a postsecondary institution under the control of the state board of regents, a community college established under Iowa Code chapter 260C, or an accredited private institution as defined in Iowa Code section 261.9, subsection 1.

"Postsecondary student" means a person who has officially registered with a postsecondary school, as determined by the school, and who physically attends class on the school's campus. For purposes of these rules, "postsecondary student" does not include a person who is exclusively registered in a correspondence course or continuing education class or who attends class exclusively by means of the

Internet or the Iowa communications network or through other means which do not require the person's physical presence on the school's campus.

"Provisional enrollment" means enrollment for a period of time not to exceed the limit specified in subrule 7.7(2) to allow the applicant to meet the requirements of these rules. A provisionally enrolled applicant is entitled access to all the benefits, activities, and opportunities of the school or licensed child care center. Provisional enrollment shall not deny the school funding for the applicant.

"Secondary school" means (a) a junior high school comprising grades 7, 8 and 9, and a senior high school; (b) a combined junior-senior high school comprising grades 7 through 12; (c) a junior high school comprising grades 7 and 8 and a high school comprising grades 9 through 12; (d) a high school comprising grades 9 through 12.

"Signature" means an original signature or the authorized use of a stamped signature or electronic signature.

"Student" means an individual who is enrolled in a licensed child care center, elementary school or secondary school.

641—7.2(139A) Persons included. The immunization requirements specified elsewhere in these rules apply to all persons enrolled or attempting to enroll in a licensed child care center or a public or nonpublic elementary or secondary school in Iowa including those who are provided competent private instruction.

641—7.3(139A) Persons excluded. Exclusions to these rules are permitted on an individual basis for medical and religious reasons. Applicants approved for medical or religious exemptions shall submit to the admitting official a valid Iowa department of public health certificate of immunization exemption.

7.3(1) To be valid, a certificate of immunization exemption for medical reasons shall contain, at a minimum, the applicant's last name, first name, and date of birth, the vaccine(s) exempted, and an expiration date (if applicable) and shall bear the signature of a physician, nurse practitioner, or physician assistant. A medical exemption may be granted to an applicant when, in the opinion of a physician, nurse practitioner, or physician assistant:

a. The required immunizations would be injurious to the health and well-being of the applicant or any member of the applicant's family or household. In this circumstance, a medical exemption may apply to a specific vaccine(s) or all required vaccines. If, in the opinion of the physician, nurse practitioner, or physician assistant issuing the medical exemption, the exemption should be terminated or reviewed at a future date, an expiration date shall be recorded on the certificate of immunization exemption; or

b. Administration of the required vaccine would violate minimum interval spacing. In this circumstance, an exemption shall apply only to an applicant who has not received prior doses of the exempted vaccine. An expiration date, not to exceed 60 calendar days, and the name of the vaccine exempted shall be recorded on the certificate of exemption.

7.3(2) A religious exemption may be granted to an applicant if immunization conflicts with a genuine and sincere religious belief.

a. To be valid, a certificate of immunization exemption for religious reasons shall contain, at a minimum, the applicant's last name, first name, and date of birth and shall bear the signature of the applicant or, if the applicant is a minor, of the applicant's parent or guardian and shall attest that immunization conflicts with a genuine and sincere religious belief and that the belief is in fact religious and not based merely on philosophical, scientific, moral, personal, or medical opposition to immunizations.

b. The certificate of immunization exemption for religious reasons is valid only when notarized.

7.3(3) Medical and religious exemptions under this rule do not apply in times of emergency or epidemic as determined by the state board of health and declared by the director of public health.

641—7.4(139A) Required immunizations.

7.4(1) Applicants enrolled or attempting to enroll shall have received the following vaccines in accordance with the doses and age requirements below:

IMMUNIZATION REQUIREMENTS

Applicants enrolled or attempting to enroll shall have received the following vaccines in accordance with the doses and age requirements listed below. If, at any time, the age of the child is between the listed ages, the child must have received the number of doses in the "Total Doses Required" column.

Institution	Age	Vaccine	Total Doses Required
Licensed Child Care Center	Less than 4 months of age	This is not a recommended administration schedule, but contains the minimum requirements for participation in licensed child care. **Routine vaccination begins at 2 months of age.**	
	4 months through 5 months of age	Diphtheria/Tetanus/Pertussis	1 dose
		Polio	1 dose
		haemophilus influenzae type B	1 dose
		Pneumococcal	1 dose
	6 months through 11 months of age	Diphtheria/Tetanus/Pertussis	2 doses
		Polio	2 doses
		haemophilus influenzae type B	2 doses
		Pneumococcal	2 doses
	12 months through 18 months of age	Diphtheria/Tetanus/Pertussis	3 doses
		Polio	2 doses
		haemophilus influenzae type B	2 doses; or 1 dose received when the applicant is 15 months of age or older.
		Pneumococcal	3 doses if the applicant received 1 or 2 doses before 12 months of age; or 2 doses if the applicant has not received any previous doses or has received 1 dose on or after 12 months of age.
	19 months through 23 months of age	Diphtheria/Tetanus/Pertussis	4 doses
		Polio	3 doses
		haemophilus influenzae type B	3 doses, with the final dose in the series received on or after 12 months of age, or 1 dose received when the applicant is 15 months of age or older.
		Pneumococcal	4 doses; or 3 doses if the applicant received 1 or 2 doses before 12 months of age; or 2 doses if the applicant has not received any previous doses or has received 1 dose on or after 12 months of age.
		Measles/Rubella[1]	1 dose of measles/rubella-containing vaccine received on or after 12 months of age; or the applicant demonstrates a positive antibody test for measles and rubella from a U.S. laboratory.
		Varicella	1 dose received on or after 12 months of age if the applicant was born on or after September 15, 1997, unless the applicant has had a reliable history of natural disease.
	24 months and older	Diphtheria/Tetanus/Pertussis	4 doses
		Polio	3 doses
		haemophilus influenzae type B	3 doses, with the final dose in the series received on or after 12 months of age; or 1 dose received when the applicant is 15 months of age or older. Hib vaccine is not indicated for persons 60 months of age or older.
		Pneumococcal	4 doses if the applicant received 3 doses before 12 months of age; or 3 doses if the applicant received 2 doses before 12 months of age; or 2 doses if the applicant received 1 dose before 12 months of age or received 1 dose between 12 and 23 months of age; or 1 dose if no doses had been received prior to 24 months of age. Pneumococcal vaccine is not indicated for persons 60 months of age or older.
		Measles/Rubella[1]	1 dose of measles/rubella-containing vaccine received on or after 12 months of age; or the applicant demonstrates a positive antibody test for measles and rubella from a U.S. laboratory.
		Varicella	1 dose received on or after 12 months of age if the applicant was born on or after September 15, 1997, unless the applicant has had a reliable history of natural disease.

Applicants enrolled or attempting to enroll shall have received the following vaccines in accordance with the doses and age requirements listed below. If, at any time, the age of the child is between the listed ages, the child must have received the number of doses in the "Total Doses Required" column.			
Institution	**Age**	**Vaccine**	**Total Doses Required**
Elementary or Secondary School (K-12)	4 years of age and older	Diphtheria/Tetanus/Pertussis [3, 4]	3 doses, with at least 1 dose of diphtheria/tetanus/pertussis-containing vaccine received on or after 4 years of age if the applicant was born on or before September 15, 2000; or 4 doses, with at least 1 dose of diphtheria/tetanus/pertussis-containing vaccine received on or after 4 years of age if the applicant was born after September 15, 2000, but before September 15, 2003; or 5 doses with at least 1 dose of diphtheria/tetanus/pertussis-containing vaccine received on or after 4 years of age if the applicant was born on or after September 15, 2003.[2] DTaP is not indicated for persons 7 years of age and older, therefore, a tetanus-and diphtheria-containing vaccine should be used.
		Polio [6]	3 doses, with at least 1 dose received on or after 4 years of age if the applicant was born on or before September 15, 2003; or 4 doses, with at least 1 dose received on or after 4 years of age if the applicant was born after September 15, 2003.[5]
		Measles/Rubella[1]	2 doses of measles/rubella-containing vaccine; the first dose shall have been received on or after 12 months of age; the second dose shall have been received no less than 28 days after the first dose; or the applicant demonstrates a positive antibody test for measles and rubella from a U.S. laboratory.
		Hepatitis B	3 doses if the applicant was born on or after July 1, 1994.
		Varicella	1 dose received on or after 12 months of age if the applicant was born on or after September 15, 1997, but born before September 15, 2003, unless the applicant has had a reliable history of natural disease; or 2 doses received on or after 12 months of age if the applicant was born on or after September 15, 2003, unless the applicant has a reliable history of natural disease.[7]

[1] Mumps vaccine may be included in measles/rubella-containing vaccine.
[2] The 5th dose of DTaP is not necessary if the 4th dose was administered on or after 4 years of age.
[3] Applicants 7 through 18 years of age who received their 1st dose of diphtheria/tetanus/pertussis-containing vaccine before 12 months of age should receive a total of 4 doses, with one of those doses administered on or after 4 years of age.
[4] Applicants 7 through 18 years of age who received their 1st dose of diphtheria/tetanus/pertussis-containing vaccine at 12 months of age or older should receive a total of 3 doses, with one of those doses administered on or after 4 years of age.
[5] If an applicant received an all-inactivated poliovirus (IPV) or all-oral poliovirus (OPV) series, a 4th dose is not necessary if the 3rd dose was administered on or after 4 years of age.
[6] If both OPV and IPV were administered as part of the series, a total of 4 doses are required, regardless of the applicant's current age.
[7] Administer 2 doses of varicella vaccine, at least 3 months apart, to applicants less than 13 years of age. Do not repeat the 2nd dose if administered 28 days or greater from the 1st dose. Administer 2 doses of varicella vaccine to applicants 13 years of age or older at least 4-weeks apart. The minimum interval between the 1st and 2nd dose of varicella for an applicant 13 years of age or older is 28 days.

7.4(2) Vaccine doses administered less than or equal to 4 days before the minimum interval or age shall be counted as valid. Doses administered greater than or equal to 5 days earlier than the minimum interval or age shall not be counted as valid doses and shall be repeated as appropriate.

7.4(3) For vaccine administration, the minimum age and intervals recommended by the advisory committee on immunization practices shall be followed.

[**ARC 8377B**, IAB 12/16/09, effective 11/18/09; **ARC 8658B**, IAB 4/7/10, effective 5/12/10]

641—7.5(139A) Required education. Each institution of higher education that has an on-campus residence hall or dormitory shall provide vaccination information on meningococcal disease to each postsecondary student enrolled in the institution of higher education. Meningococcal disease information shall be contained on student health forms. For purposes of this rule, student health form(s) means a document(s) prepared by an institution of higher education that contains, at a minimum, information on meningococcal disease, vaccination information and any recommendations issued by the national Centers for Disease Control and Prevention regarding meningococcal disease. The student health form(s) shall also include space for the postsecondary student to indicate whether or not the postsecondary student has received vaccination against meningococcal disease, including, at a minimum, the date of vaccination. The student health form(s) shall also include space for the postsecondary student to indicate whether or not the postsecondary student has received information on

meningococcal disease and benefits of vaccine. If a traditional student health form is not utilized by the institution of higher education, any document(s) containing the above information is acceptable.

641—7.6(139A) Proof of immunization.

7.6(1) A valid Iowa department of public health certificate of immunization shall be submitted by the applicant or, if the applicant is a minor, by the applicant's parent or guardian to the admitting official of the school or licensed child care center in which the applicant wishes to enroll. To be valid, the certificate shall be the certificate of immunization issued by the department, a computer-generated copy from the immunization registry, or a certificate of immunization which has been approved in writing by the department. The certificate shall contain, at a minimum, the applicant's last name, first name, and date of birth, the vaccine(s) administered, the date(s) given, and the signature of a physician, a physician assistant, a nurse, or a certified medical assistant. A faxed copy, photocopy, or electronic copy of the valid certificate is acceptable. The judgment of the adequacy of the applicant's immunization history should be based on records kept by the person signing the certificate of immunization or on that person's personal knowledge of the applicant's immunization history, or comparable immunization records from another person or agency, or an international certificate of vaccination, or the applicant's personal health records. If personal health records are used to make the judgment, the records shall include the vaccine(s) administered and the date given. Persons validating the certificate of immunization are not held responsible for the accuracy of the information used to validate the certificate of immunization if the information is from sources other than their own records or personal knowledge.

7.6(2) Persons wishing to enroll who do not have a valid Iowa department of public health certificate of immunization available to submit to the admitting official shall be referred to a physician, a physician assistant, a nurse, or a certified medical assistant to obtain a valid certificate.

641—7.7(139A) Provisional enrollment.

7.7(1) A valid Iowa department of public health provisional enrollment certificate shall be submitted by the applicant or, if the applicant is a minor, by the applicant's parent or guardian to the admitting official of the school or licensed child care center in which the applicant wishes to enroll. Applicants who have begun but not completed the required immunizations may be granted provisional enrollment. To qualify for provisional enrollment, applicants shall have received at least one dose of each of the required vaccines or be a transfer student from another school system. A transfer student is an applicant seeking enrollment from one United States elementary or secondary school into another. To be valid, the certificate shall contain, at a minimum, the applicant's last name, first name, and date of birth, the vaccine(s) administered, the date(s) given, the remaining vaccine(s) required, the reason that the applicant qualifies for provisional enrollment, and the signature of a physician, a physician assistant, a nurse, or a certified medical assistant. Persons validating the provisional certificate of immunization are not held responsible for the accuracy of the information used to validate the provisional certificate of immunization if the information is from sources other than their own records or personal knowledge. Persons signing the provisional certificate of immunization shall certify that they have informed the applicant or, if the applicant is a minor, the applicant's parent or guardian of the provisional enrollment requirements.

a. Any applicant seeking provisional enrollment who does not have a valid Iowa department of public health provisional certificate of immunization to submit to the admitting official shall be referred to a physician, a physician assistant, a nurse, or a certified medical assistant to obtain a valid certificate.

b. Reserved.

7.7(2) The amount of time allowed for provisional enrollment shall be as soon as medically feasible but shall not exceed 60 calendar days. The period of provisional enrollment shall begin on the date the provisional certificate is signed. The person signing the provisional certificate shall assign an expiration date to the certificate and shall indicate the remaining immunizations required to qualify for a certificate of immunization.

7.7(3) The applicant or parent or guardian shall ensure that the applicant receive the necessary immunizations during the provisional enrollment period and shall submit a certificate of immunization to the admitting official by the end of the provisional enrollment period.

7.7(4) Rescinded IAB 12/3/08, effective 1/7/09.

7.7(5) If at the end of the provisional enrollment period the applicant or parent or guardian has not submitted a certificate of immunization, the admitting official shall immediately exclude the applicant from the benefits, activities, and opportunities of the school or licensed child care center until the applicant or parent or guardian submits a valid certificate of immunization.

7.7(6) If at the end of the provisional enrollment period the applicant has not completed the required immunizations due to minimum interval requirements, a new Iowa department of public health provisional certificate of immunization shall be submitted to the admitting official. The admitting official must maintain all issued certificates of provisional immunization with the original provisional certificate until the applicant submits a certificate of immunization.

641—7.8(139A) Records and reporting.

7.8(1) It shall be the duty of the admitting official of a licensed child care center or elementary or secondary school to ensure that the admitting official has a valid Iowa department of public health certificate of immunization, certificate of immunization exemption, or provisional certificate of immunization on file for each student.

a. The admitting official shall keep the certificates on file in the school or licensed child care center in which the student is enrolled and assist the student or parent or guardian in the transfer of the certificate to another school or licensed child care center upon the transfer of the student to another school or licensed child care center.

b. Unless otherwise requested by the applicant, or parent or guardian, the admitting official shall retain the Iowa department of public health certificate of immunization, or certificate of immunization exemption, or provisional certificate of immunization for three years commencing upon the transfer or graduation of the applicant or the school may choose to provide the permanent immunization record to the student at time of graduation. Included with the immunization record a letter should state that this is an important document that will be needed by the student for college or employment and should be permanently retained.

7.8(2) It shall be the duty of the local boards of health to audit the Iowa department of public health certificates of immunization, certificates of immunization exemption, and provisional certificates of immunization in the schools within their jurisdiction to determine compliance with Iowa Code section 139A.8. The local boards of health shall furnish the Iowa department of public health within 60 days of the first official day of school a report of the audit. The report shall be submitted for each school within the local board of health's jurisdiction and shall include the enrollment by grade, and the number of Iowa department of public health certificates of immunization, certificates of immunization exemption, and provisional certificates of immunization by grade.

7.8(3) The local board of health and the Iowa department of public health shall have the right to have access to the Iowa department of public health certificates of immunization, certificates of immunization exemption, and the provisional certificates of immunization of children enrolled in elementary and secondary schools and licensed child care centers within the constraints of the privacy rights of parents and students.

7.8(4) The admitting official of an institution of higher education shall provide to the department of public health by December 1 each year aggregate data regarding compliance with Iowa Code section 139A.26. The data shall be forwarded to the department within 30 days. The data shall include, but not be limited to, the total number of incoming postsecondary freshmen students living in a residence hall or dormitory who have:

a. Enrolled in the institution of higher education; and

b. Been provided information on meningococcal disease; and

c. Been immunized with meningococcal vaccine.

641—7.9(139A) Providing immunization services. It shall be the duty of the local boards of health to provide immunization services where no local provision exists for the services.

641—7.10(139A) Compliance. Applicants not presenting proper evidence of immunization, or exemption, are not entitled to enrollment in a licensed child care center or elementary or secondary school under the provisions of Iowa Code section 139A.8. It shall be the duty of the admitting official to deny enrollment to any applicant who does not submit proper evidence of immunization according to rule 7.6(139A) and to exclude a provisionally enrolled applicant in accordance with rule 7.7(139A).

641—7.11(22) Iowa's immunization registry.

7.11(1) The department shall maintain a statewide immunization registry. Enrolled users are responsible for purchasing and maintaining all computer hardware related to use of the registry and for providing an Internet connection to transfer information between the user's computer and the registry.

7.11(2) Purpose and permitted uses of registry.

a. The registry shall consist of immunization information, including identifying and demographic data, to allow enrolled users to maintain and access a database of immunization histories for purposes of ensuring that patients are fully immunized.

b. The registry may be used to track inventory or utilization of pharmaceutical agents identified by the department to prepare for or respond to an emergency event.

c. Enrolled users shall not use information obtained from the registry to market services to patients or nonpatients, to assist in bill collection services, or to locate or identify patients or nonpatients for any purpose other than those expressly provided in this rule.

7.11(3) Release of information to the registry. Enrolled users shall provide immunization information including identifying and demographic data to the registry. Information provided may include, but is not limited to, the following:

a. Name of patient;
b. Gender of patient;
c. Date of birth;
d. Race;
e. Ethnicity;
f. Birth state and birth country;
g. Address;
h. Parents' names;
i. Mother's maiden name;
j. Type of vaccination administered;
k. Dose or series number of vaccine;
l. Date vaccination was administered;
m. Lot number;
n. Contraindications, precautions;
o. Provider name, license, and business address; and
p. Patient history, including previously unreported doses.

7.11(4) Confidentiality of registry information. Immunization information, including identifying and demographic data maintained on the registry, is confidential and may not be disclosed except under the following limited circumstances:

a. The department may release information from the registry to the following:

(1) The person immunized or the parent or legal guardian of the person immunized;

(2) Enrolled users of the registry who have completed an enrollment form that specifies the conditions under which the registry can be accessed and who have been issued an identification code and password by the department;

(3) Persons or entities requesting immunization data in an aggregate form that does not identify an individual either directly or indirectly.

(4) Agencies that complete an agreement with the department which specifies conditions for access to registry data and how that data will be used. Agencies shall not use information obtained from the registry to market services to patients or nonpatients, to assist in bill collection services, or to locate or identify patients or nonpatients for any purposes other than those expressly provided in this rule.

(5) A representative of a state or federal agency, or entity bound by that state or federal agency, to the extent that the information is necessary to perform a legally authorized function of that agency or the department. The state or federal agency is subject to confidentiality regulations that are the same as or more stringent than those in the state of Iowa. State or federal agencies shall not use information obtained from the registry to market services to patients or nonpatients, to assist in bill collection services, or to locate or identify patients or nonpatients for any purposes other than those expressly provided in this rule.

(6) The admitting official of a licensed child care center, elementary school, or secondary school; or medical or health care providers providing continuity of care.

b. Enrolled users shall not release immunization data obtained from the registry except to the person immunized, the parent or legal guardian of the person immunized, admitting officials of licensed child care centers and schools, medical or health care providers providing continuity of care, and other enrolled users of the registry.

[**ARC 8377B**, IAB 12/16/09, effective 11/18/09; **ARC 8658B**, IAB 4/7/10, effective 5/12/10]

641—7.12(22) Release of immunization information.

7.12(1) *Between a physician, physician assistant, nurse, or certified medical assistant and the elementary or secondary school or licensed child care center that the student attends.* A physician, a physician assistant, a nurse, or a certified medical assistant shall disclose a student's immunization information, including the student's name, date of birth, and demographic information, the month, day, year and vaccine(s) administered, and clinic source and location, to an elementary or secondary school or a licensed child care center upon written or verbal request from the elementary or secondary school or licensed child care center. Written or verbal permission from a student or parent is not required to release this information to an elementary or secondary school or licensed child care center that the student attends.

7.12(2) *Among physicians, physician assistants, nurses, or certified medical assistants.* Immunization information, including the student's last name, first name, date of birth, and demographic information, the month, day, year and vaccine(s) administered, and clinic source and location, shall be provided by a physician, physician assistant, nurse, or certified medical assistant to another health care provider without written or verbal permission from the student, parent or guardian.

7.12(3) *Among an elementary school, secondary school, and licensed child care center that the student attends.* An elementary school, secondary school, and licensed child care center shall disclose a student's immunization information, including the student's last name, first name, date of birth, and demographic information, the month, day, and year of vaccine(s) administered, and clinic source and location, to another elementary school, secondary school, and licensed child care center that the student attends. Written or verbal permission from a student, or if the student is a minor, the student's parent or guardian, is not required to release this information to an elementary school, secondary school, and licensed child care center that the student attends.

These rules are intended to implement Iowa Code sections 139A.8 and 22.7(2).

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◊ Two or more ARCs

CHAPTER 41
SAFETY REQUIREMENTS FOR THE USE OF RADIATION MACHINES AND CERTAIN USES OF RADIOACTIVE MATERIALS

641—41.1(136C) X-rays in the healing arts.

41.1(1) *Scope.* This rule establishes requirements, for which a registrant is responsible, for use of X-ray equipment and imaging systems by or under the supervision of an individual authorized by and licensed in accordance with state statutes to engage in the healing arts or veterinary medicine.

a. The provisions of Chapter 41 are in addition to, and not in substitution for, any other applicable portions of 641—Chapters 38 to 42.

b. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of July 9, 2008.

41.1(2) *Definitions.* For the purpose of this chapter, the definitions of 641—Chapters 38 and 40 may also apply. The following are specific to 641—Chapter 41.

"Accessible surface" means the external surface of the enclosure or housing of the radiation producing machine as provided by the manufacturer.

"Added filtration" means any filtration which is in addition to the inherent filtration.

"Aluminum equivalent" means the thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question.

"Attenuation block" means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy or other materials having equivalent attenuation.

"Automatic exposure control (AEC)" means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation (see also "Phototimer"). (Includes devices such as phototimers and ion chambers.)

"Base density" means the optical density due to the supporting base of the film alone. The base density of a film is the optical density that would result if an unexposed film were processed through the fixer, wash, and dryer, without first passing through the developer.

"Base plus fog density" means the optical density of a film due to its base density plus any action of the developer on the unexposed silver halide crystals. The base plus fog density can be measured by processing an unexposed film through the entire processing cycle and measuring the resultant optical density.

"Beam monitoring system" means a system designed to detect and measure the radiation present in the useful beam.

"C-arm X-ray system" means an X-ray system in which the image receptor and X-ray tube housing assembly are connected by a common mechanical support system in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.

"Cassette" means a light-tight case, usually made of thin, low X-ray absorption plastic, for holding X-ray film. One or two intensifying screens for the conversion of X-rays to visible light photons are mounted inside the cassette so that they are in close contact to the film.

"Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

"Certified components" means components of X-ray systems which are subject to regulations promulgated under Public Law 90-602, the "Radiation Control for Health and Safety Act of 1968," the Food and Drug Administration.

"Certified system" means any X-ray system which has one or more certified component(s).

"Coefficient of variation" or *"C"* means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$c = \frac{s}{\overline{x}} = \frac{1}{\overline{x}} \left[\sum_{i=1}^{n} \frac{(x_i - \overline{x})^2}{n-1} \right]^{1/2}$$

where:
s = Estimated standard deviation of the population.
$\overline{X}$ = Mean value of observations in sample.
X_i = i^{th} observation in sample.
n = Number of observations in sample.

"Computed tomography" means the production of a tomogram by the acquisition and computer processing of X-ray transmission data.

"Control chart" means a chart used to record (and control) the results of quality control testing as a function of time.

"Control limit" means the range of variation on a control chart beyond which action must be taken to correct the results of quality control testing.

"Control panel" (see X-ray control panel).

"Cooling curve" means the graphical relationship between heat units stored and cooling time.

"CT" (see "Computed tomography").

"Dead-man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

"Dedicated mammography equipment" means X-ray systems designed specifically for breast imaging, providing optimum imaging geometry, a device for breast compression and low dose exposure that can generate reproducible images of high quality.

"Densitometer" means an instrument which measures the degree of blackening (or radiographic density) of film due to radiation or light by measuring the ratio of the light intensity incident on the film to the light intensity transmitted by the film.

"Detents" means mechanical settings that limit or prevent the motion or rotation of an X-ray tube, cassette assembly, or image receptor system.

"Developer" means a chemical solution (alkaline) that changes the latent image (exposed silver halide crystals) on a film to a visible image composed of minute masses of black metallic silver.

"Developer replenishment" means the process, occurring as film travels past a certain point in the processor, triggering the activation of a pump, whereby fresh developer is added in small amounts to the solution in the developer tank of the processor. The purpose is to maintain the proper alkalinity, chemical activity, and level of solution in the developer tank.

"Diagnostic mammography" means mammography performed on an individual who, by virtue of symptoms or physical findings, is considered to have a substantial likelihood of having breast disease.

"Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

"Direct scattered radiation" means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (see "Scattered radiation").

"Entrance exposure rate" means the exposure free in air per unit time at the point where the center of the useful beam enters the patient.

"Equipment" (see "X-ray equipment").

"Field emission equipment" means equipment which uses an X-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

"Filter" means material placed in the useful beam to preferentially absorb selected radiations.

"Fixer" means a chemical solution (acidic) which removes the unexposed and undeveloped silver halide crystals from film so it will not discolor or darken with age or exposure to light. Fixer also hardens the gelatin containing the black metallic silver so film may be dried and resist damage from abrasions.

"Fixer retention" means the inadequate removal of fixer from the film by the water in the wash tank of the processor. Retained fixer causes eventual brown discoloration of the radiograph.

"Fluoroscopic imaging assembly" means a subsystem in which X-ray photons produce a visual image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical

interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

"Focal spot (actual)" means the area projected on the anode of the X-ray tube bombarded by the electrons accelerated from the cathode and from which the useful beam originates.

"Focal spot size" means the area of the target or anode that is bombarded by electrons from the cathode of the X-ray tube to produce X-rays. The smaller the focal spot, the better the limited spatial resolution of the X-ray system, especially in magnification mammography.

"Fog" means the density added to a radiograph due to unwanted action of the developer on the unexposed silver halide crystals or by light, radiation, chemical, or heat exposure during storage, handling, and processing.

"General purpose radiographic X-ray system" means any radiographic X-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

"Gonad shield" means a protective barrier for the testes or ovaries.

"Healing arts screening" means the use of radiation on human beings for the detection or evaluation of health indicators for which the individual is considered at high risk when such tests are not specifically and individually ordered by:

1. An individual authorized under 41.1(3)*"a"*(7), or
2. An individual licensed as a physician in Iowa and listed as an authorized user on an NRC or agreement state radioactive materials license.

"Heat unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, i.e., kVp × mA × second.

"Image contrast" means the amount of radiographic density difference between adjacent areas resulting from a fixed amount of attentuation difference or light exposure difference.

"Image intensifier" means a device, installed in its housing, which instantaneously converts an X-ray pattern into a corresponding light image of higher energy intensity.

"Image noise" See "Radiographic noise."

"Image quality" means the overall clarity and detail of a radiographic image. Limiting spatial resolution (or resolving power), image sharpness, and image contrast are three common measures of image quality.

"Image receptor" means any device, such as a fluorescent screen or radiographic film, which transforms incident X-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.

"Image sharpness" means the overall impression of detail and clarity in a radiographic image.

"Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

"Kilovolts peak" (see "Peak tube potential").

"kVp" (see "Peak tube potential").

"kWs" means kilowatt second.

"Leakage technique factors" means the technique factors associated with the diagnostic or therapeutic source assembly which are used in measuring leakage radiation. They are defined as follows:

a. For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, i.e., 10 milliampere seconds, or the minimum obtainable from the unit, whichever is larger.

b. For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of X-ray pulses in an hour for operation at the maximum-rated peak tube potential.

c. For all other diagnostic or therapeutic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

"Linear attenuation coefficient" or "μ" means the quotient of dN/N divided by dl when dN/N is the fraction of uncharged ionizing radiation that experience interactions in traversing a distance dl in a specified material.

"Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential. It is calculated using the following equation:

Percent line-voltage regulation = $100\ (V_n - V_l)/V_l$

where

V_n = No-load line potential and

V_l = Load line potential.

"mAs" means milliampere second.

"Maximum line current" means the root-mean-square current in the supply line of an X-ray machine operating at its maximum rating.

"Mobile X-ray equipment" (see "X-ray equipment").

"PBL" (see "Positive beam limitation").

"Phototimer" means a method for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation-monitoring device(s). The radiation-monitoring device(s) is part of an electronic circuit which controls the duration of time the tube is activated (see "Automatic exposure control").

"PID" (see "Position indicating device").

"Portable X-ray equipment" (see "X-ray equipment").

"Position indicating device" means a device on dental X-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

"Positive beam limitation" means the automatic or semiautomatic adjustment of an X-ray beam to the size of the selected image receptor, whereby exposures cannot be made without such adjustment.

"Processor" means an automated device which transports film in a controlled manner by a system of rollers through specialized sections where developing, fixing, washing, and drying of the film occur.

"Protective apron" means an apron made of radiation-absorbing materials used to reduce radiation exposure.

"Protective glove" means a glove made of radiation-absorbing materials used to reduce radiation exposure.

"Quality assurance" means the overall program of testing and maintaining the highest possible standards of quality in the acquisition and interpretation of radiographic images.

"Quality control" means the actual process of testing and maintaining the highest possible standards of quality in equipment performance and the acquisition and interpretation of radiographic images.

"Radiation therapy simulation system" means a radiographic or fluoroscopic X-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

"Radiograph" means an image receptor on which the image is created directly or indirectly by an X-ray pattern and results in a permanent record.

"Radiographic contrast" means the magnitude of optical density difference between structures of interest and their surroundings, or between areas of film receiving different amount of X-ray or visible light exposure.

"Radiographic noise" means unwanted fluctuations in optical density on the screen-film image.

"Rating" means the operating limits as specified by the component manufacturer.

"Recording" means producing a permanent form of an image resulting from X-ray photons.

"Repeat (or reject) analysis" means a systematic approach to determine the causes for radiographs being discarded or repeated, or both.

"Replenishment rate" means the amount of chemicals added in order to maintain the proper chemical activity of developer and fixer solutions.

"Response time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state midscale reading.

"Safelight" means a source of minimal visible light in a darkroom, produced at frequencies (colors) to which the film is insensitive, protecting the film from unwanted exposure (fog) while allowing personnel to function more efficiently and safely.

"Screen" means microscopic phosphor crystals on a plastic support used in conjunction with either single or double emulsion film; the screen emits visible light when exposed to X-radiation, creating a latent image on X-ray film.

"Screen-film combination" means a particular intensifying screen used with a particular type of film. Care must be taken to match the number of screens (one or two) to the number of emulsions coating the film and to match the light output spectrum of the screen to the light sensitivity of the film.

"Screen-film contact" means the close proximity of the intensifying screen to the emulsion of the film, necessary in order to achieve a sharp image on the film.

"Sensitometer" means a device used to reproducibly expose a piece of film to a number of different levels of light intensity.

"Sensitometric strip" means a sheet of film exposed by a sensitometer, resulting in a gray scale range. Such strips are used to measure the range of densities, from minimum to maximum, resulting from a reproducible set of exposures.

"Sensitometry" means a quantitative measurement of the response of film to exposure and development. Sensitometry is used to test the processor setup and stability.

"SID" (see "Source-image receptor distance").

"Source" means the focal spot of the X-ray tube.

"Source-image receptor distance" means the distance from the source to the center of the input surface of the image receptor.

"Spot check" means a procedure which is performed to ensure that a previous calibration continues to be valid.

"Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

"Spot-film device" means a device intended to transport or position a radiographic image receptor between the X-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

"Stationary X-ray equipment" (see "X-ray equipment").

"Technique factors" means the following conditions of operation:

a. For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

b. For field emission equipment rated for pulsed operation, peak tube potential in kV, and number of X-ray pulses;

c. For CT X-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, X-ray pulse width in seconds, and the number of X-ray pulses per scan, or the product of tube current, X-ray pulse width, and the number of X-ray pulses in mAs;

d. For CT X-ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and

e. For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

"Tomogram" means the depiction of the X-ray attenuation properties of a section through the body.

"Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

"Useful beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam-limiting device when the exposure controls are in a mode to cause the system to produce radiation.

"Variable-aperture beam-limiting device" means a beam-limiting device which has capacity for stepless adjustment of the X-ray field size at a given SID.

"Viewbox" means a device by which a uniform field of white light is transmitted through an X-ray so that the image on the film may be seen.

"Visible area" means that portion of the input surface of the image receptor over which incident X-ray photons are producing a visible image.

"X-ray control panel" means a device which controls input power to the X-ray high-voltage generator and the X-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an X-ray exposure.

"X-ray equipment" means an X-ray system, subsystem, or component thereof. Types of X-ray equipment are as follows:

a. "Mobile X-ray equipment" means X-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.

b. "Portable X-ray equipment" means X-ray equipment designed to be hand-carried.

c. "Stationary X-ray equipment" means X-ray equipment which is installed in a fixed location.

"X-ray exposure control" means a device, switch, button or similar means by which an operator initiates or terminates the radiation exposure. The X-ray exposure control may include such associated equipment as timers and backup timers.

"X-ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

"X-ray high-voltage generator" means a device which transforms electrical energy from the potential supplied by the X-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the X-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

"X-ray system" means an assemblage of components for the controlled production of X-rays. It includes minimally an X-ray high-voltage generator, an X-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

"X-ray table" means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography or fluoroscopy. This includes, but is not limited to, any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray (or bucky), cassette tunnel, image intensifier, or spot-film device beneath the tabletop.

41.1(3) *Administrative controls.*

a. Registrant. The registrant shall be responsible for maintaining and directing the operation of the X-ray system(s) under the registrant's administrative control, for ensuring that the requirements of these rules are met in the operation of the X-ray system(s), and for having the following minimum tests performed by a registered service facility according to the following schedule:

1. Medical/chiropractic: timer accuracy, exposure reproducibility, kVp accuracy as set forth in 41.1(6), and light field/X-ray field alignment as set forth in 41.1(6) every two years.

2. Dental/podiatry: timer accuracy, exposure reproducibility and kVp accuracy as set forth in 41.1(7) every four years.

3. Fluoroscopic: entrance exposure rate (41.1(5)*"c"*), and minimum SSD (41.1(5)*"f"*) annually.

4. Veterinary systems are exempt from the above testing requirements.

All service and installation shall be performed by persons registered under 641—subrule 39.3(3). The registrant or the registrant's agent shall ensure that the requirements of these rules are met in the operation of the X-ray system(s).

(1) An X-ray system which does not meet the provisions of these rules shall not be operated for diagnostic or therapeutic purposes unless so directed by the agency. All position locking, holding, and centering devices on X-ray system components and systems shall function as intended. All X-ray systems shall be maintained in good mechanical repair and comply with all state and local electrical code requirements.

(2) Individuals who will be operating the X-ray systems shall be adequately instructed in safe operating procedures and be competent in the safe use of the equipment. In addition:

1. Operators in medical facilities shall meet the requirements of 641—Chapter 42 as applicable, and have a current permit to practice in diagnostic radiography. The individual's permit to practice shall be posted in the immediate vicinity of the general work area and visible to the public.

2. Operators in dental facilities shall meet the requirements of the Iowa dental examiners board.

(3) A chart shall be provided in the vicinity of the diagnostic X-ray system's control panel which specifies, for all examinations performed with that system, the following information:

1. Patient's body part and anatomical size, or body part thickness, or age (for pediatrics), versus technique factors to be utilized unless automatically set by the X-ray system;

2. Type and size of the film or film-screen combination to be used;

3. Type and focal distance of the grid to be used, if any;

4. Source to image receptor distance to be used, except for dental intra-oral radiography; and

5. Type and location of placement of human patient shielding to be used (e.g., gonad).

(4) Written safety procedures shall be provided to each individual operating X-ray equipment, including patient holding and any restrictions of the operating technique required for the safe operation of the particular X-ray system. The operator shall be able to demonstrate familiarity with these procedures.

(5) Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:

1. All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by 0.5 millimeter lead equivalent.

2. The X-ray operator, other staff, ancillary personnel, and other persons required for the medical procedure shall be protected from the scattered primary radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent.

3. Human patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 millimeter lead equivalent or shall be so positioned that the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.

(6) Gonad shielding of not less than 0.50 millimeter lead equivalent shall be used for human patients, who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

(7) Individuals shall not be exposed to the useful beam unless (1) the radiation exposure occurs in the context of a previously established professional relationship between a licensed practitioner of the healing arts or a licensed registered nurse who is registered as an advanced registered nurse practitioner pursuant to Iowa Code chapter 152 and a patient, which includes a physical examination by the practitioner of the patient unless such examination is not clinically indicated; and (2) such practitioner issues a written order for the radiation exposure. The written order shall be issued prior to the exposure unless the exposure results from care provided in an emergency or surgery setting. A verbal order may be issued provided the licensed practitioner is supervising the procedure and the order is documented in the patient's record after the procedure is completed. This provision specifically prohibits deliberate exposure for the following purposes:

1. Exposure of an individual for training, demonstration, or other non-healing arts purposes; and

2. Exposure of an individual for the purpose of healing arts screening except as authorized by 41.1(3)*"a"*(11).

(8) When a patient or film must be provided with auxiliary support during a radiation exposure:

1. Mechanical holding devices shall be used when the technique permits. The written safety procedures, required by 41.1(3)*"a"*(4), shall list individual projections where holding devices cannot be utilized;

2. Written safety procedures, as required by 41.1(3)*"a"*(4), shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

3. The human holder shall be instructed in personal radiation safety and protected as required by 41.1(3)*"a"*(5)"2";

4. No individual shall be used routinely to hold film or patients; and

5. In those cases where the human patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material.

6. Each facility shall have leaded aprons and gloves available in sufficient numbers to provide protection to all personnel who are involved with X-ray operations and who are otherwise not shielded.

(9) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

1. The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens shall not be used for any routine diagnostic radiological imaging, with the exception of veterinary radiography and standard film packets for intra-oral use in dental radiography.

2. The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.

3. Portable or mobile X-ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary X-ray installation.

4. X-ray systems subject to 41.1(6) shall not be utilized in procedures where the source to human patient distance is less than 30 centimeters.

5. If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast, the grid shall:

- Be positioned properly, i.e., tube side facing the correct direction, and the grid centered to the central ray;
- If the grid is of the focused type, be at the proper focal distance for the SIDs being used.

(10) All individuals who are associated with the operation of an X-ray system are subject to the requirements of 641—subrule 40.36(3) and rules 641—40.15(136C) and 641—40.37(136C). In addition:

1. When protective clothing or devices are worn on portions of the body and a personnel monitoring device(s) is present, it (they) shall be worn in accordance with the recommendations found in Chapter 4 of the National Council of Radiation Protection and Measurements Report No. 57.

2. Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

(11) Healing arts screening. Any person proposing to conduct a healing arts screening program shall not initiate such a program in the state of Iowa without prior written approval of the agency. When requesting such approval, that person shall submit the information outlined in Appendix C of this chapter. The agency shall not approve a healing arts screening program unless the applicant submits data supporting the efficacy of the screening test in diagnosing the disease or condition being screened. If any information submitted to the agency becomes invalid or outdated, the applicant shall notify the agency in writing within five calendar days.

(12) Rescinded IAB 3/31/04, effective 5/5/04.

b. Information and maintenance record and associated information. Records in 41.1(3)*"b"*(1) and (3) below shall be maintained until the X-ray system is removed from the facility. There shall be two cycles of records on file for items in 41.1(3)*"b"*(2) below. The registrant shall maintain the following information for each X-ray system for inspection by the agency:

(1) User's manual for the X-ray system;

(2) Records of surveys, calibrations, maintenance, and modifications performed on the X-ray system(s) with the names of persons who performed such services;

(3) A copy of all correspondence with this agency regarding that X-ray system.

c. X-ray utilization log. Except for veterinary facilities, each facility shall maintain an X-ray log containing the patient's name, the type of examinations, the dates the examinations were performed, the name of the individual performing the X-ray procedure, and the number of exposures and retakes involved. When the patient or film must be provided with human auxiliary support, the name of the

human holder shall be recorded. These records shall be kept until the facility is inspected by this agency or until all films listed on the utilization log have been purged.

d. Plan review.

(1) Prior to construction of all new installations, or modifications of existing installations, or installation of equipment into existing facilities utilizing X-rays for diagnostic or therapeutic purposes, the floor plans and equipment arrangements shall be submitted to the agency for review and verification that national standards have been met. The required information is denoted in Appendices A and B of this chapter.

(2) The agency may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to the plan review and approval.

(3) The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in 641—Chapter 40.

e. Federal performance standards. All X-ray equipment shall comply with the applicable performance standards of 21 CFR 1020.30 to 1020.40 which were in effect at the time the unit was manufactured. All equipment manufactured before the effective date of 21 CFR 1020.30 to 1020.40 shall meet the requirements of the Iowa rules. Persons registered to possess the affected radiation-emitting equipment in Iowa shall be responsible for maintaining the equipment in compliance with the appropriate federal performance standards.

f. X-ray film processing facilities and practices (except for mammography). Each installation using a radiographic X-ray system and using analog image receptors (e.g., radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:

(1) Manually developed film.

1. Processing tanks shall be constructed of mechanically rigid, corrosion-resistant material; and

2. Film shall be processed in accordance with the time-temperature relationships recommended by the film developer manufacturer. The specified developer temperature and immersion time shall be posted in the darkroom. Deviations from the manufacturer's recommendations shall be in writing and on file at the facility. Documentation shall include justification for the deviation.

3. Devices shall be utilized which will indicate the actual temperature of the developer and signal the passage of a preset time appropriate to the developing time required.

(2) Automatic processors and other closed processing systems.

1. Film shall be processed in accordance with the time-temperature relationships recommended by the film developer manufacturer.

2. Processing deviations from the requirements of 41.1(3)*"f"* shall be documented by the registrant in such manner that the requirements are shown to be met or exceeded (e.g., extended processing and special rapid chemistry).

3. All processing equipment shall be in good mechanical working order.

(3) Other requirements.

1. Pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.

2. The darkroom shall be light tight and use proper safelighting such that any film type in use exposed in a cassette to X-radiation sufficient to produce an optical density from 1 to 2 when processed shall not suffer an increase in density greater than 0.1 when exposed out of the cassette in the darkroom for 2 minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film.

3. Darkrooms typically used by more than one individual shall be provided a method to prevent accidental entry while undeveloped films are being handled or processed.

4. Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.

5. Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary to best ensure radiographs of good diagnostic quality.

6. Outdated X-ray film shall not be used for diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed.

7. Film developing solutions shall be prepared in accordance with the directions given by the manufacturer and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

(4) Records shall be maintained to verify that the items in 41.1(3)*"f"* are performed according to the requirements. Records may be discarded only after an agency inspection has been completed and the facility determined to be in compliance.

g. Retention of films. Record retention of films shall be seven years for patients 18 years of age or older and seven years plus the difference between the patient's age and 18 for minors.

(1) If the facility is currently utilizing hard-copy film to store images, it may continue to use this method throughout the retention period.

(2) If the facility is currently utilizing computer media and also storing images in a hard-copy format, it may continue to use this method of retention throughout the retention period. If the images are also on computer media, the data should be backed up, or refreshed, at appropriate intervals as defined by the facility.

(3) If the facility is solely utilizing computer media to store study information for which a report is generated, the recording media is to be stored in conditions that will ensure that deterioration will not occur for the period required by this policy. The facility must maintain either retrieval or access or both to the stored images.

(4) If a patient's medical images are identified as being involved in a legal case, the records should immediately be coded appropriately, and maintained for the required time frame defined in this paragraph. At the time the records have reached the end of the appropriate time frame for retention, the previously identified responsible individuals involved in the legal action should be contacted for further instruction.

(5) If records are temporarily transferred to any party, appropriate information relating to location, date of release, and individual having custody of the records should be maintained.

(6) A facility that is ceasing operations must either transfer its film records to another facility or provide the film records to its patients. A certified letter as to the location, or disposition, of the film records must be sent to notify the patients of the transferal.

41.1(4) *General requirements for all diagnostic X-ray systems.* In addition to other requirements of this chapter, all diagnostic X-ray systems shall meet the following requirements:

a. Warning label. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This X-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

b. Battery charge indicator. On battery-powered X-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

c. Leakage radiation from the diagnostic source assembly. The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 100 milliroentgens (25.8 μC/kg) in one hour when the X-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

d. Radiation from components other than the diagnostic source assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed 2 milliroentgens (0.516 μC/kg) in one hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled X-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

e. Beam quality.

(1) Half-value layer.

1. The half-value layer of the useful beam for a given X-ray tube potential shall not be less than the values shown in Table I. If it is necessary to determine such half-value layer at an X-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made.

Table I

Design operating range (kVp)	Measured potential (kVp)	Half-value layer (mm of aluminum)
Below 50	30	0.3
	40	0.4
	49	0.5
50 to 70	50	1.2
	60	1.3
	70	1.5
Above 70	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

2. and 3. Rescinded IAB 4/8/98, effective 7/1/98.

4. For capacitor energy storage equipment, compliance with the requirements of 41.1(4)*"e"* shall be determined with the system fully charged and a setting of 10 mAs for each exposure.

5. The required minimal half-value layer of the useful beam shall include the filtration contributed by all materials which are permanently between the source and the patient.

(2) Filtration controls. For X-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration required by 41.1(4)*"e"*(1)"1" is in the useful beam for the given kVp which has been selected.

f. Multiple tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the X-ray control panel and at or near the tube housing assembly which has been selected.

g. Mechanical support of tube head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the X-ray system.

h. Technique indicators.

(1) The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated.

(2) The requirement of 41.1(4)*"h"*(1) may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

(3) The technique indicators shall be accurate to within manufacturer's standards.

i. Rescinded IAB 3/30/05, effective 5/4/05.

41.1(5) *Fluoroscopic X-ray systems except for computed tomography X-ray systems.* All fluoroscopic X-ray systems shall be image intensified and meet the following requirements:

a. Limitation of useful beam.

(1) Primary barrier.

1. The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID.

2. The X-ray tube used for fluoroscopy shall not produce X-rays unless the barrier is in position to intercept the entire useful beam.

(2) Fluoroscopic beam limitation.

1. For certified fluoroscopic systems with or without a spot film device, neither the length nor the width of the X-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.

2. For uncertified fluoroscopic systems with a spot film device, the X-ray beam with the shutter fully opened (during fluoroscopy or spot filming) shall be no larger than the largest spot film size for which the device is designed. Measurements shall be made at the maximum SID available but at no less than 20 centimeters from the tabletop to the film plane distance.

3. For uncertified fluoroscopic systems without a spot film device, the requirements of 41.1(5)*"a"*(2)"1" apply.

4. Other requirements for fluoroscopic beam limitation:

- Means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID or a visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the X-ray field;
- All equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided either with stepless adjustment of the X-ray field or with means to further limit the X-ray field size at the plane of the image receptor to 125 square centimeters or less;
- If provided, stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum attainable to a field size of 5 centimeters by 5 centimeters or less;
- For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor;
- For noncircular X-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the X-ray field which pass through the center of the visible area of the image receptor.

(3) Spot-film beam limitation. Spot-film devices shall meet the following requirements:

1. Means shall be provided between the source and the patient for adjustment of the X-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot-film selector. Such adjustment shall be automatically accomplished except when the X-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot-film devices manufactured after June 21, 1979, if the X-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option;

2. Neither the length nor the width of the X-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than 3 percent of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed 4 percent of the SID;

3. It shall be possible to adjust the X-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, 5 centimeters by 5 centimeters;

4. The center of the X-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2 percent of the SID; and

5. On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(4) Override. If a means exists to override any of the automatic X-ray field size adjustments required in 41.1(5)*"a"*(2) and 41.1(5)*"a"*(3), that means:

1. Shall be designed for use only in the event of system failure;

2. Shall incorporate a signal visible at the fluoroscopist's position which will indicate whenever the automatic field size adjustment is overridden; and

3. Shall have a clear and durable label as follows:

FOR X-RAY FIELD
LIMITATION SYSTEM FAILURE

b. Activation of the fluoroscopic tube. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the X-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

c. Exposure rate limits.

(1) Entrance exposure rate allowable limits.

1. Fluoroscopic equipment which is provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 2.6 mC/kg (10 roentgens) per minute at the point where the center of the useful beam enters the patient, except

- During recording of fluoroscopic images; or
- When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens (1.3 mC/kg) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

2. Fluoroscopic equipment which is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens (1.3 mC/kg) per minute at the point where the center of the useful beam enters the patient, except:

- During recording of fluoroscopic images; or
- When the mode or modes have an optional high level control, in which case the mode or modes shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of 5 roentgens (1.3 mC/kg) per minute at the point where the center of the useful beam enters the patient, unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

3. Compliance with the requirements of 41.1(5)*"c"* shall be determined as follows:

- If the source is below the table, exposure rate shall be measured 1 centimeter above the tabletop or cradle;

- If the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement;
- All C-arm fluoroscopes, both stationary and mobile, shall meet the entrance exposure rate limits at 30 centimeters from the input surface of the fluoroscopic imaging assembly with the source positioned at any available SID provided that the end of the spacer assembly or beam-limiting device is not closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly.
- For a lateral type fluoroscope, the exposure rate shall be measured at a point 15 centimeters from the centerline of the X-ray table and in the direction of the X-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral X-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters to the centerline of the X-ray table.

4. Fluoroscopic equipment which is provided with both automatic exposure rate control mode and a manual mode shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of 10 roentgens (2.6 mC/kg) per minute in either mode at the point where the center of the useful beam enters the patient, except:

- During recording of fluoroscopic images; or
- When the mode or modes have an optional high level control, in which case the mode or modes shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of 5 roentgens (1.3 mC/kg) per minute at the point where the center of the useful beam enters the patient, unless the high level control is activated. Special means of activitation of high level controls shall be required. The high level control shall only be operable when continuous manual activitation is provided by the operator. A continuous signal audible to the fluroscopist shall indicate that the high level control is being employed.

5. Any fluoroscopic equipment manufactured after May 19, 1995, which can exceed 5 roentgens (1.3 mC/kg) per minute shall be equipped with an automatic exposure rate control. All entrance exposure rate limits shall be 10 roentgens (2.6 mC/kg) per minute with an upper limit of 20 roentgens (5.2 mC/kg) per minute when the high level control is activated.

6. Conditions of periodic measurement of maximum entrance exposure rate are as follows:

- The measurement shall be made under the conditions that satisfy the requirements of 41.1(5)*"c"*(1)"3";
- The kVp, mA, or other selectable parameters shall be adjusted to those settings which give the maximum entrance exposure rate;
- The X-ray system(s) that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce either a milliamperage or kilovoltage or both to satisfy the conditions of 41.1(5)*"c"*(1)"3."

(2) Reserved.

d. Barrier transmitted radiation rate limits.

(1) The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed 2 milliroentgens (0.516 μC/kg) per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

(2) Measuring compliance of barrier transmission.

1. The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

2. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.

3. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.

4. Movable grids and compression devices shall be removed from the useful beam during the measurement.

e. Indication of potential and current. During fluoroscopy and cinefluorography the kV and the mA shall be continuously indicated.

f. Source-to-skin distance. The SSD shall not be less than:

(1) 38 centimeters on stationary fluoroscopes installed on or after August 1, 1974,

(2) 35.5 centimeters on stationary fluoroscopes which were in operation prior to August 1, 1974,

(3) 30 centimeters on all mobile fluoroscopes, and

(4) 20 centimeters for mobile fluoroscopes used for specific surgical application.

(5) The written safety procedures must provide precautionary measures to be adhered to during the use of this device in addition to the procedures provided in 41.1(3)*"a"*(4).

g. Fluoroscopic timer.

(1) Means shall be provided to preset the cumulative on-time of the fluoroscopic X-ray tube. The maximum cumulative time of the timing device shall not exceed five minutes without resetting.

(2) A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while X-rays are produced until the timing device is reset.

h. Control of scattered radiation.

(1) Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.

(2) Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

1. Is at least 120 centimeters from the center of the useful beam, or

2. The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, Bucky-slot cover panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in 41.1(3)*"a"*(5).

(3) The agency may grant exemptions to 41.1(5)*"h"*(2) where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the agency shall not permit such exemption.

i. Spot-film exposure reproducibility. Fluoroscopic systems equipped with spot-film (radiographic) mode shall meet the exposure reproducibility requirements of 41.1(6)*"d"* when operating in the spot-film mode.

j. Radiation therapy simulation systems. Radiation therapy simulation systems shall be exempt from all the requirements of 41.1(5)*"a," "c," "d,"* and *"g"* provided that:

(1) Such systems are designed and used in such a manner that no individual other than the patient is in the X-ray room during periods of time when the system is producing X-rays; and

(2) Systems which do not meet the requirements of 41.1(5)*"g"* are provided with a means of indicating the cumulative time that an individual patient has been exposed to X-rays. Procedures shall require in such cases that the timer be reset between examinations.

k. Dose-area-product monitor requirements.

(1) All fluoroscopic equipment installed after July 1, 2002, and used for special procedures (e.g., pacemaker implantation, diagnostic cardiac procedures (catheterization), and therapeutic cardiac procedures (angioplasty-balloon; stent; directional coronary atherectomy; rotational atherectomy; laser atherectomy; radio frequency ablation; and intravascular brachytherapy)) shall be equipped with a dose-area-product monitor capable of recording the total radiation dose received by a patient when the fluoroscopic tube is used. Equipment used and installed prior to July 1, 2002, shall be retrofitted with the radiation exposure device by January 1, 2004.

(2) Each facility using fluoroscopic equipment for special procedures shall include in the patient's chart and in a log for agency review the patient radiation exposure received per procedure. Adult doses that exceed 300 rad and doses for children (under the age of 18) that exceed 100 rad must be reviewed by

the facility's radiation safety committee. The review must document the reason why a dose exceeded 300 rad for adults or 100 rad for children, and the reason must be documented in the committee's minutes. If a facility does not have a radiation safety committee, the facility must provide the agency, within 30 days of the event, documentation stating why the patient's dose exceeded 300 rad for adults or 100 rad for children. Also, if the patient doses noted above are exceeded, the patient's physician must do a follow-up examination of the patient to determine if there is any evidence of dose recorded reaction and to ensure that proper treatment is rendered.

(3) All fluoroscopic radiation detection devices in this subrule shall be calibrated annually or after repair or replacement.

l. Equipment operation.

(1) All imaging formed by the use of fluoroscopic X-ray systems shall be directly viewed and interpreted by a licensed practitioner of the healing arts.

(2) Overhead fluoroscopy shall not be used as a positioning tool for general purpose radiographic examinations.

(3) Facilities that use fluoroscopic X-ray systems shall maintain a record of cumulative fluoroscopic exposure time used and the number of spot films for each examination. This record shall indicate patient identification, type of examination, date of examination, and operator's name.

m. Additional requirements for stationary fluoroscopic systems used for cardiac catheterization procedures.

(1) Protective barriers shall be available for use by individuals whose presence is required in the room during activation of the X-ray tube(s). If a protective barrier includes or consists of a transparent viewing panel, the viewing panel shall afford protection of not less than 0.5 millimeter of lead equivalent.

(2) Protective aprons of not less than 0.25 millimeter of lead equivalent shall be worn in the fluoroscopy room by all individuals (except the patient). Any individual required to be in the room for short periods of time may not be required to wear a protective apron if exposure levels below minimum as seen on film badge reports can be verified. Individuals not using protective aprons should follow ALARA by using time and distance to reduce exposure. Any declared pregnant individual must meet the requirements of 641—40.22(136C).

n. Supervision of fluoroscopy. The use of fluoroscopy by radiologic technologists and radiologic students shall be performed under the direct supervision of a licensed practitioner or an advanced registered nurse practitioner (ARNP), pursuant to 655—subrule 7.2(2), for the purpose of localization to obtain images for diagnostic or therapeutic purposes. The use of fluoroscopy by radiologist assistants shall be as defined in 641—42.6(136C).

41.1(6) *Radiographic systems other than fluoroscopic, dental intraoral, veterinary, or computed tomography X-ray systems.*

a. Beam limitation. The useful beam shall be limited to the area of clinical interest. This shall be considered met if a positive beam-limiting device meeting manufacturer's specifications and the requirements of 41.1(6)*"h"*(2) have been properly used or if evidence of collimation is shown on at least three sides or three corners of the film (for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge.)

(1) General purpose stationary and mobile X-ray systems and veterinarian systems (other than portable) installed after July 1, 1998.

1. Only X-ray systems provided with means for independent stepless adjustment of at least two dimensions of the X-ray field shall be used.

2. A method shall be provided for visually defining the perimeter of the X-ray field.

- Illuminance shall be greater than 7.5 foot-candles or 80.3 LUX at 100 centimeters or maximum SID whichever is less.
- The total misalignment of the edges of the visually defined field with the respective edges of the X-ray field along either the length or width of the visually defined field shall not exceed 2 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the X-ray beam.

3. The agency may grant an exemption on noncertified X-ray systems to 41.1(6)*"a"*(1)"1" and "2" provided the registrant makes a written application for such exemption and in that application demonstrates it is impractical to comply with 41.1(6)*"a"*(1)"1" and "2"; and the purpose of 41.1(6)*"a"*(1)"1" and "2" will be met by other methods.

(2) Additional requirements for stationary general purpose X-ray systems. In addition to the requirements of 41.1(6)*"a"*(1), stationary general purpose X-ray systems, both certified and noncertified, shall meet the following requirements:

1. A method shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, to align the center of the X-ray field with respect to the center of the image receptor to within 2 percent of the SID, and to indicate the SID to within 2 percent;

2. The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted; and

3. Indication of field size dimensions and SIDs shall be specified in inches or centimeters, and shall be such that aperture adjustments result in X-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

(3) X-ray systems designed for one image receptor size. Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the X-ray field with the center of the image receptor to within 2 percent of the SID, or shall be provided with means to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

(4) Systems designed for or provided with special attachments for mammography. Rescinded IAB 4/8/98, effective 7/1/98.

(5) X-ray systems other than those described in 41.1(6)*"a"*(1), (2), and (3), and veterinary systems installed prior to July 1, 1998, and all portable veterinary X-ray systems.

1. Means shall be provided to limit the X-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID when the axis of the X-ray beam is perpendicular to the plane of the image receptor.

2. Means shall be provided to align the center of the X-ray field with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. Compliance shall be determined with the axis of the X-ray beam perpendicular to the plane of the image receptor.

3. 41.1(6)*"a"*(5)"1" and "2" may be met with a system that meets the requirements for a general purpose X-ray system as specified in 41.1(6)*"a"*(1) or, when alignment means are also provided, may be met with either:

- An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or
- A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

b. Radiation exposure control devices.

(1) Timers.

1. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action.

2. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In

addition, it shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided. Except for dental panoramic systems, termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

(2) X-ray control.

1. Manual exposure control. An X-ray control shall be incorporated into each X-ray system such that an exposure can be terminated by the operator at any time except for exposure of one-half second or less, or during serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

2. Each X-ray control shall be located in such a way as to meet the following requirements: Stationary X-ray systems (except podiatry and veterinary units) shall be required to have the X-ray exposure switch permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure and so that the operator can view the patient while making any exposures; and mobile and portable X-ray systems which are:

- Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of 41.1(6)*"b"*(2)"2"; or
- Used for greater than one hour and less than one week at the same location, i.e., a room or suite, or in a clinical setting for routine extremities only, or where moving the X-ray system from room to room is impractical, shall meet the requirement of the above paragraph or be provided with a 6.5 foot (1.98 m) high protective barrier which is placed at least 2.7 meters (9 feet) from the tube housing assembly. Written procedures must instruct the operator to remain in the protected area during the entire exposure. Stationary podiatric systems which do not meet the above requirements shall be provided with a 9-foot exposure button cord which allows the operator to remain behind a protective barrier during the entire exposure. If the protective barrier is moveable, written procedures must be on file at the facility, which dictate that the operator will remain behind the barrier during the entire exposure.

3. The X-ray control shall provide visual indication observable at or from the operator's protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(3) Automatic exposure controls. When an automatic exposure control is provided:

1. Indication shall be made on the control panel when this mode of operation is selected;

2. If the X-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to 2 pulses;

3. The minimum exposure time for all equipment other than that specified in 41.1(6)*"b"*(3)"2" shall be equal to or less than one-sixtieth second or a time interval required to deliver 5 mAs, whichever is greater;

4. Either the product of peak X-ray tube potential, current, and exposure time shall be limited to not more than 60 kWs per exposure, or the product of X-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except that, when the X-ray tube potential is less than 50 kVp, the product of X-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and

5. A visible signal shall indicate when an exposure has been terminated at the limits required by 41.1(6)*"b"*(3)"4," and manual resetting shall be required before further automatically timed exposures can be made.

(4) Reproducibility. With a timer setting of 0.5 seconds or less, the average exposure period (T) shall be greater than or equal to five times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when four timer tests are performed:

$$\overline{T} \geq 5\ (T_{max} - T_{min})$$

(5) Exposure duration (timer) linearity. For systems having independent selection of exposure time settings, the average ratios (X_1) of exposure to the indicated timer setting, in units of C $kg^{-1}s^{-1}$ (mR/s),

obtained at any two clinically used timer settings shall not differ by more than 0.10 times their sum. This is written as:

$$(X_1 - X_2) \leq 0.1\ (X_1 + X_2)$$

where X_1 and X_2 are the average C $kg^{-1}s^{-1}$ (mR/s) values.

c. Source-to-skin distance. All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to equal to or greater than 30 centimeters except for veterinary systems.

d. Exposure reproducibility. When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, the coefficient of variation of exposure for both manual and automatic exposure control systems shall not exceed 0.05. This requirement applies to clinically used techniques.

e. Radiation from capacitor energy storage equipment in standby status. Radiation emitted from the X-ray tube when the system is fully charged and the exposure switch or timer is not activated shall not exceed a rate of 2 milliroentgens (0.516 μC/kg) per hour at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

f. Accuracy. Deviation of measured technique factors from indicated values of kVp and exposure time shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed 10 percent of the indicated value for kVp and 20 percent for time.

g. mA/mAs linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed X-ray tube potential within the range of 40 percent to 100 percent of the maximum rated:

(1) Equipment having independent selection of X-ray tube current (mA). The average ratios (X_i) of exposure to the indicated milliampere-seconds product (C $kg^{-1}mAs^{-1}$ (or mR/mAs)) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 \leq 0.10\ (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at each of two consecutive tube current settings, or at two settings differing by no more than a factor of 2 where the tube current selection is continuous.

(2) Equipment having a combined X-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios (X_i) of exposure to the indicated milliampere-seconds product, in units of mR/mAs (or C $kg^{-1}mAs^{-1}$), obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 \leq 0.10\ (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at any two consecutive mAs selector settings, or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

(3) Measuring compliance. Determination of compliance shall be based on 10 exposures taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the X-ray tube manufacturer.

h. Additional requirements applicable to certified systems only. Diagnostic X-ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirement(s) which relate to that certified component(s).

(1) Beam limitation for stationary and mobile general purpose X-ray systems.

1. There shall be provided a means of stepless adjustment of the X-ray field. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters.

2. When a light localizer is used to define the X-ray field, it shall provide an average illumination of not less than 160 lux or 15 foot-candles at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems manufactured on and after May 27, 1980, are exempt from this requirement.

3. The edge of the light field at 100 centimeters or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than 4 in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than 3 in the case of beam-limiting devices designed for use on mobile equipment. The contrast ratio is defined as I_1/I_2 where I_1 is the illumination 3 millimeters from the edge of the light field toward the center of the field; and I_2 is the illumination 3 millimeters from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring instrument aperture of 1 millimeter in diameter.

(2) Beam limitation and alignment on stationary general purpose X-ray systems equipped with PBL. If PBL is being used, the following requirements shall be met:

1. PBL shall prevent the production of X-rays when

- Either the length or width of the X-ray field in the plane of the image receptor differs, except as permitted by 41.1(6)*"h"*(3), from the corresponding image receptor dimensions by more than 3 percent of the SID; or
- The sum of the length and width differences as stated in 41.1(6)*"h"*(2)"1" above without regard to sign exceeds 4 percent of the SID;

2. Compliance with 41.1(6)*"h"*(2)"1" shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor. Compliance shall be determined no sooner than 5 seconds after insertion of the image receptor;

3. The PBL system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters;

4. The PBL system shall be designed such that if a change in image receptor does not cause an automatic return to PBL function as described in 41.1(6)*"h"*(2)"1," then any change of image receptor size or SID must cause the automatic return.

(3) Beam limitation for portable X-ray systems. Beam limitation for portable X-ray systems shall meet the beam limitation requirements of 41.1(6)*"a"* or 41.1(6)*"h"*(2).

i. Tube stands for portable X-ray systems. A tube stand or other mechanical support shall be used for portable X-ray systems, so that the X-ray tube housing assembly need not be handheld during exposures.

j. Systems used in a clinical (nonsurgical) setting shall be restricted to one room within a location or suite which meets the requirements of 41.1(3)*"d."*

41.1(7) *Intraoral dental radiographic systems.* In addition to the provisions of 41.1(3) and 41.1(4), the requirements of 41.1(7) apply to X-ray equipment and associated facilities used for dental radiography. Requirements for extraoral dental radiographic systems are covered in 41.1(6). Only systems meeting the requirements of 41.1(7) shall be used.

a. Source-to-skin distance. X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance to not less than:

(1) 18 centimeters if operable above 50 kVp, or

(2) 10 centimeters if not operable above 50 kVp.

b. Beam limitation. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the X-ray beam such that:

(1) If the minimum source-to-skin distance (SSD) is 18 centimeters or more, the X-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than 7 centimeters; and

(2) If the minimum SSD is less than 18 centimeters, the X-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than 6 centimeters.

(3) The position indicating device shall be shielded and open-ended. The shielding shall be equivalent to the requirements of 41.1(4)*"c."*

c. Exposure control.

(1) Exposure initiation.

1. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action; and

2. It shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.

(2) Exposure indication. Means shall be provided for visual indication observable at or from the operator's protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated except in X-ray systems that cannot be altered to meet this requirement.

(3) Exposure termination.

1. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition:

2. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

3. An X-ray control shall be incorporated into each X-ray system such that an exposure can be terminated by the operator at any time, except for exposures of one-half (½) second or less.

(4) Exposure duration (timer) linearity. For systems having independent selection of exposure time settings, the average ratios (X_1) of exposure to the indicated timer setting, in units of C $kg^{-2}s^{-1}$ (mR/s), obtained at any two clinically used timer settings shall not differ by more than 0.10 times their sum. This is written as:

$$(X_1 - X_2) \leq 0.1\ (X_1 + X_2)$$

where X_1 and X_2 are the average values.

(5) Each X-ray exposure switch shall be located in such a way as to meet the following requirements:

1. Stationary X-ray systems shall be required to have the X-ray exposure switch located in a protected area or have an exposure switch cord of sufficient length to permit the operator to activate the unit while in a protected area, e.g., corridor outside the operatory. The procedures required under 41.1(3)*"a"*(4) must instruct the operator to remain in the protected area during the entire exposure.

2. Mobile and portable X-ray systems which are:

- Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of 41.1(7)*"c"*(5)"1."
- Used for greater than one hour and less than one week at the same location, i.e., a room or suite, shall meet the requirements of the above paragraph or be provided with a 6.5 foot (1.98 m) high protective barrier or means to allow the operator to be at least 9 feet (2.7 meters) from the tube housing assembly while making exposure.

3. Portable or hand-held dental X-ray systems designed with a backscatter shield may be used without the additional protective barrier, but the operator must wear a protective apron. The operator must stand directly behind the unit to allow the shield to function as designed.

d. Reproducibility. When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific combination of selected technique factors.

e. mA/mS linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed X-ray tube potential within the range of 40 percent to 100 percent of the maximum rated.

(1) Equipment having independent selection of X-ray tube current (mA). The average ratios (X_1) of exposure to the indicated milliampere-seconds product, in units of C kg^{-1} mAs^{-1} (or mR/mAs), obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$(X_1 - X_2) \leq 0.1\ (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at each of two consecutive tube current settings, or at two settings differing by no more than a factor of 2 where the tube current selection is continuous.

(2) Equipment having a combined X-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios (X_1) of exposure to the indicated milliampere-seconds product, in units of C kg^{-1} mAs^{-1} (or mR/mAs), obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum:

$$(X_1 - X_2) \leq 0.1\ (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at any two mAs selector settings, or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

(3) Measuring compliance. Determination of compliance shall be based on 10 exposures taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the X-ray tube manufacturer.

f. *Accuracy.* Deviation of technique factors from indicated values for kVp and exposure time (if time is independently selectable) shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications the deviation shall not exceed 10 percent of the indicated value for kVp and 20 percent for time.

g. *kVp limitations.* Dental X-ray machine with a nominal fixed kVp of less than 50 kVp shall not be used to make diagnostic dental radiographs of humans.

h. *Administrative controls.*

(1) Patient and film holding devices shall be used when the techniques permit.

(2) The tube housing and the PID shall not be hand-held during an exposure.

(3) The X-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of 41.1(7)*"b"*(1).

(4) Dental fluoroscopy without image intensification shall not be used.

i. *Portable or hand-held dental X-ray systems.* Portable or hand-held dental X-ray systems designed with a backscatter shield shall:

(1) Be used only where it is impractical to us a portable dental system;

(2) Be used as the manufacturer indicates;

(3) Not be used with the backscatter shield removed, if applicable; and

(4) Be exempted from 41.1(4)*"g."*

41.1(8) Rescinded IAB 6/4/97, effective 7/9/97.

41.1(9) *Bone densitometry units.*

a. No additional shielding for the room is required.

b. Film badges, OSL devices, or TLDs must be issued for the first six months to all personnel operating the unit. If monitoring indicates no exposure, the IDPH may allow discontinuance of monitoring upon written request. When new procedures are started that have not been previously monitored, monitoring must be reinstated for six months and another request for discontinuance submitted to the agency.

c. Operators, other than physicians, must possess a health education background to include anatomy and physiology and must complete the manufacturer's training session pertaining to bone densitometry or equivalent. A permit to practice for operators is not required.

d. Specific operating procedures must be prepared and made available at the operator's position.

e. Bone densitometry on human patients shall be conducted only under a prescription of a licensed physician, a licensed physician assistant as defined in Iowa Code section 148C.1, subsection 6, or a

licensed registered nurse who is registered as an advanced registered nurse practitioner pursuant to Iowa Code chapter 152.

f. During the operation of the bone densitometry system:

(1) The operator, ancillary personnel, and members of the general public shall be positioned at least one meter from the patient and bone densitometry system during the examination.

(2) The operator shall advise the patient that the bone densitometry examination is a type of X-ray procedure.

g. Equipment shall be maintained and operated in accordance with the manufacturer's specifications. Records of maintenance shall be kept for inspection by the agency.

41.1(10) *Veterinary medicine radiographic installations.*

a. *Equipment.*

(1) The protective tube housing shall be equivalent to the requirements of 41.1(4)*"c."*

(2) Diaphragms or cones shall be provided for collimating the useful beam to the area of clinical interest and shall provide the same degree of protection as is required of the housing.

(3) The total filtration permanently in the useful beam shall not be less than 0.5 millimeters aluminum equivalent for machines operating up to 50 kVp, 1.5 millimeters aluminum equivalent for machines operating between 50 and 70 kVp, and 2.5 millimeters aluminum equivalent for machines operating above 70 kVp.

b. *Operator protection.*

(1) All wall, ceiling, and floor areas shall be equivalent to or provided with applicable protective barriers to ensure compliance with 641—40.15(136C) and 40.21(136C) and subrule 40.26(1).

(2) All stationary, mobile or portable X-ray systems shall be provided with either a 2 meter (6.5 feet) high protective barrier for operator protections during exposures, or shall be provided with means to allow the operator to be at least 2.7 meters (9 feet) from the tube housing assembly during exposures.

c. *Operating procedures.* Veterinary medicine radiographic installations are exempt from the requirements of 641—41.1(136C) except for 641—subrules 41.1(3) and 41.1(10).

(1) No individual other than the operator shall be in the X-ray room while exposures are being made unless such individual's assistance is required, and

(2) The operator shall stand behind the protective barrier of 9 feet from the useful beam and the animal during radiographic exposures, or

(3) When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and shall be so positioned that no part of the holder's body will be struck by the useful beam. The exposure of any individual used for this purpose shall be monitored.

41.1(11) *Computed tomography X-ray systems.*

a. Definitions. In addition to the definitions provided in 641—38.2(136C), 641—40.2(136C), and 41.1(2), the following definitions shall be applicable to 41.1(11):

"Computed tomography dose index" means the integral from –7T to +7T of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan, that is:

$$\overline{\text{CTDI}} = \frac{1}{nT} \int_{-7T}^{+7T} D(z)\, dz$$

where:

z = Position along a line perpendicular to the tomographic plane.

D(z)= Dose at position z.

T = Nominal tomographic section thickness.

n = Number of tomograms produced in a single scan.

This definition assumes that the dose profile is centered around z = 0 and that, for a multiple tomogram system, the scan increment between adjacent scans is nT.

"Contrast scale" means the change in the linear attenuation coefficient per CTN relative to water, that is:

$$\overline{CS} = \frac{\mu_x - \mu_w}{\overline{CTN_x} - \overline{CTN_w}}$$

where:

μ_x = Linear attenuation coefficient of the material of interest.

μ_w = Linear attenuation coefficient of water.

$\overline{CTN_x}$ = of the material of interest.

$\overline{CTN_w}$ = of water.

"CS" (see "Contrast scale").

"CT conditions of operation" means all selectable parameters governing the operation of a CT X-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in 41.1(2).

"CTDI" (see "Computed tomography dose index").

"CT gantry" means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames which hold these components.

"CTN" (see "CT number").

"CT number" means the number used to represent the X-ray attenuation associated with each elemental area of the CT image.

$$\overline{CTN} = \frac{k(\mu_x - \mu_w)}{\mu_w}$$

where:

k = A constant. (The constant has a normal value of 1,000 when the Houndsfield scale of CTN is used.)

μ_x = Linear attenuation coefficient of the material of interest.

μ_w = Linear attenuation coefficient of water.

"Dose profile" means the dose as a function of position along a line.

"Elemental area" means the smallest area within a tomogram for which the X-ray attenuation properties of a body are depicted (see also "Picture element").

"Multiple tomogram system" means a computed tomography X-ray system which obtains X-ray transmission data simultaneously during a single scan to produce more than one tomogram.

"Noise" means the standard deviation of the fluctuation in CTN expressed as a percentage of the attenuation coefficient of water. Its estimate (S_s) is calculated using the following expression:

$$S_n = \frac{100 \cdot \overline{CS} \cdot s}{\mu_w}$$

where:

$\overline{CS}$ = Linear attenuation coefficient of the material of interest.

μ_w = Linear attenuation coefficient of water.

s = Estimated standard deviation of the CTN of picture elements in a specified area of the CT image.

"Nominal tomographic section thickness" means the full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which X-ray transmission data are collected.

"Picture element" means an elemental area of a tomogram.

"Reference plane" means a plane which is displaced from and parallel to the tomographic plane.

"Scan" means the complete process of collecting X-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

"Scan increment" means the amount of relative displacement of the patient with respect to the CT X-ray system between successive scans measured along the direction of such displacement.

"Scan sequence" means a preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

"Scan time" means the period of time between the beginning and end of X-ray transmission data accumulation for a single scan.

"Single tomogram system" means a CT X-ray system which obtains X-ray transmission data during a scan to produce a single tomogram.

"Tomographic plane" means that geometric plane which is identified as corresponding to the output tomogram.

"Tomographic section" means the volume of an object whose X-ray attenuation properties are imaged in a tomogram.

b. Requirements for equipment.

(1) Termination of exposure.

1. Means shall be provided to terminate the X-ray exposure automatically by either deenergizing the X-ray source or shuttering the X-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a backup timer or devices which monitor equipment function.

2. A visible signal shall indicate when the X-ray exposure has been terminated through the means required by 41.1(11)*"b"*(1)"1."

3. The operator shall be able to terminate the X-ray exposure at any time during a scan, or series of scans under CT X-ray system control, of greater than one-half second duration.

(2) Tomographic plane indication and alignment.

1. For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

2. For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes.

3. If a device using a light source is used to satisfy 41.1(11)*"b"*(2)"1" or "2," the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

(3) Beam-on and shutter status indicators and control switches.

1. The CT X-ray control and gantry shall provide visual indication whenever X-rays are produced and, if applicable, whether the shutter is open or closed.

2. Each emergency button or switch shall be clearly labeled as to its function.

(4) Indication of CT conditions of operation. The CT X-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

(5) Extraneous radiation. When data are not being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by 41.1(4)*"c."*

(6) Maximum surface CTDI identification. The angular position where the maximum surface CTDI occurs shall be identified to allow for reproducible positioning of a CT dosimetry phantom.

(7) Additional requirements applicable to CT X-ray systems containing a gantry manufactured after September 3, 1985.

1. The total error in the indicated location of the tomographic plane or reference plane shall not exceed 5 millimeters.

2. If the X-ray production period is less than one-half second, the indication of X-ray production shall be actuated for at least one-half second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

3. The deviation of indicated scan increment versus actual increment shall not exceed plus or minus 1 millimeter with any mass from 0 to 100 kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

4. Premature termination of the X-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

c. Facility design requirements.

(1) Aural communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel.

(2) Viewing systems.

1. Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

2. When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

d. Surveys, calibrations, spot checks, and operating procedures.

(1) Surveys.

1. All CT X-ray systems shall have a survey made by, or under the direction of, a qualified expert. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

2. The registrant shall obtain a written report of the survey from the qualified expert, and a copy of the report shall be made available to the agency upon request.

(2) Radiation calibrations.

1. The calibration of the radiation output of the CT X-ray system shall be performed by, or under the direction of, a qualified expert who is physically present at the facility during such calibration.

2. The calibration of a CT X-ray system shall be performed at intervals specified by a qualified expert and after any change or replacement of components which, in the opinion of the qualified expert, could cause a change in the radiation output.

3. The calibration of the radiation output of a CT X-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding two years.

4. CT dosimetry phantom(s) shall be used in determining the radiation output of a CT X-ray system. Such phantom(s) shall meet the following specifications and conditions of use: CT dosimetry phantom(s) shall be right circular cylinders of polymethyl methacrylate of density 1.19 plus or minus 0.01 grams per cubic centimeter. The phantom(s) shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing CT X-ray systems designed to image any section of the body and 16.0 centimeters for systems designed to image the head or for whole body scanners operated in the head scanning mode; CT dosimetry phantom(s) shall provide means for the placement of a dosimeter(s) along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided; any effects on the doses measured due to the removal of phantom material

to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom; and all dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

5. The calibration shall be required for each type of head, body, or whole-body scan performed at the facility.

6. Calibration shall meet the following requirements: The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be measurable. Where less than three nominal tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness; the CTDI[3] along the two axes specified in 41.1(11)*"d"*(2)"4" shall be measured. (For the purpose of determining the CTDI, the manufacturer's statement as to the nominal tomographic section thickness for that particular system may be utilized.) The CT dosimetry phantom shall be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation shall correspond to typical values used by the registrant; and the spot checks specified in 41.1(11)*"d"*(3) shall be made.

7. Calibration procedures shall be in writing. Records of calibrations performed shall be maintained for inspection by the agency.

(3) Spot checks.

1. The spot-check procedures shall be in writing and shall have been developed by a qualified expert.

2. The spot-check procedures shall incorporate the use of a CT dosimetry phantom which has a capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean CTN for water or other reference material.

3. All spot checks shall be included in the calibration required by 41.1(11)*"d"*(2) and at time intervals and under system conditions specified by a qualified expert.

4. Spot checks shall include acquisition of images obtained with the CT dosimetry phantom(s) using the same processing mode and CT conditions of operation as are used to perform calibrations required by 41.1(11)*"d"*(2). The images shall be retained, until a new calibration is performed, in two forms as follows: photographic copies of the images obtained from the image display device; and images stored in digital form on a storage medium compatible with the CT X-ray system.

5. Written records of the spot checks performed shall be maintained for inspection by the agency.

(4) Operating procedures.

1. The CT X-ray system shall not be operated except by a licensed practitioner or an individual who has been specifically trained in its operation in accordance with 641—subrule 42.2(9).

2. Information shall be available at the control panel regarding the operation and calibration of the system. Such information shall include the following: dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained; instructions on the use of the CT dosimetry phantom(s) including a schedule of spot checks appropriate for the system, allowable variations for the indicated parameters, and the results of at least the most recent spot checks conducted on the system; the distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized; and a current technique chart available at the control panel which specifies for each routine examination the CT conditions of operation and the number of scans per examination.

3. If the calibration or spot check of the CT X-ray system identifies that a system operating parameter has exceeded a tolerance established by the qualified expert, use of the CT X-ray system on patients shall be limited to those uses permitted by established written instructions of the qualified expert.

41.1(12) *X-ray machines used for mammography.* Rescinded IAB 4/8/98, effective 7/1/98.

[**ARC 8659B**, IAB 4/7/10, effective 5/12/10]

641—41.2(136C) Use of radionuclides in the healing arts.

41.2(1) *Purpose and scope.*

a. This rule establishes requirements and provisions for the use of radionuclides in the healing arts and for issuance of licenses authorizing the medical use of this material. These requirements and provisions provide for the protection of the public health and safety. The requirements and provisions of this rule are in addition to, and not in substitution for, the applicable portions of 641—Chapters 38 to 40. The requirements and provisions of these rules apply to applicants and licensees subject to this rule unless specifically exempted.

b. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of September 2, 2009.

41.2(2) *Definitions.* For the purpose of this chapter, the definitions of 641—Chapters 38 to 40 may also apply. As used in 41.2(136C), the following definitions apply:

"Area of use" means a portion of a physical structure that has been set aside for the purpose of receiving, using, or storing radioactive material.

"Authorized medical physicist" means an individual who:

a. Meets the requirements of 41.2(74) and 41.2(77); or

b. Is identified as an authorized medical physicist or teletherapy physicist on:

1. A specific medical use license issued by this agency, the NRC, or an agreement state;
2. A medical use permit issued by an NRC master material licensee;
3. A permit issued by an NRC or agreement state broad scope medical use licensee; or
4. A permit issued by an NRC master material license broad scope medical use permittee.

"Authorized nuclear pharmacist" means a pharmacist who:

a. Has met the appropriate requirements of 41.2(77) and 41.2(78), or before May 3, 2006, meets the requirements in 10 CFR 35.980(a) and 10 CFR 35.59; or:

b. Is identified as an authorized nuclear pharmacist on:

1. A specific license issued by the agency, NRC or agreement state that authorizes medical use or the practice of nuclear pharmacy;
2. A permit issued by an NRC master material licensee that authorizes medical use or the practice of nuclear pharmacy;
3. A permit issued by the NRC or agreement state broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or
4. A permit issued by an NRC master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

c. Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

d. Is designated as an authorized nuclear pharmacist in accordance with 641—39.4(29)*"j"*(2)"3."

"Authorized user" means a physician, dentist, or podiatrist who has met the appropriate requirements of 41.2(67)*"a,"* 41.2(68)*"a,"* 41.2(69)*"a,"* 41.2(70)*"a,"* 41.2(72)*"a,"* 41.2(73)*"a,"* 41.2(81)*"a,"* or 41.2(82)*"a,"* or before May 3, 2006, meets the requirements in 10 CFR 35.910(a), 35.920(a), 35.930(c), 35.940(a), 35.950(a), or 35.960(a) and 10 CFR 35.59; or who is identified on:

1. A current Iowa, NRC, or agreement state license that authorizes the medical use of radioactive material;
2. A permit issued by an NRC master material licensee that is authorized to permit the medical use of radioactive material;
3. A permit issued by an NRC, agreement state, or Iowa-specific licensee of broad scope that is authorized to permit medical use of radioactive material; or
4. A permit issued by an NRC master material license broad scope permittee that is authorized to permit medical use of radioactive material.

"Dedicated check source" means a radioactive source that is used to ensure the constant operation of a radiation detection or measurement device over several months or years. This source may also be used for other purposes.

"Management" means the chief executive officer or that individual's designee.

"Medical institution" means an organization in which several medical disciplines are practiced.

"Mobile nuclear medicine service" means the transportation and medical use of radioactive material.

"Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

"Pharmacist" means an individual licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

"Radiation safety officer" means an individual who, in addition to the definition in 641—38.2(136C), meets the requirements of 41.2(77) and 41.2(65)*"a,"* or 41.2(65)*"c"*(1), or before May 3, 2006, meets the requirements in 10 CFR 35.900(a) and 10 CFR 35.59; or is identified as a radiation safety officer on a specific medical use license issued by Iowa, the NRC, or agreement state or a medical use permit issued by an NRC master material licensee.

"Teletherapy physicist" means an individual identified as the qualified teletherapy physicist on an agency license.

"Unit dosage" means a dosage prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

"Visiting authorized user" means an authorized user who is not identified on the license of the licensee being visited.

41.2(3) *License required.*

a. No person shall manufacture, produce, acquire, receive, possess, use, or transfer radioactive material for medical use except in accordance with a specific license issued pursuant to these rules.

b. Unless prohibited by license condition, an individual may receive, possess, use, or transfer radioactive material in accordance with these rules under the supervision of an authorized user as provided in 41.2(11).

c. An individual may prepare unsealed radioactive material for medical use in accordance with these rules under the supervision of an authorized nuclear pharmacist or authorized user as provided in 41.2(11) unless prohibited by license condition.

d. A licensee may conduct research involving human subjects using radioactive material provided that the research is conducted, funded, supported, or regulated by another federal agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its license before conducting such research. Both types of licensees shall, at a minimum, obtain informed consent from the human subjects and obtain prior review and approval of the research activities by an Institutional Review Board in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects.

Nothing in this subrule relieves the licensee from complying with applicable FDA, federal, and other state requirements governing radioactive drugs or devices.

e. An applicant that satisfies the requirements of 641—paragraph 39.4(28)*"b"* may apply for a Type A specific license of broad scope.

41.2(4) *License amendments.* A licensee shall apply for and receive a license amendment:

a. Before using radioactive material for a method or type of medical use not permitted by the license issued under this rule;

b. Before permitting anyone, except a visiting authorized user described in 41.2(12), to work as an authorized user or authorized nuclear pharmacist under the license;

c. Before changing a radiation safety officer or teletherapy physicist;

d. Before receiving radioactive material in excess of the amount authorized on the license;

e. Before adding to or changing the address or addresses of use identified in the application or on the license; and

f. Before changing statements, representations, and procedures which are incorporated into the license.

41.2(5) *Notifications.*

a. A licensee shall provide to the agency a copy of the board certification, the NRC or agreement state license, or the permit issued by a licensee of broad scope for each individual no later than 30 days after the date that the licensee permits the individual to work as a visiting authorized user or a visiting authorized nuclear pharmacist.

b. A licensee shall notify the agency by letter no later than 30 days after:

(1) An authorized user, an authorized nuclear pharmacist, radiation safety officer, or teletherapy physicist permanently discontinues performance of duties under the license or has a name change; or

(2) The licensee's mailing address changes.

c. The licensee shall mail the documents required in this subrule to the Iowa Department of Public Health, Des Moines, Iowa.

d. Exemptions regarding Type A specific licenses of broad scope. A licensee possessing a Type A specific license of broad scope for medical use is exempt from the following:

(1) The provision of 41.2(4)*"b"*;

(2) The provisions of 41.2(4)*"e"* regarding additions to or changes in the areas of use only at the addresses specified in the license;

(3) The provision of 41.2(5)*"a"*;

(4) The provisions of 41.2(5)*"b"*(1) for authorized user or an authorized nuclear pharmacist.

41.2(6) *Maintenance of records.*

a. Each record required by this rule must be legible throughout the retention period specified by each subrule. The record may be original or reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period.

b. The record may also be stored on electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications must include all pertinent information such as stamps, initials, and signatures.

c. The licensee shall maintain adequate safeguards against tampering with and loss of records specified in 41.2(6)*"a"* and *"b."*

41.2(7) *ALARA program.*

a. Each licensee shall develop and implement a written program to maintain radiation doses and releases of radioactive material in effluents to unrestricted areas as low as reasonably achievable in accordance with 641—subrule 40.1(3).

b. To satisfy the requirement of 41.2(7)*"a"*:

(1) The management, radiation safety officer, and all authorized users shall participate in the establishment, implementation, and operation of the program as required by these rules or the radiation safety committee; or

(2) For licensees that are not medical institutions, management and all authorized users shall participate in the program as required by the radiation safety officer.

c. The ALARA program shall include an annual review by the radiation safety committee for licensees that are medical institutions, or management and the radiation safety officer for licensees that are not medical institutions, of summaries of the types and amounts of radioactive material used, occupational dose reports, and continuing education and training for all personnel who work with or in the vicinity of radioactive material. The purpose of the review is to ensure that individuals make every reasonable effort to maintain occupational doses, doses to the general public, and releases of radioactive material as low as reasonably achievable, taking into account the state of technology, and the cost of improvements in relation to benefits.

d. The licensee shall retain a current written description of the ALARA program for the duration of the license. The written description shall include:

(1) A commitment by management to keep occupational doses as low as reasonably achievable;

(2) A requirement that the radiation safety officer brief management once each year on the radiation safety program;

(3) Personnel exposure investigational levels as established in accordance with 41.2(9)*"b"*(8) that, when exceeded, will initiate an investigation by the radiation safety officer of the cause of the exposure; and

(4) Personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the radiation safety officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence.

41.2(8) *Radiation safety officer.*

a. A licensee shall appoint a radiation safety officer responsible for implementing the radiation safety program. The licensee, through the radiation safety officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's radioactive material program.

b. The radiation safety officer shall:

(1) Investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, and disposals, and other deviations from approved radiation safety practice and implement corrective actions as necessary;

(2) Implement written policy and procedures for:

1. Authorizing the purchase of radioactive material;
2. Receiving and opening packages of radioactive material;
3. Storing radioactive material;
4. Keeping an inventory record of radioactive material;
5. Using radioactive material safely;
6. Taking emergency action if control of radioactive material is lost;
7. Performing periodic radiation surveys;
8. Performing checks and calibrations of survey instruments and other safety equipment;
9. Disposing of radioactive material;
10. Training personnel who work in or frequent areas where radioactive material is used or stored; and
11. Keeping a copy of all records and reports required by the agency rules, a copy of these rules, a copy of each licensing request and license and amendments, and the written policy and procedures required by the rules; and

(3) For medical use not sited at a medical institution, approve or disapprove radiation safety program changes with the advice and consent of management prior to submittal to the agency for licensing action; or

(4) For medical use sited at a medical institution, assist the radiation safety committee in the performance of its duties.

41.2(9) *Radiation safety committee.* Each medical institution licensee shall establish a radiation safety committee to oversee the use of radioactive material.

a. The committee shall meet the following administrative requirements:

(1) Membership must consist of at least three individuals and shall include an authorized user of each type of use permitted by the license, the radiation safety officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a radiation safety officer. Other members may be included as the licensee deems appropriate.

(2) The committee shall meet at least once each calendar quarter.

(3) To establish a quorum and to conduct business, one-half of the committee's membership shall be present, including the radiation safety officer and the management's representative.

(4) The minutes of each radiation safety committee meeting shall include:

1. The date of the meeting;
2. Members present;
3. Members absent;
4. Summary of deliberations and discussions;
5. Recommended actions and the numerical results of all ballots; and
6. Document any reviews required in 41.2(7)*"c"* and 41.2(9)*"b."*

(5) The committee shall provide each member with a copy of the meeting minutes and retain one copy until the agency authorizes its disposition.

b. To oversee the use of licensed material, the committee shall:

(1) Be responsible for monitoring the institutional program to maintain occupational doses as low as reasonably achievable;

(2) Review:

1. Review, on the basis of safety and with regard to the training and experience standards of this rule, and approve or disapprove any individual who is to be listed as an authorized user, an authorized nuclear pharmacist, the radiation safety officer, or teletherapy physicist before submitting a license application or request for amendment or renewal;

2. Review on the basis of the board certification, the license, or the permit identifying an individual, and approve or disapprove any individual prior to allowing that individual to work as an authorized user or authorized nuclear pharmacist.

(3) Review on the basis of safety and approve or disapprove each proposed method of use of radioactive material;

(4) Review on the basis of safety, and approve with the advice and consent of the radiation safety officer and the management representative, or disapprove procedures and radiation safety program changes prior to submittal to the agency for licensing action;

(5) Review quarterly, with the assistance of the radiation safety officer, occupational radiation exposure records of all personnel working with radioactive material;

(6) Review quarterly, with the assistance of the radiation safety officer, all incidents involving radioactive material with respect to cause and subsequent actions taken;

(7) Review annually, with the assistance of the radiation safety officer, the radioactive material program; and

(8) Establish a table of investigational levels for occupational dose that, when exceeded, will initiate investigations and considerations of action by the radiation safety officer.

41.2(10) *Authority and responsibilities for the radiation protection program.*

a. In addition to the radiation protection program requirements of 641—40.10(136C), a licensee's management shall approve in writing:

(1) Requests for a license application, renewal, or amendment before submittal to this agency;

(2) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist; and

(3) Radiation protection program changes that do not require a license amendment.

b. A licensee's management shall appoint a radiation safety officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the radiation safety officer, shall ensure that the radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

c. For up to 60 days each year, a licensee may permit an authorized user or an individual qualified to be a radiation safety officer under 41.2(65) or 41.2(75) to function as a temporary radiation safety officer to perform the functions of radiation safety officer, as provided in 41.2(10)*"g,"* if the licensee takes the actions required in 41.2(10)*"b," "e," "g,"* and *"h"* and notifies this agency in accordance with 41.2(5).

d. A licensee may simultaneously appoint more than one temporary radiation safety officer in accordance with 41.2(10)*"c"* if needed to ensure that the licensee has a temporary radiation safety officer who satisfies the requirements to be a radiation safety officer for each of the different types of by-product material permitted on the license.

e. A licensee shall establish the authority, duties, and responsibilities of the radiation safety officer in writing.

f. Licensees that are authorized for two or more different types of uses of radioactive materials or two or more types of units under this rule shall establish a radiation safety committee to oversee all uses of radioactive material permitted by the license.

g. A licensee shall provide the radiation safety officer sufficient authority, organizational freedom, time, resources, and management prerogative to:

(1) Identify radiation safety problems;

(2) Initiate, recommend, or provide corrective solutions;

(3) Verify implementation of corrective actions; and

(4) Stop unsafe operations.

h. A licensee shall retain a record of actions taken under 41.2(10) in accordance with 641—40.80(136C).

41.2(11) *Supervision.*

a. A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by 41.2(3) shall, in addition to the requirements in 641—40.111(136C):

(1) Instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, rules of this chapter, and license conditions appropriate to that individual's use of radioactive material;

(2) Review the supervised individual's use of radioactive material, provide reinstruction as needed and review records kept to reflect this use;

(3) Require the authorized user to be immediately available to communicate with the supervised individual;

(4) Require the authorized user to be able to be physically present and available to the supervised individual on one hour's notice (the supervising authorized user need not be present for each use of radioactive material); and

(5) Require that only those individuals certified and issued a current permit to practice in accordance with 641—Chapter 42 as a nuclear medicine technologist or a radiation therapist, as applicable, or an Iowa-licensed physician and designated by the authorized user, shall be permitted to administer radionuclides (sealed sources only for radiation therapists) or radiation to patients or human research subjects. For a nuclear medicine technologist or a radiation therapist, the individual's permit to practice shall be posted in the immediate vicinity of the general work area and be visible to the public.

b. A license shall require the supervised individual receiving, possessing, using or transferring radioactive material under 41.2(3) to:

(1) Follow the instructions of the supervising authorized user for the medical uses of by-product material;

(2) Follow the written radiation protection and written directive procedures established by the radiation safety officer; and

(3) Comply with these rules and the license conditions with respect to the use of radioactive material.

c. A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by 41.2(3)*"c,"* shall, in addition to the requirements in 641—40.111(136C):

(1) Instruct the supervised individual in the preparation of radioactive material for medical use and the principles of and procedures for radiation safety and in the licensee's written procedures for maintaining written directives, as appropriate to that individual's use of radioactive material;

(2) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, written radiation protection procedures established by the licensee, the regulations of this chapter and license conditions; and

(3) Require the supervising authorized nuclear pharmacist or physician who is an authorized user to periodically review the work of the supervised individual as it pertains to preparing radioactive material for medical use and the records kept to reflect that work.

d. A licensee that supervises an individual is responsible for the acts and omissions of the supervised individual.

41.2(12) *Visiting authorized user and visiting authorized nuclear pharmacist.*

a. A licensee may permit any visiting authorized user or visiting authorized nuclear pharmacist to use licensed material for medical use under the terms of the licensee's license for 60 days each year if:

(1) The visiting authorized user or visiting authorized nuclear pharmacist has the prior written permission of the licensee's management and, if the use occurs on behalf of an institution, the institution's radiation safety committee;

(2) The licensee has a copy of an agency, agreement state, licensing state or U.S. Nuclear Regulatory Commission license that identifies the visiting authorized user or visiting authorized nuclear pharmacist by name as an authorized user for medical use; and

(3) Only those procedures for which the visiting authorized user or visiting authorized nuclear pharmacist is specifically authorized by an agency (agreement state, licensing state or U.S. Nuclear Regulatory Commission) license are performed by that individual.

b. A licensee need not apply for a license amendment in order to permit a visiting authorized user or visiting authorized nuclear pharmacist to use licensed material as described in 41.2(12)*"a."*

c. A licensee shall retain copies of the records specified in 41.2(12)*"a"* for five years from the date of the last visit.

41.2(13) *Mobile nuclear medicine service administrative requirements.*

a. The agency will only license mobile nuclear medicine services in accordance with this rule and other applicable requirements of these rules.

b. Mobile nuclear medicine service licensees shall retain for the duration of service a letter signed by the management of each location where services are rendered that authorizes use of radioactive material and clearly delineates the authority of the licensee and client.

c. If a mobile nuclear medicine service provides services that the client is also authorized to provide, the client is responsible for ensuring that services are conducted in accordance with the rules in this chapter while the mobile nuclear medicine service is under the client's direction.

d. A mobile nuclear medicine service shall not have radioactive material delivered directly from the manufacturer or the distributor to the client's address of use.

e. Mobile nuclear medicine service licensees shall also perform the following:

(1) Check instruments used to measure the activity of unsealed radioactive material for proper function before use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by this rule must include a constancy check;

(2) Check survey instruments for proper operation with a dedicated check source before use at each client's address;

(3) Before leaving a client's address, survey all areas of use to ensure compliance with the requirements of 641—Chapters 40 and 41.

41.2(14) *Records and reports of misadministrations and reportable medical events.*

a. When a misadministration or reportable medical event, as defined in 641—38.2(136C), occurs, the licensee shall notify the agency by telephone. The licensee shall also notify the referring physician of the affected patient or human research subject and the patient or human research subject or a responsible relative or guardian, unless the referring physician agrees to inform the patient or human research subject or believes, based on medical judgment, that telling the patient or human research subject or the patient's or human research subject's responsible relative or guardian would be harmful to one or the other, respectively. These notifications must be made within 24 hours after the licensee discovers the misadministration or reportable medical event. If the referring physician, patient or human research subject, or the patient's or human research subject's responsible relative or guardian cannot be reached within 24 hours, the licensee shall notify them as soon as practicable. The licensee is not required to notify the patient or human research subject or the patient's or human research subject's responsible relative or guardian without first consulting the referring physician; however, the licensee shall not delay medical care for the patient or human research subject because of this notification requirement including remedial care as a result of the misadministration or reportable medical event because of any delay in notification.

b. Written reports.

(1) The licensee shall submit a written report to the agency within 15 days after discovery of the misadministration or reportable medical event. The written report must include the licensee's name, the prescribing physician's name, a brief description of the event, why the event occurred, the effect on the patient or the human research subject, what improvements are needed to prevent recurrence, actions taken to prevent recurrence, whether the licensee notified the patient or the human research subject or the patient's or the human research subject's responsible relative or guardian (this individual will subsequently be referred to as "the patient or the human research subject"), and if not, why not, and if the patient or the human research subject was notified, what information was provided to that individual. The report must not include the patient's or the human research subject's name or other information that could lead to identification of the patient or the human research subject.

(2) If the patient or the human research subject was notified, the licensee shall also furnish, within 15 days after discovery of the misadministration or reportable medical event, a written report to the patient or the human research subject and the referring physician by sending either:

1. A copy of the report that was submitted to the agency; or

2. A brief description of both the event and the consequences as they may affect the patient or the human research subject, provided a statement is included that the report submitted to the agency can be obtained from the licensee.

c. Rescinded IAB 4/4/01, effective 5/9/01.

d. Each licensee shall retain a record of each misadministration for ten years and each reportable medical event for three years. The record shall contain the names of all individuals involved in the event, including the physician, allied health personnel, the patient or human research subject, and the patient's or human research subject's referring physician, the patient's or human research subject's social security number or identification number if one has been assigned, a brief description of the event, why it occurred, the effect on the patient or human research subject, what improvements are needed to prevent recurrence, and the action taken, if any, to prevent recurrence.

e. Aside from the notification requirement, nothing in 41.2(14)*"a"* to 41.2(14)*"d"* shall affect any rights or duties of licensees and physicians in relation to each other, patients or human research subjects, or responsible relatives or guardians.

f. Report and notification of a dose to an embryo/fetus or a nursing child.

(1) A licensee shall report any dose to an embryo/fetus that is greater than 5 rem (50 mSv) dose equivalent that is a result of an administration of by-product material or radiation from by-product material to a pregnant individual unless the embryo/fetus was specifically approved, in advance, by the authorized user.

(2) A licensee shall report any dose to a nursing child that is a result of an administration of by-product material to a breast-feeding individual that:

1. Is greater than 5 rem (50 mSv) total effective dose equivalent; or

2. Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

(3) The licensee shall notify this agency by telephone no later than the next calendar day after a dose to the embryo/fetus or nursing child that requires a report in 41.2(14)*"f"*(1) or (2).

(4) The licensee shall submit a written report to the agency within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in 41.2(14)*"f"*(1) or (2).

1. The written report must include:

- The licensee's name;
- The name of the prescribing physician;
- A brief description of the event;
- Why the event occurred;
- The effect, if any, on the embryo/fetus or the nursing child;
- What actions, if any, have been taken or are planned to prevent recurrence; and
- Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

2. The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

(5) The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under 41.2(14)*"f"*(1) or (2), unless the referring physician personally informs the licensee either that the physician will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(6) A licensee shall:

1. Annotate a copy of the report provided to the agency with the:

- Name of the pregnant individual or the nursing child who is the subject of the event; and
- Social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the event; and

2. Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

41.2(15) *Suppliers.* A licensee shall use for medical use only:

a. Radioactive material manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to these rules or the equivalent regulations of another agreement state, a licensing state or the U.S. Nuclear Regulatory Commission; and

b. Reagent kits that have been manufactured, labeled, packaged, and distributed in accordance with an approval issued by the U.S. Food and Drug Administration;

c. Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to these rules, or the equivalent regulations of another agreement state, a licensing state, or the U.S. Nuclear Regulatory Commission.

41.2(16) *Quality control of imaging equipment.* Each licensee shall establish written quality control procedures for all equipment used to obtain images from radionuclide studies. As a minimum, the procedures shall include quality control procedures recommended by equipment manufacturers or procedures which have been approved by the agency. The licensee shall conduct quality control procedures in accordance with written procedures.

41.2(17) *Possession, use, calibration, and check of dose calibrators.*

a. A medical use licensee authorized to administer radiopharmaceuticals shall possess a dose calibrator and use it to measure the amount of activity administered to each patient or human research subject.

b. A licensee shall:

(1) Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy the requirement of this section, the check shall be done on frequently used settings with a sealed source of not less than 10 microcuries (370 kBq) of radium-226 or 50 microcuries (1.85 MBq) of any other photon-emitting radionuclide with a half-life greater than 90 days;

(2) Test each dose calibrator for accuracy upon installation and at intervals not to exceed 12 months thereafter by assaying at least two sealed sources containing different radionuclides, the activity of which the manufacturer has determined within 5 percent of the stated activity, with minimum activity of 10 microcuries (370 kBq) for radium-226 and 50 microcuries (1.85 MBq) for any other photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 keV and 500 keV;

(3) Test each dose calibrator for linearity upon installation and at intervals not to exceed three months thereafter over the range of use between 30 microcuries (1.1 megabequerels) and the highest dosage that will be administered; and

(4) Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.

c. A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries (370 kBq) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

d. A licensee shall also perform checks and tests required by 41.2(17)*"b"* following adjustment or repair of the dose calibrator.

e. A licensee shall retain a record of each check and test required by 41.2(17) for three years. The records required by 41.2(17)*"b"* shall include:

(1) For 41.2(17)*"b"*(1), the model and serial number of the dose calibrator, the identity and calibrated activity of the radionuclide contained in the check source, the date of the check, the activity measured, the instrument settings, and the initials of the individual who performed the check;

(2) For 41.2(17)*"b"*(2), the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, the instrument settings, the identity of the individual performing the test, and the signature of the radiation safety officer;

(3) For 41.2(17)*"b"*(3), the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, the identity of the individual performing the test, and the signature of the radiation safety officer; and

(4) For 41.2(17)*"b"*(4), the model and serial number of the dose calibrator, the configuration calibrated activity of the source measured, the activity of the source, the activity measured and the instrument setting for each volume measured, the date of the test, the identity of the individual performing the test, and the signature of the radiation safety officer.

41.2(18) *Calibration and check of survey instruments.*

a. A licensee shall ensure that the survey instruments used to show compliance with this rule have been calibrated before first use, annually, and following repair.

b. To satisfy the requirements of 41.2(18)*"a,"* the licensee shall:

(1) Calibrate all required scale readings up to 1000 millirems (10 mSv) per hour with a radiation source;

(2) For each scale that shall be calibrated, calibrate two readings separated by at least 50 percent of scale rating; and

(3) Conspicuously note on the instrument the apparent dose rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

c. To satisfy the requirements of 41.2(18)*"b,"* the licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent and shall conspicuously attach a correction chart or graph to the instrument. A licensee may not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20 percent.

d. A licensee shall check each survey instrument for proper operation with the dedicated check source before each use. The licensee is not required to keep records of these checks.

e. The licensee shall retain a record of each calibration required in 41.2(18)*"a"* for three years. The record shall include:

(1) A description of the calibration procedure; and

(2) A description of the source used and the certified dose rates from the source, the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

f. To meet the requirements of 41.2(18)*"a," "b,"* and *"c,"* the licensee may obtain the services of individuals licensed by the agency, the U.S. Nuclear Regulatory Commission, an agreement state, or

a licensing state to perform calibrations of survey instruments. Records of calibrations which contain information required by 41.2(18)*"e"* shall be maintained by the licensee.

g. Rescinded IAB 8/1/07, effective 9/5/07.

41.2(19) *Assay of radiopharmaceutical dosages.* A licensee shall:

a. Assay, prior to medical use, the activity of each radiopharmaceutical dosage that contains more than 30 microcuries (1.1 megabecquerels) of a photon-emitting radionuclide;

b. Assay, before medical use, the activity of each radiopharmaceutical dosage of a photon-emitting radionuclide to verify that the dosage does not exceed 30 microcuries (1.1 MBq);

c. Measure, by direct measurement or by combination of measurements and calculations, the activity of each dosage of an alpha- or beta-emitting radionuclide prior to medical use, except for unit dosages obtained from a manufacturer or preparer licensed pursuant to 641—paragraph 39.4(29)*"j"* or equivalent NRC or agreement state requirements;

d. Not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent unless otherwise directed by the authorized user; and

e. Retain a record of the assays required by 41.2(19)*"a"* for three years. To satisfy this requirement, the record shall contain the:

(1) Generic name, trade name, or abbreviation of the radiopharmaceutical, its lot number, and expiration dates and the radionuclide;

(2) Patient's or human research subject's name and identification number if one has been assigned;

(3) Prescribed dosage and activity of the dosage at the time of assay, or a notation that the total activity is less than 30 microcuries (1.1 megabecquerels);

(4) Date and time of the assay and administration; and

(5) Initials of the individual who performed the assay.

41.2(20) *Authorization for calibration and reference sources.* Any person authorized by 41.2(3) for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration and reference use:

a. Sealed sources manufactured and distributed by persons specifically licensed pursuant to 641—Chapter 39 or equivalent provisions of the U.S. Nuclear Regulatory Commission, agreement state or licensing state and that do not exceed 15 millicuries (555 MBq) each;

b. Any radioactive material listed in 41.2(31) or 41.2(33) with a half-life of 100 days or less in individual amounts not to exceed 15 millicuries (555 MBq);

c. Any radioactive material listed in 41.2(31) or 41.2(33) with a half-life greater than 100 days in individual amounts not to exceed 200 microcuries (7.4 MBq) each; and

d. Technetium-99m in individual amounts not to exceed 50 millicuries (1.85 GBq).

41.2(21) *Requirements for possession of sealed sources and brachytherapy sources.*

a. A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the agency and shall maintain the instructions for the duration of source use in a legible form convenient to users.

b. A licensee in possession of a sealed source shall ensure that:

(1) The source is tested for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee; and

(2) The source is tested for leakage at intervals not to exceed six months or at intervals approved by the agency, another agreement state, a licensing state or the U.S. Nuclear Regulatory Commission.

c. To satisfy the leak test requirements of 41.2(21)*"b,"* the licensee shall ensure that:

(1) Leak tests are capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample or, in the case of radium, the escape of radon at the rate of 0.001 microcurie (37 Bq) per 24 hours;

(2) Test samples are taken from the source or from the surfaces of the device in which the source is mounted or stored on which radioactive contamination might be expected to accumulate; and

(3) Test samples are taken when the source is in the "off" position.

d. A licensee shall retain leak test records for five years. The records shall contain the model number, and serial number, if assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in microcuries (becquerels), a description of the method used to measure each test sample, the date of the test, and the signature of the radiation safety officer.

e. If the leak test reveals the presence of 0.005 microcurie (185 Bq) or more of removable contamination, the licensee shall:

(1) Immediately withdraw the sealed source from use and store it in accordance with the requirements of these rules; and

(2) File a report with the agency within five days of receiving the leak test results. The report shall describe the equipment involved, the model and serial number of the leaking source, the radionuclide and its estimated activity, the test results, the date of the test, and the action taken.

f. A licensee need not perform a leak test on the following sources:

(1) Sources containing only radioactive material with a half-life of less than 30 days;

(2) Sources containing only radioactive material as a gas;

(3) Sources containing 100 microcuries (3.7 MBq) or less of beta or photon-emitting material or 10 microcuries (370 kBq) or less of alpha-emitting material; [and]

(4) Seeds of iridium-192 encased in nylon ribbon; and

(5) Sources stored and not being used. The licensee shall, however, test each such source for leakage before any use or transfer unless it has been tested for leakage within six months before the date of use or transfer.

g. A licensee in possession of a sealed source or brachytherapy source shall conduct a physical inventory of all such sources at intervals not to exceed three months. The licensee shall retain each inventory record for five years. The inventory records shall contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its estimated activity, the location of each source, date of the inventory, and the signature of the radiation safety officer.

h. A licensee in possession of a sealed source or brachytherapy source shall survey with a radiation survey instrument at intervals not to exceed three months all areas where such sources are stored. This does not apply to teletherapy sources in teletherapy units or sealed sources in diagnostic devices.

i. A licensee shall retain a record of each survey required in 41.2(21)*"h"* for three years. The record shall include the date of the survey, a sketch of each area that was surveyed, the measured dose rate at several points in each area expressed in millirems (microsieverts) per hour, the model number and serial number of the survey instrument used to make the survey, and the signature of the radiation safety officer.

41.2(22) *Syringe shields.*

a. A licensee shall keep syringes that contain radioactive material to be administered in a radiation shield.

b. Unless otherwise approved by this agency, a licensee shall require each individual who prepares or administers radiopharmaceuticals to use a syringe radiation shield unless the use of the shield is contraindicated for that patient or human research subject.

41.2(23) *Syringe labels.* Unless utilized immediately, a licensee shall conspicuously label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical, with the radiopharmaceutical name or its abbreviation, the type of diagnostic study or therapy procedure to be performed, or the patient's or human research subject's name.

41.2(24) *Vial shields.* A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield.

41.2(25) *Vial shield labels.* A licensee shall conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical with the radiopharmaceutical name or its abbreviation.

41.2(26) *Surveys for contamination and ambient radiation dose rate.*

a. A licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

b. A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radioactive wastes are stored.

c. A licensee shall conduct the surveys required by 41.2(26)*"a"* and *"b"* so as to be able to measure dose rates as low as 0.1 millirem (1 μSv) per hour.

d. A licensee shall establish dose rate action levels for the surveys required by 41.2(26)*"a"* and *"b"* and shall require that the individual performing the survey immediately notify the radiation safety officer if a dose rate exceeds an action level.

e. A licensee shall survey for removable contamination each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered and each week where radioactive materials are stored.

f. A licensee shall conduct the surveys required by 41.2(26)*"e"* so as to be able to detect contamination on each wipe sample of 2000 disintegrations per minute (33.3 Bq).

g. A licensee shall establish removable contamination action levels for the surveys required by 41.2(26)*"e"* and shall require that the individual performing the survey immediately notify the radiation safety officer if contamination exceeds action levels.

h. A licensee shall retain a record of each survey required by 41.2(26)*"a," "b,"* and *"e"* for two years. The record must include the date of the survey, a sketch of each area surveyed, action levels established for each area, the measured dose rate at several points in each area expressed in millirems (microsieverts) per hour or the removable contamination in each area expressed in disintegrations per minute (becquerels) per 100 square centimeters, the serial number and the model number of the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.

i. A licensee does not need to perform the surveys required in this subrule in an area where the patient or human research subject is confined and cannot be released under 41.2(27).

41.2(27) *Release of patients or human research subjects containing radiopharmaceuticals or permanent implants.*

a. The licensee may authorize the release from its control of any individual who has been administered unsealed radioactive materials or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 0.5 rem (5 mSv). (NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses," describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 0.5 rem (5 mSv).)

b. The licensee shall provide the released individual with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 0.1 rem (1 mSv). If the dose to a breast-feeding infant or child could exceed 0.1 rem (1 mSv) assuming there were no interruption of breast feeding, the instructions shall also include:

(1) Guidance on the interruption or discontinuation of breast feeding, and

(2) Information on the consequences of failure to follow the guidance.

c. The licensee shall maintain a record of the basis for authorizing the release of an individual, for three years after the date of release, if the total effective dose equivalent is calculated by:

(1) Using the retained activity rather than the activity administered,

(2) Using an occupancy factor less than 0.25 at 1 meter,

(3) Using the biological or effective half-life, or

(4) Considering the shielding by tissue.

d. The licensee shall maintain a record for three years after the date of release that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast feeding could result in a total effective dose equivalent exceeding 0.5 rem (5 mSv). IDPH Regulatory Guide, Release of Patients Administered Radioactive Materials describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 0.5 rem (5 mSv).

41.2(28) *Mobile nuclear medicine service technical requirements.* A licensee providing mobile nuclear medicine service shall:

a. Transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;

b. Bring into each location of use all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;

c. Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at a location of use;

d. Check survey instruments and dose calibrators as required in 41.2(17)*"b"*(1)*"d"* and *"e"* and 41.2(18)*"d"* and check all other transported equipment for proper function before medical use at each location of use;

e. Carry a calibrated survey meter in each vehicle that is being used to transport radioactive material and, before leaving a client location of use, survey all areas of radiopharmaceutical use with a radiation detection survey instrument to ensure that all radiopharmaceuticals and all associated radioactive waste have been removed; and

f. Retain a record of each survey required by 41.2(28)*"e"* for three years. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area of use expressed in millirems (microsieverts) per hour, the model and serial number of the instrument used to make the survey, and the initials of the individual who performed the survey.

41.2(29) *Storage of volatiles and gases.*

a. A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shippers' radiation shield and container.

b. A licensee shall store and use a multidose container in a properly functioning fume hood.

41.2(30) *Decay-in-storage.*

a. A licensee may hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:

(1) Holds radioactive material for decay a minimum of ten half-lives;

(2) Monitors radioactive material at the container surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;

(3) Removes or obliterates all radiation labels; and

(4) Separates and monitors each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background radiation level before disposal.

b. For radioactive material disposed in accordance with 41.2(30)*"a,"* the licensee shall retain a record of each disposal for three years. The record must include the date of the disposal, the date on which the radioactive material was placed in storage, the radionuclides disposed, the model and serial number of the survey instrument used, the background dose rate, the radiation dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

41.2(31) *Use of unsealed radioactive material for uptake, dilution, or excretion studies for which a written directive is not required.* Except for quantities that require a written directive under 41.2(87), a licensee may use for uptake, dilution, excretion and imaging studies any unsealed radioactive material prepared for medical use that is either:

a. Obtained from a manufacturer or preparer licensed pursuant to 641—paragraph 39.4(29)*"j"* or equivalent U.S. Nuclear Regulatory Commission or agreement state requirements; or

b. Prepared by:

(1) An authorized nuclear pharmacist,

(2) A physician who is an authorized user and who meets the requirements specified in 41.2(68) or 41.2(69) and has work experience in eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; or before May 3, 2006, who meets the requirements of 10 CFR 35.290; or

(3) An individual under the supervision, as specified in 41.2(11), of the authorized nuclear pharmacist in 41.2(31)*"b"*(1) or the physician who is an authorized user in 41.2(31)*"b"*(2); or

c. Obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

d. Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

41.2(32) *Possession of survey instrument.* A licensee authorized to use radioactive material for uptake, dilution, and excretion studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem (1.0 μSv) per hour to 50 millirems (500 μSv) per hour. The instrument shall be operable and calibrated in accordance with 41.2(18).

41.2(33) *Use of radiopharmaceuticals, generators, and reagent kits for imaging and localization studies.* Except for the quantities that require written directive under 41.2(87), a licensee may use for imaging and localization studies any unsealed by-product material prepared for medical use that is either:

a. Obtained from a manufacturer or preparer licensed pursuant to 641—paragraph 39.4(29)*"j"* or equivalent NRC or agreement state requirements;

b. Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in 41.2(68) or 41.2(69), or an individual under the supervision of either as specified in 41.2(11);

c. Obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

d. Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

41.2(34) *Permissible molybdenum-99 concentration.*

a. A licensee shall not administer a radiopharmaceutical containing more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m (0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m).

b. A licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators shall measure the molybdenum-99 concentration in each eluate or extract.

c. A licensee who must measure molybdenum concentration shall retain a record of each measurement for three years. The record shall include, for each elution or extraction of technetium-99m, the measured activity of the technetium expressed in millicuries (megabecquerels), the measured activity of molybdenum expressed in microcuries (kilobecquerels), the ratio of the measures expressed as microcuries of molybdenum per millicurie of technetium (kilobecquerels of molybdenum per megabecquerel of technetium), the date of the test, and the initials of the individual who performed the test.

d. A licensee shall report immediately to the agency each occurrence of molybdenum-99 concentration exceeding the limits specified in 41.2(34)*"a."*

41.2(35) *Control of aerosols and gases.*

a. A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed by 641—40.15(136C) and 641—40.26(136C) of these rules.

b. The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

c. A licensee shall only administer radioactive gases in rooms that are at negative pressure compared to surrounding rooms.

d. Before receiving, using, or storing a radioactive gas, the licensee shall calculate the amount of time needed after a release to reduce the concentration in the area of use to the occupational limit listed in Appendix B of 641—Chapter 40. The calculation shall be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.

e. A licensee shall post the time calculated in 41.2(35)*"a"* at the area of use and require that, in case of a gas spill, individuals evacuate the room until the posted time has elapsed.

f. A licensee shall check the operation of collection systems monthly and measure the ventilation rates in areas of use at intervals not to exceed six months. Records of these checks and measurements shall be maintained for three years.

g. A copy of the calculations required in 41.2(35)*"d"* shall be recorded and retained for the duration of the license.

41.2(36) *Possession of survey instruments.* A licensee authorized to use radioactive material for imaging and localization studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem (1 μSv) per hour to 50 millirems (500 μSv) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 1 millirem (10 μSv) per hour to 1000 millirems (10 mSv) per hour. The instruments shall be operable and calibrated in accordance with 41.2(18).

41.2(37) *Use of radiopharmaceuticals for therapeutic use or unsealed by-product material for which a written directive is required.* Material must be:

a. Obtained from a manufacturer or preparer licensed by the NRC or an agreement state to manufacture and prepare by-product material for medical use; or

b. Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements of 41.2(68) or 41.2(69), or an individual under the supervision of either as specified in 41.2(11); or

c. Obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with the Investigational New Drug (IND) protocol accepted by FDA; or

d. Prepared by the licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA.

41.2(38) *Safety instruction.*

a. A licensee shall provide oral and written radiation safety instruction for all personnel caring for patients or human research subjects undergoing radiopharmaceutical therapy and hospitalized for compliance with 41.2(27). Refresher training shall be provided at intervals not to exceed one year.

b. To satisfy 41.2(38)*"a,"* the instruction shall describe the licensee's procedures for:

(1) Patient or human research subject control;

(2) Visitor control;

(3) Contamination control;

(4) Waste control;

(5) Notification of the radiation safety officer, radiation safety officer designee, or authorized user in case of the patient's or human research subject's death or medical emergency; and

(6) Training requirements specified in 641—40.110(136C) and 40.116(136C) and adopted by reference and included herein.

c. A licensee shall keep a record of individuals receiving instruction required by 41.2(38)*"a,"* a description of the instruction, the date of instruction, and the name of the individual who gave the instruction. Such record shall be maintained for inspection by the agency for three years.

41.2(39) *Safety precautions.*

a. For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with 41.2(27), a licensee shall:

(1) Provide a private room with a private sanitary facility or a room, with a private sanitary facility, with another individual who also has received therapy with unsealed radioactive material and who also cannot be released under 41.2(27);

(2) Post the patient's or human research subject's door with a "Caution: Radioactive Material" sign and note on the door or on the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room;

(3) Authorize visits by individuals under 18 years of age only on a case-by-case basis with the approval of the authorized user after consultation with the radiation safety officer;

(4) Promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of 641—subrule 40.26(1) which is adopted by reference and included herein and retain for three years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in millirems (μSv) per hour, the instrument used to make the survey, and the initials of the individual who made the survey;

(5) Either monitor material and items removed from the patient's or human research subject's room to determine that any contamination cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle these materials and items as radioactive waste;

(6) Provide the patient or human research subject with radiation safety guidance that will help to keep radiation dose to household members and the public as low as reasonably achievable before authorizing release of the patient or human research subject;

(7) Survey the patient's or human research subject's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient or human research subject to the room. The room must not be reassigned until removable contamination is less than 200 disintegrations per minute (3.33 Bq) per 100 square centimeters; and

(8) Measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine-131 during the period which starts the first day after administration and ends the fourth day after administering the dosage, and retain for the period required by 641—paragraph 40.82(2)*"c"* which is adopted and included herein a record of each thyroid burden measurement, date of measurement, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements.

b. A licensee shall notify the radiation safety officer or the authorized user immediately if the patient or human research subject dies or has a medical emergency.

41.2(40) *Possession of survey instruments.* A licensee authorized to use radioactive material for radiopharmaceutical therapy shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem (1 μSv) per hour to 50 millirems (500 μSv) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 1 millirem (10 μSv) per hour to 1000 millirems (10 mSv) per hour. The instruments shall be operable and calibrated in accordance with 41.2(18).

41.2(41) *Use of sealed sources for diagnosis.* A licensee shall use only sealed sources for diagnostic medical uses as approved in the Sealed Source and Device Registry.

41.2(42) *Availability of survey instrument.* A licensee authorized to use radioactive material as a sealed source for diagnostic purposes shall have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem (1 μSv) per hour to 50 millirems (500 μSv) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range of 1 millirem (10 μSv) per hour to 1000 millirems (10 mSv) per hour. The instrument shall be operable and calibrated in accordance with 41.2(18).

41.2(43) *Use of sources for brachytherapy.* A licensee shall use only brachytherapy sources for therapeutic medical uses:

a. As approved in the Sealed Source and Device Registry; or

b. In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of 41.2(15) are met.

41.2(44) *Safety instruction.*

a. The licensee shall provide oral and written radiation safety instruction to all personnel caring for a patient or human research subject receiving implant therapy. Refresher training shall be provided at intervals not to exceed one year.

b. To satisfy 41.2(44)*"a,"* the instruction shall describe:

(1) Size and appearance of the brachytherapy sources;

(2) Safe handling and shielding instructions in case of a dislodged source;

(3) Procedures for patient or human research subject control;

(4) Procedures for visitor control, to include routine visitation of hospitalized individuals in accordance with 641—40.26(136C) and visitation authorized in accordance with 641—40.26(136C);

(5) Procedures for notification of the radiation safety officer, radiation safety officer designee, or authorized user if the patient or human research subject dies or has a medical emergency; and

(6) Training requirements specified in 641—40.110(136C) and 40.116(136C) as adopted by reference and included herein.

c. A licensee shall maintain a record of individuals receiving instruction required by 41.2(44)*"a,"* a description of the instruction, the date of instruction, and the name of the individual who gave the instruction for three years.

41.2(45) *Safety precautions.*

a. For each patient or human research subject receiving implant therapy a licensee shall:

(1) Not place the patient or human research subject in the same room with a patient who is not receiving radiation therapy unless the licensee can demonstrate compliance with the requirement of 641—40.26(136C) as adopted by reference and included herein at a distance of 1 meter from the implant;

(2) Post the patient's or human research subject's door with a "Caution: Radioactive Materials" sign and note on the door or the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room;

(3) Authorize visits by individuals under 18 years of age only on a case-by-case basis with the approval of the authorized user after consultation with the radiation safety officer;

(4) Promptly after implanting the sources, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with 641—40.26(136C) as adopted by reference and included herein; and retain for three years a record of each survey that includes the time and date of the survey, a sketch of the area or list of points surveyed, the measured dose rate at several points expressed in millirems (mSv) per hour, the instrument used to make the survey, and the initials of the individual who made the survey;

(5) Provide the patient or human research subject with radiation safety guidance that will help keep the radiation dose to household members and the public as low as reasonably achievable before releasing the patient or human research subject if the patient or human research subject was administered a permanent implant; and

(6) Have applicable emergency response equipment available near each treatment room to respond to a source dislodged from the patient or lodged within the patient following removal of the source applicators.

b. A licensee shall notify the radiation safety officer, radiation safety officer designee, or authorized user immediately if the patient or human research subject dies or has a medical emergency.

41.2(46) *Brachytherapy sources inventory.*

a. Each time brachytherapy sources are returned to an area of storage from an area of use, the licensee shall immediately count or otherwise verify the number returned to ensure that all sources taken from the storage area have been returned.

b. A licensee shall make a record of brachytherapy source utilization which includes:

(1) The names of the individuals permitted to handle the sources;

(2) The number and activity of sources removed from storage, the room number of use and patient's or human research subject's name, the time and date they were removed from storage, the number and activity of sources in storage after the removal, and the initials of the individual who removed the sources from storage; and

(3) The number and activity of sources returned to storage, the room number of use and patient's or human research subject's name, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

c. Immediately after implanting sources in a patient or human research subject and immediately after removal of sources from a patient or human research subject, the licensee shall make a radiation survey of the patient or human research subject and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey.

d. A licensee shall maintain the records required in 41.2(46)*"b"* and *"c"* for three years.

e. A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use. As soon as possible after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

41.2(47) *Release of patients or human research subjects treated with temporary implants.*

a. Immediately after removing the last temporary implant source from a patient or human research subject, the licensee shall perform a radiation survey of the patient or human research subject with a radiation detection survey instrument to confirm that all sources have been removed and, for remote afterloaders, returned to the safe shielded position. The licensee shall not release from confinement for medical care a patient or human research subject treated by temporary implant until all sources have been removed.

b. A licensee shall maintain a record of patient or human research subject surveys which demonstrate compliance with 41.2(47)*"a"* for three years. Each record shall include the date of the survey, the name of the patient or human research subject, the dose rate from the patient or human research subject expressed as millirems (microsieverts) per hour and measured within 1 meter from the patient or human research subject, and the initials of the individual who made the survey.

41.2(48) *Possession of survey instruments.* A licensee authorized to use radioactive material for implant therapy shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem (1 μSv) per hour to 50 millirems (500 μSv) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 1 millirem (10 μSv) per hour to 1000 millirems (10 mSv) per hour. The instruments shall be operable and calibrated in accordance with 41.2(18).

41.2(49) *Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.* A licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses as approved in the Sealed Source and Device Registry or in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of 41.2(15) are met.

41.2(50) *Installation, maintenance, adjustment, and repair.*

a. Only a person specifically licensed by the NRC or an agreement state shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), or reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

b. Except for low-dose-rate remote afterloader units, only a person specifically licensed by the NRC or an agreement state shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

c. For low-dose-rate remote afterloader units, only a person specifically licensed by the NRC or an agreement state or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

d. A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units for three years. The record must include the date, description of the service, and the name of the individual who performed the work.

41.2(51) *Amendments.* In addition to the requirements specified in 41.2(4), a licensee shall apply for and receive a license amendment before:

a. Making any change in the treatment room shielding;

b. Making any change in the location of the teletherapy unit within the treatment room;

c. Using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room;

d. Relocating the teletherapy unit; or

e. Allowing an individual not listed on the licensee's license to perform the duties of the teletherapy physicist.

41.2(52) *Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma sterotactic radiosurgery units.*

a. A licensee shall:

(1) Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

(2) Permit only individuals approved by the authorized user, radiation safety officer, or authorized medical physicist to be present in the treatment room during treatment with the source;

(3) Prevent dual operation of more than one radiation producing device in a treatment room, if applicable; and

(4) Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source in the shielded position, or to remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include:

1. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

2. The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

3. The names and telephone numbers of the authorized users, the authorized medical physicist, and the radiation safety officer to be contacted if the unit or console operates abnormally.

b. A copy of the procedures required by 41.2(52)*"a"*(4) must be physically located at the unit console.

c. A licensee shall post instructions at the unit console to inform the operator of:

(1) The location of the procedures required by 41.2(52)*"a"*(4); and

(2) The names and telephone numbers of the authorized users, the authorized medical physicist, and the radiation safety officer to be contacted if the unit or console operates abnormally.

d. A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, appropriate to the individual's assigned duties, in:

(1) The procedures identified in 41.2(52)*"a"*(4); and

(2) The operating procedures for the unit.

e. The licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of emergency procedures, initially and at least annually.

f. A licensee shall retain a record for three years of individuals receiving instruction required by 41.2(52)*"d,"* a description of the instruction, the date of instruction, and the name of the individual who gave the instruction. A copy of the procedures required in 41.2(52)*"a"*(4) and 41.2(52)*"d"*(2) shall be retained for three years.

41.2(53) *Safety precautions for remote afterloader units, teletherapy units, and gamma sterotactic radiosurgery units.*

a. A licensee shall control access to the teletherapy room by a door at each entrance.

b. A licensee shall equip each entrance to the teletherapy room with an electrical interlock system that shall:

(1) Prevent the operator from turning the primary beam of radiation "on" unless each treatment room entrance door is closed;

(2) Turn the beam of radiation "off" immediately when an entrance door is opened; and

(3) Prevent the primary beam of radiation from being turned "on" following an interlock interruption until all treatment room entrance doors are closed and the beam "on-off" control is reset at the console.

c. A licensee shall require any individual entering the treatment room to ensure, through the use of appropriate monitors, that radiation levels have returned to ambient levels.

d. Except for low-dose-rate remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or human research subject from the treatment console during irradiation.

e. For licensed activities where sources are placed within the patient's or human research subject's body, the licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

f. In addition to the requirements specified in 41.2(53)*"a"* through *"e,"* a licensee shall:

(1) For medium-dose-rate and pulsed-dose-rate remote afterloader units, require:

1. An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who have been trained in the operation of and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and

2. An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who have been trained to remove the source applicator in the event of an emergency involving the unit to be immediately available during continuation of all patient treatments involving the unit.

(2) For high-dose-rate remote afterloader units, require:

1. An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

2. An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who have been trained in the operation and emergency response for the unit, to be physically present during the continuation of all patient treatments involving the unit.

(3) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit. As used in this subparagraph, "physically present" means to be within hearing distance of normal voice.

(4) Notify the radiation safety officer, or the radiation safety officer designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

g. A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source remaining in the unshielded position or lodged within the patient following completion of the treatment.

41.2(54) *Possession of survey instrument.* A licensee authorized to use radioactive material in a teletherapy unit shall possess either a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem (1 μSv) per hour to 50 millirems (500 μSv) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range of 1 millirem (10 μSv) per hour to 1000 millirems (10 mSv) per hour. The instruments shall be operable and calibrated in accordance with 41.2(18).

41.2(55) *Radiation monitoring device.*

a. A licensee shall have in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status.

b. Each radiation monitor shall be capable of providing visible notice of a teletherapy unit malfunction that results in an exposed or partially exposed source. The visible indicator of high radiation levels shall be observable by an individual entering the teletherapy room.

c. Each radiation monitor shall be equipped with a backup power supply separate from the power supply to the teletherapy unit. This backup power supply may be a battery system.

d. A radiation monitor shall be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients or human research subjects.

e. A licensee shall maintain a record of the check required by 41.2(55)*"d"* for three years. The record shall include the date of the check, notation that the monitor indicates when the source is exposed, and the initials of the individual who performed the check.

f. If a radiation monitor is inoperable, the licensee shall require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism. The instrument or dosimeter shall be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in 41.2(55)*"e."*

g. A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

41.2(56) *Viewing system.* A licensee shall construct or equip each teletherapy room to permit continuous observation of the patient or human research subject from the teletherapy unit console during irradiation.

41.2(57) *Dosimetry equipment.*

a. Except for low-dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions shall be met:

(1) The system must have been calibrated using a system or source traceable to the National Institute of Standards and Technology and published protocols accepted by nationally recognized bodies, or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The calibration must have been performed within the previous two years and after any servicing that may have affected system calibration; or

(2) The system must have been calibrated within the previous four years; 18 to 30 months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past 24 months by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The results of the intercomparison must indicate that the calibration factor of the licensee's system has not changed by more than 2 percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, if applicable, and sources of the same radionuclide as the source used at the licensee's facility.

b. The licensee shall have available for use a dosimetry system for spot-check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with 41.2(57)*"a."* This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in 41.2(57)*"a."*

c. The licensee shall maintain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 41.2(57)*"a"* and *"b,"* the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by the American Association of Physicists in Medicine.

41.2(58) *Full calibration measurements on teletherapy units, remote afterloader units, and gamma stereotactic radiosurgery units.*

a. Teletherapy units.

(1) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements for each teletherapy unit:

1. Before the first medical use of the unit; and
2. Before medical use under the following conditions:

- Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output of the last full calibration corrected mathematically for radioactive decay;
- Following replacement of the source or following reinstallation of the teletherapy unit in a new location;
- Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

3. At intervals not exceeding one year.

(2) To satisfy the requirements of 41.2(58)*"a"*(1), full calibration measurements must include determination of:

1. The output within ±3 percent for the range of field sizes and for the distance or range of distances used for medical use;
2. The coincidence of the radiation field and the field indicated by the light beam localizing device;

3. The uniformity of the radiation field and its dependence on the orientation of the useful beam;
4. Timer accuracy and linearity over the range of use;
5. On-off error; and
6. The accuracy of all distance measuring and localization devices in medical use.

(3) A licensee shall use the dosimetry system described in 41.2(57) to measure the output for one set of exposure conditions. The remaining radiation measurements required in 41.2(58)*"a"*(2)"1" may be made using the dosimetry system that indicates relative dose rates.

(4) A licensee shall make full calibration measurements required by 41.2(58)*"a"* in accordance with published protocols accepted by nationally recognized bodies.

(5) A licensee shall mathematically correct the outputs determined in 41.2(58)*"a"*(2)"1" for physical decay for intervals not exceeding one month for cobalt-60, six months for cesium-137, or at intervals consistent with 1 percent of all other radionuclides.

(6) Full calibration measurements required by 41.2(58)*"a"*(1) and physical decay corrections required in 41.2(58)*"a"*(5) must be performed by the authorized medical physicist.

(7) A licensee shall maintain a record of each calibration for the duration of the license. The record shall include the date of the calibration; the manufacturer's name, model number, and serial number for both the unit and the source; tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy; a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device; the measured timer accuracy for a typical treatment time; the calculated "on-off" error; the estimated accuracy of each distance measuring or localization device; and the signature of the authorized medical physicist.

b. Remote afterloader units.

(1) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements for each unit:

1. Before the first medical use of the unit; and
2. Before medical use under the following conditions:

- Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and
- Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

3. At intervals not exceeding one quarter of a year for high-dose-rate, medium-dose-rate, and pulsed-dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and
4. At intervals not exceeding one year for low-dose-rate remote afterloader units.

(2) To satisfy the requirements of 41.2(58)*"b"*(1), full calibration measurements must include, as applicable, determination of:

1. The output within ±5 percent;
2. Source positioning accuracy to within ±1 millimeter;
3. Source retraction with backup battery upon power failure;
4. Length of the source transfer tubes;
5. Timer accuracy and linearity over the typical range of use;
6. Length of the applicators; and
7. Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

(3) A licensee shall use the dosimetry system described in 41.2(57) to measure the output.

(4) A licensee shall make full calibration measurements required by 41.2(58)*"b"*(1) in accordance with published protocols accepted by nationally recognized bodies.

(5) In addition to the requirements for full calibrations for low-dose-rate remote afterloader units in 41.2(58)*"b"*(2), a licensee shall perform an autoradiograph of the source to verify inventory and source arrangement at intervals not exceeding one quarter of a year.

(6) For low-dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with 41.2(58)*"b."*

(7) A licensee shall mathematically correct the outputs determined in 41.2(58)*"b"*(2)"1" for physical decay intervals consistent with 1 percent physical decay.

(8) Full calibration measurements required by 41.2(58)*"b"*(1) and physical decay corrections required by 41.2(58)*"b"*(7) must be performed by the authorized medical physicist.

(9) A licensee shall retain a record of each calibration in accordance with 41.2(58)*"a"*(7).

c. Gamma stereotactic radiosurgery units.

(1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit:

1. Before the first medical use of the unit;
2. Before medical use under the following conditions:

- Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;
- Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and
- Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

3. At intervals not exceeding one year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

(2) To satisfy the requirement of 41.2(58)*"c"*(1), full calibration measurements must include determination of:

1. The output within ±3 percent;
2. Relative helmet factors;
3. Isocenter coincidence;
4. Timer accuracy and linearity over the range of use;
5. On-off error;
6. Trunnion centricity;
7. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
8. Helmet microswitches;
9. Emergency timing circuits; and
10. Stereotactic frames and localizing devices (trunnions).

(3) A licensee shall use the dosimetry system described in 41.2(57) to measure the output for one set of exposure conditions. The remaining radiation measurements required in 41.2(58)*"c"*(2)"1" may be made using a dosimetry system that indicates relative dose rates.

(4) A licensee shall make full calibration measurements required by 41.2(58)*"c"*(1) in accordance with published protocols accepted by nationally recognized bodies.

(5) A licensee shall mathematically correct the outputs determined in 41.2(58)*"c"*(2)"1" at intervals not exceeding one month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

(6) Full calibration measurements required by 41.2(58)*"c"*(1) and physical decay corrections required in 41.2(58)*"c"*(5) must be performed by the authorized medical physicist.

(7) A licensee shall retain a record of each calibration in accordance with 41.2(58)*"a"*(7).

41.2(59) *Periodic spot checks for teletherapy units, remote afterloader units, and gamma stereotactic radiosurgery units.*

a. Teletherapy units.

(1) A licensee authorized to use teletherapy units for medical use shall perform output spot checks on each teletherapy unit once in each calendar month that include determination of:

1. Timer accuracy and timer linearity over the range of use;
2. On-off error;
3. The coincidence of the radiation field and the field indicated by the light beam localizing device;
4. The accuracy of all distance measuring and localization devices used for medical use;
5. The output for one typical set of operating conditions measured with the dosimetry system described in 41.2(57); and

6. The difference between the measurement made in 41.2(59)*"a"*(1)"5" and the anticipated output expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

(2) A licensee shall perform measurements required by 41.2(59)*"a"*(1) in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

(3) A licensee shall have the authorized medical physicist review the results of each spot check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the result of each spot check.

(4) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot checks of each teletherapy facility once in each calendar month and after each source installation to ensure proper operation of:

1. Electrical interlocks at each teletherapy room entrance;
2. Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);
3. Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;
4. Viewing and intercom systems;
5. Treatment room doors from inside and outside the treatment room; and
6. Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(5) If the results of the spot checks required in 41.2(59)*"a"*(4) indicate the malfunction of any system, the licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(6) A licensee shall retain for three years a record of each spot check required in 41.2(59)*"a."* The record must include:

1. The date of the spot check;
2. The manufacturer's name, model number, and serial number of the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;
3. An assessment of timer linearity and constancy;
4. The calculated on-off error;
5. A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;
6. The determined accuracy of each distance measuring and localization device;
7. The difference between the anticipated output and the measured output;
8. Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical source exposure indicator light, and the viewing and intercom system and doors; and
9. The name of the individual who performed the periodic spot check and the signature of the authorized medical physicist who reviewed the record of the spot check.

(7) A licensee shall retain a copy of the procedures required by 41.2(59)*"a"*(2) until the licensee no longer possesses the teletherapy unit.

b. Remote afterloader units.

(1) A licensee authorized to use a remote afterloader unit for medical use shall perform spot checks of each remote afterloader facility and on each unit:

1. Before the first use of a high-dose-rate, medium-dose-rate, or pulsed-dose-rate remote afterloader unit on a given day;
2. Before each patient treatment with a low-dose-rate remote afterloader unit; and
3. After each source installation.

(2) A licensee shall perform the measurements required by 41.2(59)*"b"*(1) in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

(3) A licensee shall have the authorized medical physicist review the results of each spot check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot check.

(4) To satisfy the requirements of 41.2(59)*"b"*(1), spot checks must, at a minimum, ensure proper operation of:

1. Electrical interlocks at each remote afterloader unit room entrance;
2. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
3. Viewing and intercom systems in each high-dose-rate, medium-dose-rate, and pulsed-dose-rate remote afterloader facility;
4. Emergency response equipment;
5. Radiation monitors used to indicate the source position;
6. Timer accuracy;
7. Clock (date and time) in the unit's computer; and
8. Decayed source(s) activity in the unit's computer.

(5) If the results of the spot checks required in 41.2(59)*"b"*(4) indicate the malfunction of any system, the licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or spot check the malfunctioning system.

(6) A licensee shall retain for three years a record of each spot check required in 41.2(59)*"b"*(4). The record must include:

1. The date of the spot check;
2. The manufacturer's name, model number, and serial number for the remote afterloader unit and source;
3. An assessment of timer accuracy;
4. Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and
5. The name of the individual who performed the periodic spot check and the signature of the authorized medical physicist who reviewed the record of the spot check.

(7) A licensee shall retain a copy of the procedures required in 41.2(59)*"b"*(2) until the licensee no longer possesses the remote afterloader unit.

c. Gamma stereotactic radiosurgery units.

(1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot checks for the gamma stereotactic radiosurgery facility and on each unit:

1. Monthly;
2. Before the first use of the unit on a given day; and
3. After each source installation.

(2) A licensee shall:

1. Perform the measurements required by 41.2(59)*"c"*(1) in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.
2. Have the authorized medical physicist review the results of each spot check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot check.

(3) To satisfy the requirements of 41.2(59)*"c"*(1)"1," spot checks must, at a minimum:

1. Ensure proper operation of treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off; helmet microswitches; emergency timing circuits; and stereotactic frames and localizing devices (trunnions).
2. Determine:

- The output for one typical set of operating conditions measured with the dosimetry system described in 41.2(57);

- The difference between the measurement made in the above bulleted point and the anticipated output expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);
- Source output against computer calculation;
- Timer accuracy and linearity over the range of use;
- On-off error; and
- Trunnion centricity.

(4) To satisfy the requirements of 41.2(59)*"c"*(1)"2" and "3," spot checks must ensure proper functioning of:

1. Electrical interlocks at each gamma stereotactic radiosurgery room entrance;
2. Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;
3. Viewing and intercom systems;
4. Timer termination;
5. Radiation monitors used to indicate room exposures; and
6. Emergency off buttons.

(5) A licensee shall arrange as soon as possible for the repair of any system identified in 41.2(59)*"c"*(3) that is not operating properly.

(6) If the results of the spot checks required in 41.2(59)*"c"*(4) indicate the malfunction of any system, the licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(7) A licensee shall retain for three years a record of each spot check required by 41.2(59)*"c"*(3) and (4). The record must include:

1. The date of the spot check;
2. The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the survey instrument used to measure the output of the unit;
3. An assessment of timer linearity and accuracy;
4. The calculated on-off error;
5. A determination of trunnion centricity;
6. The difference between the anticipated output and the measured output;
7. An assessment of source output against computer calculations;
8. Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, on-off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and
9. The name of the individual who performed the periodic spot check and the signature of the authorized medical physicist who reviewed the record of the spot check.

(8) A licensee shall retain a copy of the procedures required in 41.2(59)*"c"*(2) until the licensee no longer possesses the gamma stereotactic radiosurgery unit.

41.2(60) *Radiation surveys for teletherapy facilities.*

a. In addition to the survey requirements in 641—40.36(136C), a person licensed under 641—41.2(136C) shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry.

b. The licensee shall make the survey required in 41.2(60)*"a"* at installation of a new source, and following repairs to the source shielding, the source driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source, or compromise the radiation safety of the source.

c. A licensee shall maintain a record of the radiation measurements made following installation of a source for the duration of the license. The record shall include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the teletherapy unit, the source, and the instrument used to measure radiation levels, each dose rate measured around the

teletherapy source while in the "off" position and the average of all measurements, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in millirems (μSv) per hour, the calculated maximum level of radiation over a period of one week for each restricted and unrestricted area, and the signature of the radiation safety officer.

41.2(61) *Safety spot checks for teletherapy facilities.*

a. A licensee shall promptly check all systems listed in 41.2(59)*"g"* for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by 41.2(51).

b. If the results of the safety spot checks required in 41.2(61)*"a"* indicate the malfunction of any system specified in 41.2(59), the licensee shall lock the control console in the "off" position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

c. A licensee shall maintain a record of the safety spot checks following installation of a source for three years. The record shall include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, doors, and the signature of the radiation safety officer.

41.2(62) *Modification of teletherapy unit or room before beginning a treatment program.* If the survey required by 41.2(60) indicates that any individual member of the public is likely to receive a dose greater than those permitted by 641—40.26(136C) before beginning the treatment program, the licensee shall:

a. Either equip the unit with stops or add additional radiation shielding to ensure compliance with 641—40.26(136C);

b. Perform the survey required by 41.2(60) again; and

c. Include in the report required by 41.2(63) the results of the initial survey, a description of the modification made to comply with 41.2(62)*"a,"* and the results of the second survey; or

d. Request and receive a license amendment under 641—40.26(136C) that authorizes radiation levels in unrestricted areas greater than those permitted by 641—40.26(136C).

41.2(63) *Reports of teletherapy surveys, checks, tests, and measurements.* A licensee shall furnish a copy of the records required in 41.2(60), 41.2(61), and 41.2(62) and the output from the teletherapy source expressed as rems (sieverts) per hour at 1 meter from the source as determined during the full calibration required in 41.2(58) to the agency within 30 days following completion of the action that initiated the record requirement.

41.2(64) *Five-year inspection.*

a. A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during teletherapy source replacement or at intervals not to exceed five years, whichever comes first, to ensure proper functioning of the source exposure mechanism.

b. This inspection and servicing shall be performed only by persons specifically licensed to do so by the agency, an agreement state, or the U.S. Nuclear Regulatory Commission.

c. A licensee shall maintain a record of the inspection and servicing for the duration of the license. The record shall contain the inspector's name, the inspector's license number, the date of inspection, the manufacturer's name and model number and serial number for both the teletherapy unit and gamma stereotactic radiosurgery unit and source, a list of components inspected, a list of components serviced and the type of service, a list of components replaced, and the signature of the inspector.

41.2(65) *Training for radiation safety officer.* Except as provided in 41.2(75), the licensee shall require an individual fulfilling the responsibilities of the radiation safety officer as provided in 41.2(8) to be an individual who:

a. Is certified by a specialty board whose certification process has been recognized by this agency, NRC, or an agreement state and who meets the requirements in 41.2(65)*"d"* and *"e."* (The names of the specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall:

(1) Require all candidates for certification to:

1. Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

2. Have five or more years of professional experience in health physics (graduate training may be substituted for no more than two years of the required experience) including at least three years in applied health physics; and

3. Pass an examination administered by diplomats of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

(2) Require all candidates for certification to:

1. Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

2. Have two years of either full-time practical training or supervised experience in medical physics either under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the agency, NRC, or an agreement state, or in clinical nuclear medicine facilities providing either diagnostic or therapeutic services under the direction of physicians who meet the requirements for authorized users in 41.2(68) or 41.2(69); and

3. Pass an examination administered by diplomats of the specialty board that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

b. Has completed a structured educational program consisting of both:

(1) 200 hours of classroom and laboratory training in the following areas:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity;

4. Radiation biology; and

5. Radiation dosimetry; and

(2) One year of full-time radiation safety experience under the supervision of the individual identified as the radiation safety officer on an agency, NRC, or agreement state license or permit issued by the NRC master material licensee that authorizes similar types of use of radioactive material involving the following:

1. Shipping, receiving, and performing related radiation surveys;

2. Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

3. Securing and controlling radioactive material;

4. Using administrative controls to avoid mistakes in the administration of radioactive material;

5. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

6. Using emergency procedures to control radioactive material; and

7. Disposing of radioactive material; or

c. (1) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the agency, NRC, or an agreement state under 41.2(74) and has experience in radiation safety for similar types of use of radioactive material for which the licensee is seeking the approval of the individual as a radiation safety officer and who meets the requirements in 41.2(65)*"d"* and *"e"*; or

(2) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has radiation safety officer responsibilities; and

d. Has obtained written attestation, signed by a preceptor radiation safety officer, that the individual has satisfactorily completed the requirements in 41.2(65)*"e"* and 41.2(65)*"a"*(1)"1" and "2" or 41.2(65)*"a"*(2)"1" and "2" or 41.2(65)*"b"*(1) or 41.2(65)*"c"*(1), and has achieved a level of radiation safety knowledge sufficient to function independently as a radiation safety officer for a medical use licensee; and

e. Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee is seeking approval. This training requirement may be satisfied by completing

training that is supervised by a radiation safety officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type of use for which the licensee is seeking approval.

41.2(66) *Training for experienced radiation safety officer.* Rescinded IAB 3/29/06, effective 5/3/06.

41.2(67) *Training for uptake, dilution, and excretion studies.* Except as provided in 41.2(75), the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under 41.2(31) to be a physician who:

a. Is certified by a medical specialty board whose certification process has been recognized by the agency, NRC, or an agreement state and who meets the requirements in 41.2(67)*"c."* (The names of specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies as described in 41.2(67)*"c"*(1)"1" and "2"; and

(2) Pass an examination administered by diplomats of the specialty board that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

b. Is an authorized user under 41.2(68) or 41.2(69), or before May 3, 2006, meets the requirements in 10 CFR 35.190, 35.290, or 35.390, or meets equivalent agreement state requirements; or

c. (1) Has completed 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include:

1. Classroom and laboratory training in radiation physics and instrumentation; radiation protection; mathematics pertaining to the use and measurement of radioactivity, chemistry of radioactive material for medical use, and radiation biology; and

2. Work experience, under the supervision of an authorized user who meets the requirements in 41.2(67), 41.2(68), or 41.2(69), or before May 3, 2006, the requirements in 10 CFR 35.190, 35.290, or 35.390, or equivalent agreement state requirements, involving:

- Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- Calculating, measuring, and safely preparing patient or human research subject dosages;
- Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
- Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
- Administering dosages of radioactive drugs to patients or human research subjects; and

(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 41.2(67), 41.2(68), or 41.2(69), or before May 3, 2006, the requirements in 10 CFR 35.190, 35.290, or 35.390, or equivalent agreement state requirements, that the individual has satisfactorily completed the requirements in 41.2(67)*"a"*(1) or 41.2(67)*"c"*(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized in 41.2(31).

41.2(68) *Training for imaging and localization studies.* Except as provided in 41.2(75), the licensee shall require the authorized user of unsealed radioactive material specified in 41.2(33) to be a physician who:

a. Is certified by a medical specialty board whose certification process has been recognized by the agency, NRC, or an agreement state and who meets the requirements in 41.2(68)*"c."* (The names of specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on

the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies as described in 41.2(68)*"c"*(1)"1" and "2"; and

(2) Pass an examination administered by diplomats of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

b. Is an authorized user under 41.2(69) and meets the requirements in 41.2(68)*"c"*(1)"2," seventh bulleted paragraph, or before May 3, 2006, meets the requirements in 10 CFR 35.290, or equivalent agreement state requirements; or

c. (1) Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience must include, at a minimum:

1. Classroom and laboratory training in the following areas:

- Radiation physics and instrumentation;
- Radiation protection;
- Mathematics pertaining to the use and measurement of radioactivity;
- Chemistry of radioactive material for medical use;
- Radiation biology, and

2. Work experience, under the supervision of an authorized user who meets the requirements in 41.2(68) or 41.2(68)*"c"*(1)"2," seventh bulleted paragraph, and 41.2(69), or before May 3, 2006, meets the requirements in 10 CFR 35.290, or equivalent agreement state requirements, involving:

- Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- Calculating, measuring, and safely preparing patient or human research subject dosages;
- Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
- Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
- Administering dosages of radioactive drugs to patients or human research subjects; and
- Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 41.2(68) or 41.2(69) and 41.2(68)*"c"*(1)"2," seventh bulleted paragraph, or before May 3, 2006, meets the requirements in 10 CFR 35.290, or equivalent agreement state requirements, that the individual has satisfactorily completed the requirements in 41.2(68)*"a"*(1) or 41.2(68)*"c"*(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 41.2(31) and 41.2(33).

41.2(69) *Training for use of unsealed by-product material for which a written directive is required.* Except as provided in 41.2(75), the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under 41.2(37) to be a physician who:

a. Is certified by a medical specialty board whose certification process has been recognized by the agency, NRC, or an agreement state and who meets the requirements in 41.2(69)*"b"*(1)"2," seventh bulleted paragraph, and 41.2(69)*"b"*(2). (The names of the specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on the NRC's Web page.) To be recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include

700 hours of training and experience as described in 41.2(69)*"b"*(1)"1" through 41.2(69)*"b"*(1)"2," fifth bulleted paragraph. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed radioactive material for which a written directive is required; or

b. (1) Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience must include:

1. Classroom and laboratory training in the following areas:

- Radiation physics and instrumentation;
- Radiation protection;
- Mathematics pertaining to the use and measurement of radioactivity;
- Chemistry of radioactive material for medical use; and
- Radiation biology; and

2. Work experience, under the supervision of an authorized user who meets the requirements in 41.2(69), or before May 3, 2006, meets the requirements in 10 CFR 35.390, or equivalent agreement state requirements. A supervising authorized user who meets the requirements in 41.2(69)*"b,"* or before May 3, 2006, meets the requirements in 10 CFR 35.390(b) must also have experience in administering dosages in the same dosage category or categories (i.e., 41.2(69)*"b"*(1)"2," seventh bulleted paragraph) as the individual requesting authorized user status. The work experience must involve:

- Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- Calculating, measuring, and safely preparing patient or human research subject dosages;
- Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
- Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
- Reserved.
- Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:

– Oral administration of less than or equal to 33 millicuries (1.22 Gigabecquerels) of sodium iodide I-131, for which a written directive is required;

– Oral administration of greater than 33 millicuries (1.22 Gigabecquerels) of sodium iodide I-131 (experience with at least three cases in this category also satisfies the requirement in the above category);

– Parenteral administration of either any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required; or

– Parenteral administration of any other radionuclide for which a written directive is required; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(69)*"a"*(1) and 41.2(69)*"b"*(1)"2," seventh bulleted paragraph, or 41.2(69)*"b"*(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 41.2(37). The written attestation must be signed by a preceptor authorized user who meets the requirements in 41.2(69), or before May 3, 2006, meets the requirements in 10 CFR 35.390, or equivalent agreement state requirements. The preceptor authorized user who meets the requirements in 41.2(69)*"b,"* or before May 3, 2006, meets the requirements in 10 CFR

35.390(b), must have experience in administering dosages in the same dosage category or categories (i.e., 41.2(69)*"b"*(1)"2," seventh bulleted paragraph) as the individual requesting authorized user status.

c. For training only for oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 millicuries (1.22 Gigabecquerels) or quantities greater than 33 millicuries (1.22 Gigabecquerels), see 41.2(81) or 41.2(82).

41.2(70) *Training for use of manual brachytherapy sources.* Except as provided in 41.2(75), the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized in 41.2(43) to be a physician who:

a. Is certified by a medical specialty board whose certification process has been recognized by the agency, NRC, or an agreement state, and who meets the requirements in 41.2(70)*"b"*(3). (The names of the specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete a minimum of three years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomats of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

b. (1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

1. 200 hours of classroom and laboratory training in the following areas:

- Radiation physics and instrumentation;
- Radiation protection;
- Mathematics pertaining to the use and measurement of radioactivity; and
- Radiation biology; and

2. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 41.2(70), or before May 3, 2006, meets the requirements in 10 CFR 35.490, or equivalent agreement state requirements at a medical institution, involving:

- Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- Checking survey meters for proper operation;
- Preparing, implanting, and removing brachytherapy sources;
- Maintaining running inventories of material on hand;
- Using administrative controls to prevent a medical event involving the use of radioactive material; and
- Using emergency procedures to control radioactive material; and

(2) Has completed three years of supervised clinical experience in radiation oncology under an authorized user who meets the requirements in 41.2(70), or before May 3, 2006, meets the requirements in 10 CFR 35.490, or equivalent agreement state requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required in 41.2(70)*"b"*(1)"2"; and

(3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 41.2(70), or before May 3, 2006, meets the requirements in 10 CFR 35.490, or equivalent agreement state requirements, that the individual has satisfactorily completed the requirements in 41.2(70)*"a"*(1) or 41.2(70)*"b"*(1) and (2), and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses in 41.2(43).

41.2(71) *Training for ophthalmic use of strontium-90.* Except as provided in 41.2(75), the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who:

a. Is an authorized user under 41.2(70), or before May 3, 2006, meets the requirements in 10 CFR 35.490 or 35.491, or equivalent agreement state requirements; or

b. (1) Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity; and
4. Radiation biology; and

(2) Has completed supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve:

1. Examination of each individual to be treated;
2. Calculation of the dose to be administered;
3. Administration of the dose; and
4. Follow-up and review of each individual's case history; and

(3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 41.2(70) or 41.2(71), or before May 3, 2006, meets the requirements in 10 CFR 35.490 or 35.491, or equivalent agreement state requirements, that the individual has satisfactorily completed the requirements in 41.2(71)*"b"*(1) and (2) and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

41.2(72) *Training for use of sealed sources for diagnosis.* Except as provided in 41.2(75), the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under 41.2(41) to be a physician, dentist, or podiatrist who:

a. Is certified by a specialty board whose certification process includes all of the requirements in 41.2(72)*"b"* and *"c"* and whose certification has been recognized by the agency, NRC, or an agreement state. (The names of the specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on the NRC's Web page.); or

b. Has completed eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include:

(1) Radiation physics and instrumentation;
(2) Radiation protection;
(3) Mathematics pertaining to the use and measurement of radioactivity; and
(4) Radiation biology; and

c. Has completed training in the use of the device for the uses requested.

41.2(73) *Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.* Except as provided in 41.2(75), the licensee shall require an authorized user of a sealed source for use authorized in 41.2(49) to be a physician who:

a. Is certified by a medical specialty board whose certification process has been recognized by the agency, NRC, or an agreement state, and who meets the requirements in 41.2(73)*"b"*(3) and 41.2(73)*"c."* (The names of the specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete a minimum of three years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders, and external beam therapy; or

b. (1) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:

1. 200 hours of classroom and laboratory training in the following areas:

- Radiation physics and instrumentation;
- Radiation protection;
- Mathematics pertaining to the use and measurement of radioactivity; and
- Radiation biology; and

2. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 41.2(73), or before May 3, 2006, meets the requirements in 10 CFR 35.690, or equivalent agreement state requirements at a medical institution, involving:

- Reviewing full calibration measurements and periodic spot checks;
- Preparing treatment plans and calculating treatment doses and times;
- Using administrative controls to prevent a medical event involving the use of radioactive material;
- Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;
- Checking and using survey meters; and
- Selecting the proper dose and how it is to be administered; and

(2) Has completed three years of supervised clinical experience in radiation therapy under an authorized user who meets the requirements in 41.2(73), or before May 3, 2006, meets the requirements in 10 CFR 35.690, or equivalent agreement state requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by 41.2(73)*"b"*(1)"2"; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(73)*"a"*(1) or 41.2(73)*"b"*(1) and (2), and 41.2(73)*"c,"* and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in 41.2(73), or before May 3, 2006, the requirements in 10 CFR 35.690, or equivalent agreement state requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and

c. Has received training in device operation, safety procedures, and clinical use for the type of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type of use for which the individual is seeking authorization.

41.2(74) *Training for an authorized medical physicist.* Except as provided in 41.2(75), the licensee shall require the authorized medical physicist to be an individual who:

a. Is certified by a specialty board whose certification process has been recognized by the agency, NRC, or an agreement state and who meets the requirements in 41.2(74)*"b"*(2) and 41.2(74)*"c."* (The names of the specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(2) Have two years of either full-time practical training or supervised experience in medical physics:

1. Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the agency, NRC, or an agreement state; or

2. In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in 41.2(70) or 41.2(73); and

(3) Pass an examination, administered by diplomats of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

b. (1) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and must include:

1. Performing sealed source leak tests and inventories;
2. Performing decay corrections;
3. Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units, as applicable; and
4. Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units, as applicable; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(74)*"a"*(1) and (2) and 41.2(74)*"c"* or 41.2(74)*"b"*(1) and 41.2(74)*"c,"* and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in 41.2(74), or before May 3, 2006, the requirements in 10 CFR 35.51, or equivalent agreement state requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

c. Has training for the type of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist who is authorized for the type of use for which the individual is seeking authorization.

41.2(75) *Training for experienced radiation safety officer, authorized medical physicist, nuclear pharmacist, authorized nuclear pharmacist, authorized users and teletherapy or medical physicists.*

a. (1) An individual identified as a radiation safety officer, teletherapy or medical physicist, or nuclear pharmacist on an agency, NRC or agreement state license or a permit issued by an NRC or agreement state broad scope licensee or master material license permit or by a master material license permittee of broad scope before January 1, 2003, does not need to comply with the training requirements of 41.2(65), 41.2(74), or 41.2(78).

(2) An individual identified as a radiation safety officer, an authorized medical physicist, or an authorized nuclear pharmacist on the agency, NRC, or agreement state license or permit issued by the agency, NRC, or agreement state broad scope licensee or issued by master material license permit or issued by a master material license permittee of broad scope between January 1, 2003, and May 3, 2006, need not comply with the training requirements of 41.2(65), 41.2(74), or 41.2(78).

b. (1) Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the agency, the NRC, or agreement state, a permit issued by an NRC master material licensee, a permit issued by an NRC broad scope licensee, or a permit issued by an NRC master material license broad scope permittee before January 1, 2003, who perform only those medical uses for which they were authorized before that date need not comply with the training requirements of 41.2(67), 41.2(68), 41.2(69), 41.2(70), 41.2(71), 41.2(72), 41.2(73), 41.2(81), 41.2(82), or 41.2(89).

(2) Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material issued by the agency, the NRC, or agreement state, a permit issued by an NRC master material licensee, a permit issued by an NRC broad scope licensee, or a permit issued by an NRC

master material license broad scope permittee who perform only those medical uses for which they were authorized between January 1, 2003, and May 3, 2006, need not comply with the training requirements of 41.2(67), 41.2(68), 41.2(69), 41.2(70), 41.2(71), 41.2(72), 41.2(73), 41.2(81), 41.2(82), or 41.2(89).

41.2(76) *Physician training in a three-month program.* Rescinded IAB 8/1/07, effective 9/5/07.

41.2(77) *Recentness of training.* The training and experience specified in 41.2(65) to 41.2(78) and 41.2(81), 41.2(82), and 41.2(89) shall have been obtained within the seven years preceding the date of application or the individual shall have had related continuing education and continuing applicable experience since the required training and experience were completed.

41.2(78) *Training for an authorized nuclear pharmacist.* Except as provided in 41.2(75), the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

a. Is certified as a nuclear pharmacist by a specialty board whose certification process includes all of the requirements of 41.2(78)*"b."* (The names of the specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

(2) Hold a current, active license to practice pharmacy;

(3) Provide evidence of having acquired at least 4,000 hours of combined training and experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2,000 hours of the required training and experience; and

(4) Pass an examination in nuclear pharmacy administered by diplomats of the specialty board that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

b. Has completed 700 hours in a structured education program consisting of both:

(1) 200 hours of classroom and laboratory training in the following areas:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of radioactive material for medical use; and
5. Radiation biology; and

(2) Supervised practical experience in a nuclear pharmacy involving:

1. Shipping, receiving, and performing related radiation surveys;
2. Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;
3. Calculating, assaying, and safely preparing dosages for patients or human research subjects;
4. Using administrative controls to avoid medical events in the administration of by-product material; and
5. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

c. Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual satisfactorily completed the requirements in 41.2(78)*"a"*(1), (2), and (3), or 41.2(78)*"b"*(1) and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

41.2(79) *Training for experienced nuclear pharmacists.* Rescinded IAB 8/1/07, effective 9/5/07.

41.2(80) *Training for nuclear medicine technologists.* Rescinded IAB 4/2/03, effective 5/7/03.

41.2(81) *Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 millicuries (1.22 Gigabecquerels).* Except as provided in 41.2(75), the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a

written directive in quantities less than or equal to 33 millicuries (1.22 Gigabecquerels) to be a physician who:

a. Is certified by a medical specialty board whose certification process includes all of the requirements in 41.2(81)*"c"*(1) and (2) and whose certification process has been recognized by the agency, NRC, or an agreement state and who meets the requirements in 41.2(81)*"c"*(3). (The names of the specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on the NRC's Web page.); or

b. Is an authorized user under 41.2(69)*"a"* or *"b"* for uses in the oral administration of less than or equal to 33 millicuries (1.22 Gigabecquerels) of sodium iodide I-131 for which a written directive is required, or oral administration of greater than 33 millicuries (1.22 Gigabecquerels) of sodium iodide I-131, or before May 3, 2006, who meets the requirements in 10 CFR 35.390, 35.392, or 35.394, or meets equivalent agreement state requirements; or

c. (1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of radioactive material for medical use; and
5. Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in 41.2(69)*"a"* or *"b,"* or 41.2(82), or before May 3, 2006, meets the requirements in 10 CFR 35.390, 35.392, or 35.394, or equivalent agreement state requirements. A supervising authorized user who meets the requirements in 41.2(69)*"b"* must also have experience in administering dosages as follows: oral administration of less than or equal to 33 millicuries (1.22 Gigabecquerels) of sodium iodide I-131, for which a written directive is required; or oral administration of greater than 33 millicuries (1.22 Gigabecquerels) of sodium iodide I-131. The work experience must involve:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
3. Calculating, measuring, and safely preparing patient or human research subject dosages;
4. Using administrative controls to prevent a medical event involving the use of radioactive material;
5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
6. Administering dosages to patients or human research subjects that include at least three cases involving the oral administration of less than or equal to 33 millicuries (1.22 Gigabecquerels) of sodium iodide I-131; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(81)*"c"*(1) and (2), and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under 41.2(37). The written attestation must be signed by a preceptor authorized user who meets the requirements in 41.2(69), 41.2(81), or 41.2(82), or before May 3, 2006, meets the requirements in 10 CFR 35.390, 35.392, or 35.394, or equivalent agreement state requirements. A preceptor authorized user who meets the requirements in 41.2(69)*"b"* must also have experience in administering dosages as follows: oral administration of less than or equal to 33 millicuries (1.22 Gigabecquerels) of sodium iodide I-131, for which a written directive is required; or oral administration of greater than 33 millicuries (1.22 Gigabecquerels) of sodium iodide I-131.

41.2(82) *Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 33 millicuries (1.22 Gigabecquerels).* Except as provided in 41.2(75), the

licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 33 millicuries (1.22 Gigabecquerels) to be a physician who:

a. Is certified by a medical specialty board whose certification process includes all of the requirements in 41.2(82)*"c"*(1) and (2), and whose certification has been recognized by the agency, NRC, or agreement state, and who meets the requirements in 41.2(82)*"c"*(3). (The names of the specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on the NRC's Web page.); or

b. Is an authorized user under 41.2(69)*"a"* or *"b"* for oral administration of greater than 33 millicuries (1.22 Gigabecquerels) of sodium iodide I-131, or before May 3, 2006, meets the requirements in 10 CFR 35.390 or 35.394, or meets equivalent agreement state requirements; or

c. (1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of radioactive material for medical use; and
5. Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in 41.2(69)*"a"* or *"b,"* or 41.2(82), or before May 3, 2006, meets the requirements in 10 CFR 35.390 or 35.394, or equivalent agreement state requirements. A supervising authorized user who meets the requirements in 41.2(69)*"b"* must also have experience in oral administration of greater than 33 millicuries (1.22 Gigabecquerels) of sodium iodide I-131. The work experience must involve:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
3. Calculating, measuring, and safely preparing patient or human research subject dosages;
4. Using administrative controls to prevent a medical event involving the use of radioactive material;
5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
6. Administering dosages to patients or human research subjects that include at least three cases involving the oral administration of greater than 33 millicuries (1.22 Gigabecquerels) of sodium iodide I-131; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(82)*"c"*(1) and (2), and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized in 41.2(37). The written attestation must be signed by a preceptor authorized user who meets the requirements in 41.2(69) or 41.2(82), or before May 3, 2006, meets the requirements in 10 CFR 35.390 or 35.394, or equivalent agreement state requirements. A preceptor authorized user who meets the requirements in 41.2(69)*"b"* must also have experience in oral administration of greater than 33 millicuries (1.22 Gigabecquerels) of sodium iodide I-131.

41.2(83) *Provisions for the protection of human research subjects.*

a. A licensee may conduct research involving human research subjects only if the licensee uses the radioactive materials authorized on its specific license for the uses authorized on its license.

b. If the research is conducted, funded, supported, or regulated by another federal agency that has implemented Federal Policy for the Protection of Human Subjects (Federal Policy), the licensee shall, before conducting research:

(1) Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and

(2) Obtain "informed consent," as defined and described in the Federal Policy, from the human research subjects.

c. If the research will not be conducted, funded, supported, or regulated by another federal agency that has implemented the Federal Policy, the licensee shall, before conducting research, apply for and receive a specific amendment to its medical use license. The amendment request must include a written commitment that the licensee will, before conducting research:

(1) Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and

(2) Obtain "informed consent," as defined and described in the Federal Policy, from the human research subjects.

d. Nothing in this subrule relieves a licensee from complying with the other requirements of these rules.

41.2(84) *Calibration measurements of brachytherapy sources.*

a. Before the first medical use of a brachytherapy source on or after January 1, 2003, a licensee shall have:

(1) Determined the source output or activity using a dosimetry system that meets the requirements of 41.2(57);

(2) Determined the source positioning accuracy within applicators; and

(3) Used published protocols currently accepted by nationally recognized bodies to meet the requirements of 41.2(84)*"a."*

b. A licensee may use measurements that are provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine and that are made in accordance with 41.2(84)*"a"*(1) and (2).

c. A licensee shall mathematically correct the outputs or activities determined in 41.2(84)*"a"* for physical decay at intervals consistent with 1 percent physical decay.

d. A licensee shall retain a record of each calibration for three years after the last use of the source. The record must include:

(1) The date of the calibration;

(2) The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;

(3) The source output or activity;

(4) The source positioning accuracy within the applicators; and

(5) The signature of the authorized medical physicist.

41.2(85) *Decay of strontium-90 sources for ophthalmic treatment.*

a. Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under 41.2(84).

b. A licensee shall retain a record of the activity of each strontium-90 source in accordance with 41.2(84).

41.2(86) *Therapy-related computer systems.* The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance must include, as applicable, verification of:

a. The source-specific input parameters required by the dose calculation algorithm;

b. The accuracy of dose, dwell time, and treatment time calculations at representative points;

c. The accuracy of isodose plots and graphic displays;

d. The accuracy of the software used to determine sealed source positions from radiographic images; and

e. The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

41.2(87) *Written directives.* Each licensee or registrant shall meet the following objectives:

a. Prior to administration, a written directive must contain the patient's or human research subject's name and the following information:

(1) For any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131: the dosage;

(2) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration;

(3) For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose;

(4) For teletherapy: the total dose, dose per fraction, number of fractions, treatment site, and overall treatment period;

(5) For high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or

(6) For all other brachytherapy, including low-, medium-, and pulsed-dose-rate remote afterloaders:

1. Prior to implantation: treatment site, the radioisotope, number of sources, and source strengths; and

2. After implantation but prior to completion of the procedure: the radioisotope, treatment site, number of sources, and total source strength and exposure time (or, equivalently, the total dose);

(7) For therapeutic use of radiation machines, see 41.3(14);

b. Prior to each administration, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;

c. The final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives;

d. Each administration is in accordance with the written directive through checking both manual and computer-generated dose calculations and verifying that any computer-generated dose calculations are correctly transferred into the consoles of the medical units authorized by 641—Chapter 41;

e. Any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken;

f. If, because of the emergent nature of the patient's or human research subject's condition, a delay in order to provide a written directive jeopardizes the patient's or human research subject's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's or human research subject's record. A written directive must be prepared within 48 hours of the oral directive; and

g. A copy of the written directive in auditable form shall be retained for three years after the date of administration.

h. A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed by-product material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

41.2(88) *Other medical uses of by-product material or radiation from by-product material.* A licensee may use by-product material or a radiation source approved for medical use which is not specifically addressed in 641—41.2(136C)(e.g., Y-90 microspheres, liquid brachytherapy, intravascular brachytherapy) if:

a. The applicant or licensee has submitted the information required by the agency; and

b. The applicant or licensee has received written approval from the agency in a license or license amendment and uses the material in accordance with the regulations and specific conditions the agency considers necessary for the medical use of the material.

41.2(89) *Training for the parenteral administration of unsealed by-product material requiring a written directive.* Except as provided in 41.2(75), the licensee shall require an authorized user for the parenteral administration requiring a written directive to be a physician who:

a. Is an authorized user under 41.2(69), or before May 3, 2006, meets the requirements in 10 CFR 35.390, for uses listed in 41.2(89), or meets equivalent agreement state requirements; or

b. Is an authorized user under 41.2(70) or 41.2(73), or before May 3, 2006, meets the requirements in 10 CFR 35.490 or 35.690, or meets equivalent agreement state requirements, and who meets the requirements in 41.2(89)*"d"*; or

c. Is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state under 41.2(70) or 41.2(73), or before May 3, 2006, meets the requirements in 10 CFR 35.490 or 35.690, and who meets the requirements in 41.2(89)*"d"*; or

d. (1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of either any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or parenteral administration of any other radionuclide for which a written directive is required. The training must include:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of radioactive material for medical use; and
5. Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in 41.2(69) or 41.2(89), or before May 3, 2006, meets the requirements in 10 CFR 35.390, or equivalent agreement state requirements, in the parenteral administration for which a written directive is required, of either any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in 41.2(69) or before May 3, 2006, meets the requirements in 10 CFR 35.390 must have experience in administering dosages of either any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or parenteral administration of any other radionuclide for which a written directive is required. The work experience must involve:

1. Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;
2. Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;
3. Calculating, measuring, and safely preparing patient or human research subject dosages;
4. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
5. Using procedures to contain spilled radioactive material safely, and using proper decontamination procedures; and
6. Administering dosages to patients or human research subjects, that include at least three cases involving the parenteral administration for which a written directive is required, of either any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or at least three cases involving the parenteral administration of any other radionuclide for which a written directive is required; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(89)*"b"* or *"c,"* and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed by-product material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in 41.2(69) or 41.2(89), or before May 3, 2006, meets the requirements in 10 CFR 35.390, or equivalent agreement state requirements. A preceptor authorized user who meets the requirements in 41.2(69), or before May 3, 2006, meets the requirements in 10 CFR 35.390, must have experience in administering dosages of either any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or at least three cases involving the parenteral administration of any other radionuclide for which a written directive is required.

[**ARC 7983B**, IAB 7/29/09, effective 9/2/09]

641—41.3(136C) Therapeutic use of radiation machines.

41.3(1) Scope and applicability.

a. This subrule establishes requirements, for which the registrant is responsible, for use of therapeutic radiation machines.

b. The use of therapeutic radiation machines shall be by, or under the supervision of, a physician who meets the training/experience criteria established by 41.3(5).

c. Unless specifically required otherwise by 641—41.3(136C), all registrants are subject to the requirements of 641—Chapters 38 to 40.

41.3(2) Definitions. In addition to the definitions provided in 641—38.2(136C) and 641—40.2(136C), the following definitions are specific to 641—41.3(136C).

"Accessible surface" means surface of equipment or of an equipment part that can be easily or accidentally touched by persons without the use of a tool.

"Added filtration" means any filtration which is in addition to the inherent filtration.

"Beam-limiting device" means a field defining collimator, integral to the therapeutic radiation machine, which provides a means to restrict the dimensions of the useful beam.

"Beam-scattering foil" means a thin piece of material (usually metallic) placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.

"Bent beam linear accelerator" means a linear accelerator geometry in which the accelerated electron beam must change direction by passing through a bending magnet.

"Contact therapy system" means a therapeutic radiation machine with a short target-to-skin distance (TSD), usually less than 5 centimeters.

"Dose monitor unit (DMU)" means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

"External beam radiation therapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

"Field flattening filter" means a filter used to homogenize the absorbed dose rate over the radiation field.

"Filter" means material placed in the useful beam to change beam quality or its intensity profile in therapeutic radiation machines.

"Gantry" means that part of a radiation therapy system supporting and allowing movements of the radiation head around a center of rotation.

"Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

"Isocenter" means the center of the sphere through which the useful beam axis passes while the gantry moves through its full range of motions.

"Megavolt (MV) (mega electron volt (MeV))" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of 1 million volts in a vacuum. (Note: Current convention is to use MV for photons and MeV for electrons.)

"Monitor unit (MU)." See "Dose monitor unit."

"Moving beam radiation therapy" means radiation therapy with continuous displacement of one or more mechanical axes relative to the patient during irradiation. It includes arc therapy, skip therapy, conformal therapy, intensity modulation, and rotational therapy.

"Nominal treatment distance" means:

1. For electron irradiation, the distance from the scattering foil, virtual source, or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam.

2. For X-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For nonisocentric equipment, this distance shall be that specified by the manufacturer.

"Periodic quality assurance check" means a procedure which is performed to ensure that a previous calibration continues to be valid.

"Practical range of electrons" corresponds to classical electron range where the only remaining contribution to dose is from bremsstrahlung X-rays. A further explanation may be found in "Clinical

Electron Beam Dosimetry: Report of AAPM Radiation Therapy Committee Task Group 25" (Medical Physics 18(1): 73-109, Jan/Feb 1991) and ICRU Report 35, "Radiation Dosimetry: Electron Beams with Energies Between 1 and 50 MeV," International Agency on Radiation Units and Measurements, September 15, 1984.

"Radiation field." See "Useful beam."

"Radiation head" means the structure from which the useful beam emerges.

"Radiation therapy physicist" means an individual qualified in accordance with 41.3(6).

"Redundant beam monitoring system" means a combination of two dose monitoring systems in which each system is designed to terminate irradiation in accordance with a preselected number of dose monitor units.

"Shadow tray" means a device attached to the radiation head to support auxiliary beam blocking material.

"Stationary beam radiation therapy" means radiation therapy without displacement of one or more mechanical axes relative to the patient during irradiation.

"Target" means that part of an X-ray tube or accelerator onto which is directed a beam of accelerated particles to produce ionizing radiation or other particles.

"Tenth-value layer (TVL)" means the thickness of a specified material which attenuates X-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate or absorbed dose rate is reduced to one-tenth of the value measured without the material at the same point.

"Therapeutic radiation machine" means X-ray or electron-producing equipment designed and used for external beam radiation therapy.

"Virtual source" means a point from which radiation appears to originate.

41.3(3) Registration or license requirements. No person shall receive, possess, use, transfer, own, or acquire therapeutic radiation machines except as authorized in a registration issued pursuant to 641—39.1(136C) to 39.4(136C).

41.3(4) General administrative requirements for facilities using therapeutic radiation machines.

a. Administrative controls. The registrant shall be responsible for directing the operation of the therapeutic radiation machines which have been registered with the agency. The registrant or the registrant's agent shall ensure that the requirements of 41.3(136C) are met in the operation of the therapeutic radiation machine(s).

b. A therapeutic radiation machine which does not meet the provisions of these regulations shall not be used for irradiation of patients unless authorized by the agency.

41.3(5) Training for external beam radiation therapy authorized users. The registrant for any therapeutic radiation machine subject to 41.3(17) or 41.3(18) shall require the authorized user to be a physician who:

a. Is certified in:

(1) Radiology or therapeutic radiology by the American Board of Radiology; or

(2) Radiation oncology by the American Osteopathic Board of Radiology; or

(3) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

b. Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, 500 hours of supervised work experience, and a minimum of three years of supervised clinical experience.

c. To satisfy the requirement for instruction in 41.3(5)*"b"* above, the classroom and laboratory training shall include:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of ionization radiation; and

(4) Radiation biology.

d. To satisfy the requirement for supervised work experience in 41.3(4)*"b"* above, training shall be under the supervision of an authorized user and shall include:

(1) Reviewing the full calibration measurements and periodic quality assurance checks;

(2) Evaluating prepared treatment plans and calculation of treatment times/patient treatment settings;

(3) Using administrative controls to prevent misadministrations;

(4) Implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console; and

(5) Checking and using radiation survey meters.

e. To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user. The supervised clinical experience shall include:

(1) Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations/contraindications;

(2) Selecting proper dose and how it is to be administered;

(3) Calculating the external beam radiation therapy doses and collaborating with the authorized user in the review of patients' progress; consideration of the need to modify originally prescribed doses or treatment plans as warranted by patients' reaction to radiation; and

(4) Postadministration follow-up and review of case histories.

f. Notwithstanding the requirements of 41.3(5)*"b,"* the registrant for any therapeutic radiation machine subject to 41.3(17) and 41.3(18) may also submit the training of the prospective authorized user physician for agency review.

g. A physician shall not act as an authorized user for any therapeutic radiation machine until such time as said physician's training has been reviewed and approved by the registrant.

41.3(6) Training for radiation therapy physicist. The registrant for any therapeutic radiation machine subject to 41.3(17) or (18) shall require the radiation therapy physicist to:

a. Be registered with the agency, under the provisions of 641—subrule 39.3(3) of these regulations, as a provider of radiation services in the area of calibration and compliance surveys of external beam radiation therapy units; and

b. Be certified by the American Board of Radiology in:

(1) Therapeutic radiological physics; or

(2) Roentgen-ray and gamma-ray physics; or

(3) X-ray and radium physics; or

(4) Radiological physics; or

c. Be certified by the American Board of Medical Physics in radiation oncology physics; or

d. Be certified by the Canadian College of Physicists in Medicine; or

e. Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed one year of full-time training in therapeutic radiological physics and also one year of full-time work experience under the supervision of a radiation therapy physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in 41.3(16)*"a,"*41.3(17)*"c"* and *"d,"* and 41.3(18)*"e"* and *"f"* under the supervision of a radiation therapy physicist during the year of work experience.

f. Rescinded IAB 4/3/02, effective 5/8/02.

41.3(7) Qualifications of operators.

a. Individuals who will be operating a therapeutic radiation machine for medical use shall be adequately instructed in the safe operating procedures, be competent in the safe use of the equipment in accordance with 641—Chapter 42 as applicable, and hold a current permit to practice in radiation therapy.

b. Each operator's permit to practice under 641—Chapter 42 shall be posted in the immediate vicinity of the general work area and visible to the public.

41.3(8) Written safety procedures and rules shall be developed by a radiation therapy physicist and shall be available in the control area of a therapeutic radiation machine, including any restrictions

required for the safe operation of the particular therapeutic radiation machine. The operator shall be able to demonstrate familiarity with these rules. All individuals associated with the operation of a therapeutic radiation machine shall be instructed in and shall comply with procedures for maintaining written directives.

41.3(9) Individuals shall not be exposed to the useful beam except for medical therapy purposes and unless such exposure has been ordered in writing by a physician. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other non-healing arts purposes.

41.3(10) Records of visiting authorized users. Notwithstanding the provisions of 41.3(5), a registrant may permit any physician to act as a visiting authorized user for up to 60 days per calendar year under the following conditions:

a. The visiting authorized user has the prior written permission of the registrant's management and, if the use occurs on behalf of an institution, the institution's radiation safety committee;

b. The visiting authorized user meets the requirements of 41.3(5); and

c. The registrant maintains copies of all records specified in 41.3(5) for five years from the date of the last visit.

41.3(11) Information and maintenance record and associated information. The registrant shall maintain the following information in a separate file or package for each therapeutic radiation machine for inspection by the agency:

a. Report of acceptance testing;

b. Records of all surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by 41.3(136C), as well as the name(s) of person(s) who performed such activities;

c. Records of maintenance or modifications, or both, performed on the therapeutic radiation machine after July 9, 1997, as well as the name(s) of person(s) who performed such services;

d. Signature of person authorizing the return of therapeutic radiation machine to clinical use after service, repair, or upgrade.

e. Records of training specified in 41.3(5) and 41.3(6).

41.3(12) Records retention. All records required by 641—41.3(136C) shall be retained until disposal is authorized by the agency unless another retention period is specifically authorized in 41.3(136C). All required records shall be retained in an active file from at least the time of generation until the next agency inspection. Any required record generated before the last agency inspection may be microfilmed or otherwise archived as long as a complete copy can be retrieved until such time the agency authorizes final disposal.

41.3(13) Form of records. Rescinded IAB 4/5/00, effective 5/10/00.

41.3(14) Written directives. Each registrant shall meet the following:

a. A written directive must be dated and signed by an authorized user prior to the administration of radiation.

(1) If, because of the patient's condition, a delay in the order to provide a written revision to an existing directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in writing in the patient's record and a revised written directive is signed by an authorized user within 48 hours of the oral revision.

(2) The written directive must contain the patient or human research subject's name, the type and energy of the beam, the total dose, dose per fraction, treatment site, and number of fractions.

(3) A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the external beam dose, or the next fractional dose.

(4) The registrant shall retain a copy of the written directive for three years.

b. Procedures for administration. The registrant shall have written procedures that provide the following information:

(1) Prior to the administration of each course of radiation treatment, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;

(2) Each administration is in accordance with the written directive;

(3) External beam radiation therapy final plans of treatment and related calculations are in accordance with the respective written directives by:

1. Checking both manual and computer-generated dose calculations to verify that they are correct and in accordance with the written directive; and

2. Verifying that any computer-generated calculations are correctly transferred into the consoles of authorized therapeutic medical units;

(4) Any unintended deviation from the written directive is identified, evaluated and appropriate action is taken; and

(5) The registrant retains a copy of the procedures for administrations for the duration of the registration.

41.3(15) Reports and notifications of misadministrations.

a. A registrant shall report any event resulting from intervention of a patient or human research subject in which the administration of external beam radiation results, or will result, in unintended permanent functional damage to an organ or a physiological system as determined by a physician.

b. Other than events that result from intervention by a patient or human research subject, a registrant shall report any event in which the administration of an external beam radiation therapy dose results in:

(1) A dose that differs from the prescribed dose by more than 5 rem (0.05 sievert) effective dose equivalent, 50 rem (0.5 sievert) to an organ or tissue, or 50 rem (0.5 sievert) shallow dose equivalent to the skin, and either:

1. The total dose delivered differs from the prescribed dose by 20 percent or more; or

2. The fractionated dose delivered differs from the prescribed dose for a single fraction by 50 percent or more.

(2) A dose that exceeds 5 rem (0.05 sievert) effective dose equivalent, 50 rem (0.5 sievert) to an organ or tissue, or 50 rem (0.5 sievert) shallow dose equivalent to the skin from either of the following:

1. An administration of the wrong treatment modality;

2. An administration to the wrong individual or human research subject.

(3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rem (0.5 sievert) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive.

c. The registrant shall notify the agency by telephone no later than the next calendar day after the discovery of a misadministration.

d. The registrant shall submit a written report to the agency within 15 days after the discovery of a misadministration. The written report shall include:

(1) The registrant's name;

(2) The name of the prescribing physician;

(3) A brief description of the event;

(4) Why the event occurred;

(5) The effect, if any, on the individual or individuals who received the misadministration;

(6) Actions, if any, that have been taken, or are planned, to prevent recurrence;

(7) Certification that the registrant notified the individual or the individual's responsible relative or guardian, and if not, why not.

e. The report to the agency shall not contain the individual's name or any other information that could lead to the identification of the individual.

f. The registrant shall provide notification of the event to the referring physician and also notify the individual who is the subject of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the registrant either that the referring physician will inform the individual or that, based on medical judgment, the physician's telling the individual would be harmful. The registrant is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the registrant shall notify the individual as soon as possible thereafter. The registrant may not delay any

appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the misadministration may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the registrant shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event may be obtained from the registrant upon request. The registrant shall provide such a written description if requested.

g. Aside from the notification requirement, nothing in this subrule affects any rights or duties of registrants and physicians in relation to each other, to individuals affected by the misadministration, or to individuals' responsible relatives or guardians.

h. A copy of the record required in this subrule shall be provided to the referring physician, if other than the registrant, within 15 days after discovery of the misadministration.

i. Records of misadministrations. A registrant shall retain a record of misadministrations reported in this subrule for three years. The record must contain the following:

(1) The registrant's name and the names of the individuals involved;

(2) The social security number or other identification number, if one has been assigned, of the individual who is the subject of the misadministration;

(3) A brief description of the event; why it occurred; and the effect, if any, on the individual;

(4) The actions, if any, taken or planned to prevent recurrence; and

(5) Whether the registrant notified the individual or the individual's responsible relative or guardian, and, if not, whether such failure to notify was based on guidance from the referring physician.

41.3(16) General technical requirements for facilities using therapeutic radiation machines.

a. Protection surveys.

(1) The registrant shall ensure that radiation protection surveys of all new facilities, and existing facilities not previously surveyed, are performed with an operable radiation measurement survey instrument calibrated within the past 12 months. The radiation protection survey shall be performed by, or under the direction of, a radiation therapy physicist or a certified health physicist and shall verify that, with the therapeutic radiation machine in a "BEAM-ON" condition, with the largest clinically available treatment field and with a scattering phantom in the useful beam of radiation:

1. Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in 641—subrule 40.15(1); and

2. Radiation levels in unrestricted areas do not exceed the limits specified in 641—paragraphs 40.26(1)*"a"*and *"b."*

(2) In addition to the requirements of 41.3(16)*"a"*(1), a radiation protection survey shall also be performed prior to any subsequent medical use and:

1. After making any change in the treatment room shielding;

2. After making any change in the location of the therapeutic radiation machine within the treatment room;

3. After relocating the therapeutic radiation machine; or

4. Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.

(3) The survey record shall indicate all instances where the facility, in the opinion of the radiation therapy physicist or a certified health physicist, is in violation of applicable regulations. The survey record shall also include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the therapeutic radiation machine, the instrument(s) used to measure radiation levels, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in microsieverts or millirems per hour, the calculated maximum level of radiation over a period of one week for each restricted and unrestricted area, and the signature of the individual responsible for conducting the survey.

(4) If the results of the surveys required by 41.3(16)*"a"*(1) or (2) indicate any radiation levels in excess of the respective limit specified in 41.3(16)*"a"*(1), the registrant shall lock the control in the "OFF" position and not use the unit:

1. Except as may be necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding; or

2. Until the registrant has received a specific exemption in writing from the agency.

b. Modification of radiation therapy unit or room before beginning a treatment program. If the survey required by 41.3(16)*"a"* indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by 641—paragraphs 40.26(1)*"a"* and *"b,"* before beginning the treatment program the registrant shall:

(1) Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with 641—paragraphs 40.26(1)*"a"* and *"b"*;

(2) Perform the survey required by 41.3(16)*"a"* again; and

(3) Include in the report required by 41.3(16)*"d"* the results of the initial survey, a description of the modification made to comply with 41.3(5)*"b"*(1), and the results of the second survey; or

(4) Request and receive written authorization from the agency that authorizes radiation levels in unrestricted areas greater than those permitted by 641—paragraphs 40.26(1)*"a"* and *"b."*

c. Dosimetry equipment.

(1) The registrant shall have a calibrated dosimetry system available for use. The system shall have been calibrated by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL). The calibration shall have been performed within the previous 24 months and after any servicing that may have affected system calibration.

1. For beams with energies greater than 1 MV (1 MeV), the dosimetry system shall have been calibrated for Cobalt-60.

2. For beams with energies equal to or less than 1 MV (1 MeV), the dosimetry system shall have been calibrated at an energy (energy range) appropriate for the radiation being measured.

(2) The registrant shall have available for use a dosimetry system for quality assurance check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with 41.3(16)*"c"*(1). This comparison shall have been performed within the previous 12 months and after each servicing that may have affected system calibration. The quality assurance check system may be the same system used to meet the requirement in 41.3(16)*"c"*(1).

(3) The registrant shall maintain a record of each dosimetry system calibration, intercomparison, and comparison for the duration of the license or registration. For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 41.3(16)*"c"*(1) and (2), the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison was performed by, or under the direct supervision and in the physical presence of, a radiation therapy physicist.

d. Reports of external beam radiation therapy surveys and measurements. The registrant for any therapeutic radiation machine subject to 41.3(17) or 41.3(18) shall furnish a copy of the records required in 41.3(16)*"a"* and *"b"* to the agency within 30 days following completion of the action that initiated the record requirement.

41.3(17) Therapeutic radiation machines of less than 500 kV.

a. Equipment requirements.

(1) Leakage radiation. When the X-ray tube is operated at its maximum rated tube current for the maximum kV, the leakage air kerma rate shall not exceed the value specified at the distance specified for that classification of therapeutic radiation machine:

1. 5-50 kV systems. The leakage air kerma rate measured at any position 5 centimeters from the tube housing assembly shall not exceed 100 mrad (1 mGy) in any one hour.

2. >50 and <500 kV systems. The leakage air kerma rate measured at a distance of one meter from the target in any direction shall not exceed 1 rad (1 cGy) in any one hour. This air kerma rate

measurement may be averaged over areas no larger than 100 square centimeters. In addition, the air kerma rate at a distance of 5 centimeters from the surface of the tube housing assembly shall not exceed 30 rad (30 cGy) per hour.

3. For each therapeutic machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at positions specified in 41.3(17)*"a"*(1)"1" and 41.3(17)*"a"*(1)"2" for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the facility for inspection by the agency.

(2) Permanent beam-limiting devices. Permanent diaphragms or cones used for limiting the useful beam shall provide at least the same degree of attenuation as required for the tube housing assembly.

(3) Adjustable or removable beam-limiting devices.

1. All adjustable or removable beam-limiting devices, diaphragms, cones or blocks shall not transmit more than 5 percent of the useful beam for the most penetrating beam used;

2. When adjustable beam-limiting devices are used, the position and shape of the radiation field shall be indicated by a light beam.

(4) Filter system. The filter system shall be so designed that:

1. Filters cannot be accidentally displaced at any possible tube orientation;

2. For equipment installed after July 9, 1997, an interlock system prevents irradiation if the proper filter is not in place;

3. The air kerma rate escaping from the filter slot shall not exceed 1 rad (1 cGy) per hour at one meter under any operating conditions; and

4. Each filter shall be marked as to its material of construction and its thickness.

(5) Tube immobilization.

1. The X-ray tube shall be so mounted that it cannot accidentally turn or slide with respect to the housing aperture; and

2. The tube housing assembly shall be capable of being immobilized for stationary portal treatments.

(6) Source marking. The tube housing assembly shall be so marked that it is possible to determine the location of the source to within 5 millimeters, and such marking shall be readily accessible for use during calibration procedures.

(7) Beam block. Contact therapy tube housing assemblies shall have a removable shield of material, equivalent in attenuation to 0.5 millimeters of lead at 100 kV, which can be positioned over the entire useful beam exit port during periods when the beam is not in use.

(8) Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a preset time interval.

1. A timer which has a display shall be provided at the treatment control panel. The timer shall have a preset time selector and an elapsed time or time remaining indicator;

2. The timer shall be a cumulative timer which activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

3. The timer shall terminate irradiation when a preselected time has elapsed, if any dose monitoring system present has not previously terminated irradiation;

4. The timer shall permit accurate presetting and determination of exposure times as short as one second;

5. The timer shall not permit an exposure if set at zero;

6. The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer error correction to compensate for mechanical lag; and

7. Timer shall be accurate to within 1 percent of the selected value or one second, whichever is greater.

(9) Control panel functions. The control panel, in addition to the displays required by other provisions in 41.3(6), shall have:

1. An indication of whether electrical power is available at the control panel and if activation of the X-ray tube is possible;

2. An indication of whether X-rays are being produced;
3. Means for indicating X-ray tube potential and current;
4. The means for terminating an exposure at any time;
5. A locking device which will prevent unauthorized use of the therapeutic radiation machine; and
6. For therapeutic radiation machines manufactured after July 9, 1997, a positive display of specific filter(s) in the beam.

(10) Multiple tubes. When a control panel may energize more than one X-ray tube:
1. It shall be possible to activate only one X-ray tube at any time;
2. There shall be an indication at the control panel identifying which X-ray tube is activated; and
3. There shall be an indication at the tube housing assembly when that tube is energized.

(11) Target-to-skin distance (TSD). There shall be a means of determining the central axis TSD to within one centimeter and of reproducing this measurement to within two millimeters thereafter.

(12) Shutters. Unless it is possible to bring the X-ray output to the prescribed exposure parameters within five seconds after the X-ray "ON" switch is energized, the beam shall be attenuated by a shutter(s) having a lead equivalency not less than that of the tube housing assembly. In addition, after the unit is at operating parameters, the shutter(s) shall be controlled by the operator from the control panel. An indication of shutter position shall appear at the control panel.

(13) Low filtration X-ray tubes. Each therapeutic radiation machine equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and shall be provided with a permanent warning device on the control panel that is activated when no additional filtration is present, to indicate that the dose rate is very high.

b. Facility design requirements for therapeutic radiation machines capable of operating in the range 50 kV to 500 kV. In addition to shielding adequate to meet requirements of 41.3(19), the treatment room shall meet the following design requirements:

(1) Aural communication. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel.

(2) Viewing systems. Provision shall be made to permit continuous observation of the patient during irradiation and the viewing system shall be so located that the operator can observe the patient from the control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational.

(3) Additional requirements. Treatment rooms which contain a therapeutic radiation machine capable of operating above 150 kV shall meet the following additional requirements:
1. All protective barriers shall be fixed except for entrance doors or beam interceptors;
2. The control panel shall be located outside the treatment room or in a totally enclosed booth, which has a ceiling, inside the room;
3. Interlocks shall be provided such that all entrance doors, including doors to any interior booths, shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel; and
4. When any door referred to in 41.3(17)*"b"*(3)"3" is opened while the radiation machine is activated, the air kerma rate at a distance of one meter from the source shall be reduced to less than 1 mGy (100 mrad) per hour.

c. Full calibration measurements.

(1) Full calibration of a therapeutic radiation machine subject to 41.3(17) shall be performed by, or under the direct supervision of, a radiation therapy physicist:
1. Before the first medical use following installation or reinstallation of the therapeutic radiation machine;
2. At intervals not exceeding one year; and
3. Before medical use under the following conditions:

- Whenever quality assurance check measurements indicate that the radiation output differs by more than 5 percent from the value obtained at the last full calibration and the difference cannot be reconciled; and

- Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.

4. Notwithstanding the requirements of 41.3(17)*"c"*(1):

- Full calibration of therapeutic radiation machines with multienergy capabilities is required only for those modes or energies that are not within their acceptable range; and
- If the repair, replacement or modification does not affect all energies, full calibration shall be performed on the affected energy that is in most frequent clinical use at the facility. The remaining energies may be validated with quality assurance check procedures against the criteria in 41.3(17)*"b"*(3).

(2) To satisfy the requirement of 41.3(17)*"c"*(1), full calibration shall include all measurements recommended for annual calibration by NCRP Report 69, "Dosimetry of X-ray and Gamma Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV" (1981).

(3) The registrant shall maintain a record of each calibration for the duration of the registration. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for both the therapeutic radiation machine and the X-ray tube, the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine, and the signature of the radiation therapy physicist responsible for performing the calibration.

d. Periodic quality assurance checks.

(1) Periodic quality assurance checks shall be performed on therapeutic radiation machines, subject to 41.3(17), which are capable of operation at greater than or equal to 50 kV.

(2) To satisfy the requirement of 41.3(17)*"d"*(1), quality assurance checks shall meet the following requirements:

1. The registrant shall perform quality assurance checks in accordance with written procedures established by the radiation therapy physicist; and

2. The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed. The quality assurance check procedures shall specify that the quality assurance check shall be performed during the calibration specified in 41.3(17)*"c"*(1). The acceptable tolerance for each parameter measured in the quality assurance check, when compared to the value for that parameter determined in the calibration specified in 41.3(17)*"c"*(1), shall be stated.

(3) The cause for a parameter exceeding a tolerance set by the radiation therapy physicist shall be investigated and corrected before the system is used for patient or human research subject irradiation;

(4) Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the radiation therapy physicist's quality assurance check procedures, the system shall be recalibrated as required in 41.3(17)*"c"*(1);

(5) The registrant shall use the dosimetry system described in 41.3(16)*"c"*(2) to make the quality assurance check required in 41.3(17)*"d"*;

(6) The registrant shall have the radiation therapy physicist review and sign the results of each radiation output quality assurance check within one month of test completion;

(7) The registrant shall ensure that safety quality assurance checks of therapeutic radiation machines subject to 41.3(17) are performed at intervals not to exceed one month;

(8) Notwithstanding the requirements of 41.3(17)*"d"*(6) and (7), the registrant shall ensure that no therapeutic radiation machine is used to administer radiation to humans unless the quality assurance checks required by 41.3(17)*"d"*(6) and (7) have been performed within the 30 days prior to administration;

(9) To satisfy the requirement of 41.3(17)*"d"*(7), safety quality assurance checks shall ensure proper operation of:

1. Electrical interlocks at each external beam radiation therapy room entrance;

2. The "BEAM-ON" and termination switches;

3. Beam condition indicator lights on the access door(s), control console, and in the radiation therapy room;

4. Viewing systems;

5. If applicable, electrically operated treatment room doors from inside and outside the treatment room.

(10) The registrant shall maintain a record of each quality assurance check required by 41.3(17)*"d"*(1) and (7) for three years. The record shall include the date of the quality assurance check, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the manufacturer's name, model number and serial number of the instrument(s) used to measure the radiation output of the therapeutic radiation machine, and the signature of the individual who performed the periodic quality assurance check.

e. Operating procedures.

(1) Therapeutic radiation machines shall not be left unattended unless secured by means identified in 41.3(17)*"a"*(9)"5";

(2) When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used;

(3) The tube housing assembly shall not be held by an individual during operation unless the assembly is designed to require such holding and the peak tube potential of the system does not exceed 50 kV. In such cases, the holder shall wear protective gloves and apron of not less than 0.5 millimeters lead equivalency at 100 kV;

(4) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console; and

(5) No individual other than the patient shall be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV. At energies less than or equal to 150 kV, any individual, other than the patient, in the treatment room shall be protected by a barrier sufficient to meet the requirements of 641—40.26(136C).

(6) The therapeutic radiation machine shall not be used for irradiation of patients unless the requirements of 41.3(17)*"c"* and *"d"* have been met.

f. Possession of survey instrument(s). Each facility location authorized to use a therapeutic radiation machine in accordance with 41.3(17) shall have at its disposal appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 mrem (10 μSv) per hour to 1000 mrem (10 mSv) per hour. The survey instrument(s) shall be operable and calibrated at intervals not to exceed 12 months for the radiation measured.

41.3(18) Therapeutic radiation machines—photon therapy systems (500 kV and above) and electron therapy systems (500 keV and above).

a. Equipment requirements.

(1) Leakage radiation outside the maximum useful beam in photon and electron modes.

1. The absorbed dose due to leakage radiation (excluding neutrons) at any point outside the maximum-sized useful beam, but within a circular plane of radius two meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance (i.e., patient plane), shall not exceed a maximum of 0.2 percent and an average of 0.1 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters at a minimum of 16 points uniformly distributed in the plane;

2. Except for the area defined in 41.3(18)*"a"*(1)"1," the absorbed dose due to leakage radiation (excluding neutrons) at one meter from the electron path between the electron source and the target or electron window shall not exceed 0.5 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters;

3. For equipment manufactured after July 9, 1997, the neutron absorbed dose outside the useful beam shall be in compliance with International Electrotechnical Agency (IEC) Document 601-2-1 (most current revision); and

4. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in 41.3(18)*"a"*(1)"1" to "3" for the specified operating conditions. Records of leakage radiation measurements shall be maintained for inspection by the agency.

(2) Leakage radiation through beam-limiting devices.

1. Photon radiation. All adjustable or interchangeable beam-limiting devices shall attenuate the useful beam such that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam-limiting device(s) shall not exceed 2 percent of the maximum absorbed dose on the central axis of the useful beam measured in a 10-centimeter by 10-centimeter radiation field;

2. Electron radiation. All adjustable or interchangeable electron applicators shall attenuate the radiation including, but not limited to, photon radiation generated by electrons incident on the beam-limiting device and electron applicator and other parts of the radiation head, such that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance shall not exceed:

- A maximum of 2 percent and average of 0.5 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line seven centimeters outside the periphery of the useful beam; and
- A maximum of 10 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line two centimeters outside the periphery of the useful beam.

(3) Measurement of leakage radiation.

1. Photon radiation. Measurements of leakage radiation through the beam-limiting devices shall be made with the beam-limiting devices closed and any residual aperture blocked by at least two-tenth value layers of suitable absorbing material. In the case of overlapping beam-limiting devices, the leakage radiation through each set shall be measured independently at the depth of maximum dose. Measurements shall be made using a radiation detector with an area not exceeding ten square centimeters;

2. Electron radiation. Measurements of leakage radiation through the electron applicators shall be made with the electron beam directed into the air and using a radiation detector with an area up to but not exceeding one square centimeter suitably protected against radiation which has been scattered from material beyond the radiation detector. Measurements shall be made using one centimeter of water equivalent buildup material.

(4) Filters/wedges.

1. Each wedge filter which is removable from the system shall be clearly marked with an identification number. For removable wedge filters, the nominal wedge angle shall appear on the wedge or wedge tray (if permanently mounted to the tray). If the wedge or wedge tray is significantly damaged, the wedge transmission factor shall be redetermined;

2. If the absorbed dose rate information required by 41.3(18)*"a"*(9) relates exclusively to operation with a field-flattening filter or beam-scattering foil in place, such filter or foil shall be removable only by the use of tools;

3. For equipment manufactured after July 9, 1997, which utilizes a system of wedge filters, interchangeable field-flattening filters, or interchangeable beam-scattering foils:

- Irradiation shall not be possible until a selection of a filter or a positive selection to use "no filter" has been made at the treatment control panel, either manually or automatically;
- An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;
- A display shall be provided at the treatment control panel showing the wedge filter(s), interchangeable field-flattening filter(s), and interchangeable beam-scattering foil(s) in use; and
- An interlock shall be provided to prevent irradiation if any filter or beam-scattering foil selection operation carried out in the treatment room does not agree with the filter or beam-scattering foil selection operation carried out at the treatment control panel.

(5) Stray radiation in the useful beam. For equipment manufactured after July 9, 1997, the registrant shall determine during acceptance testing, or obtain from the manufacturer, data sufficient to ensure that X-ray stray radiation in the useful electron beam, absorbed dose at the surface during X-ray irradiation and stray neutron radiation in the useful X-ray beam are in compliance with International Electrotechnical Agency (IEC) Document 601-2-1 (most current revision).

(6) Beam monitors. All therapeutic radiation machines subject to 41.3(18) shall be provided with redundant beam monitoring systems. The sensors for these systems shall be fixed in the useful beam during treatment to indicate the dose monitor unit rate.

1. Equipment manufactured after July 9, 1997, shall be provided with at least two independently powered integrating dose meters. Alternatively, common elements may be used if the production of radiation is terminated upon failure of any common element.

2. Equipment manufactured on or before July 9, 1997, shall be provided with at least one radiation detector. This detector shall be incorporated into a useful beam monitoring system. The detector and the system into which that detector is incorporated shall meet the following requirements:

- Each detector shall be removable only with tools and, if movable, shall be interlocked to prevent incorrect positioning;
- Each detector shall form part of a beam monitoring system from whose readings in dose monitor units the absorbed dose at a reference point can be calculated;
- Each beam monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation; and

3. For equipment manufactured after July 9, 1997, the design of the beam monitoring systems shall ensure that the:

- Malfunctioning of one system shall not affect the correct functioning of the other system(s); and
- Failure of any element common to both systems which could affect the correct function of both systems shall terminate irradiation or prevent the initiation of radiation.

4. Each beam monitoring system shall have a legible display at the treatment control panel. For equipment manufactured after July 9, 1997, each display shall:

- Maintain a reading until intentionally reset;
- Have only one scale and no electrical or mechanical scale multiplying factors;
- Utilize a design such that increasing dose is displayed by increasing numbers; and
- In the event of power failure, the beam monitoring information required in 41.3(18)*"a"*(6)"4" displayed at the control panel at the time of failure shall be retrievable in at least one system for a 20-minute period of time.

(7) Beam symmetry.

1. Bent-beam linear accelerators with beam-flattening filter(s) subject to 41.3(18) shall be provided with auxiliary device(s) to monitor beam symmetry;

2. The device(s) referenced in 41.3(18)*"a"*(7)"1" shall be able to detect field asymmetry greater than 10 percent, and shall be configured to terminate irradiation if field asymmetry cannot be maintained at 10 percent or less.

(8) Selection and display of dose monitor units.

1. The preselected number of dose monitor units shall be displayed at the treatment control panel until reset manually;

2. After termination of irradiation, it shall be necessary to reset the dosimeter display before subsequent treatment can be initiated; and

3. For equipment manufactured after July 9, 1997, after termination of irradiation, it shall be necessary for the operator to reset the preselected dose monitor units before irradiation can be initiated.

4. Irradiation shall not be possible until a new selection of a number of dose monitor units has been made at the treatment control panel.

(9) Air kerma rate/absorbed dose rate. For equipment manufactured after July 9, 1997, a system shall be provided from whose readings the air kerma rate or absorbed dose rate at a reference point can be calculated. (The radiation detectors specified in 41.3(18)*"a"*(6) may form part of this system.) In addition:

1. The dose monitor unit rate shall be displayed at the treatment control panel;

2. If the equipment can deliver under any conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device shall be provided which terminates irradiation when the air kerma rate or absorbed dose rate exceeds a

value twice the specified maximum. The dose rate at which the irradiation will be terminated shall be a record maintained by the registrant;

3. If the equipment can deliver under any fault condition(s) an air kerma rate or absorbed dose rate at the nominal treatment distance more than ten times the maximum value specified by the manufacturer, a device shall be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds 400 rad (4 Gy); and

4. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the maximum value(s) specified in 41.3(18)*"a"*(7)"2" and "3" for the specified operating conditions. Records of these maximum value(s) shall be maintained at the installation for inspection by the agency.

(10) Termination of irradiation by the beam monitoring system or systems during stationary beam radiation therapy.

1. Each primary system shall terminate irradiation when the preselected number of dose monitor units has been detected by the system;

2. If the original design of the equipment included a secondary dose monitoring system, that system shall be capable of terminating irradiation when not more than 15 percent or 40 dose monitor units above the preselected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system; and

3. For equipment manufactured after July 9, 1997, an indicator on the control panel shall show which monitoring system has terminated irradiation.

(11) Termination switches. It shall be possible to terminate irradiation and equipment movement or go from an interruption condition to termination condition at any time from the operator's position at the treatment control panel.

(12) Interruption switches. If a therapeutic radiation machine has an interrupt mode, it shall be possible to interrupt irradiation and equipment movements at any time from the treatment control panel. Following an interruption it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change of a preselected value is made during an interruption, irradiation and equipment movements shall be automatically terminated.

(13) Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a preset time interval.

1. A timer shall be provided which has a display at the treatment control panel. The timer shall have a preset time selector and an elapsed time indicator;

2. The timer shall be a cumulative timer which activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

3. The timer shall terminate irradiation when a preselected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

(14) Selection of radiation type. Equipment capable of both X-ray therapy and electron therapy shall meet the following additional requirements:

1. Irradiation shall not be possible until a selection of radiation type (X-rays or electrons) has been made at the treatment control panel;

2. The radiation type selected shall be displayed at the treatment control panel before and during irradiation;

3. An interlock system shall be provided to ensure that the equipment can principally emit only the radiation type which has been selected;

4. An interlock system shall be provided to prevent irradiation with X-rays, except to obtain a verification image, when electron applicators are fitted;

5. An interlock system shall be provided to prevent irradiation with electrons when accessories specific for X-ray therapy are fitted; and

6. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

(15) Selection of energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:

1. Irradiation shall not be possible until a selection of energy has been made at the treatment control panel;

2. The nominal energy value selected shall be displayed at the treatment control panel until reset manually for the next irradiation. After termination of irradiation, it shall be necessary to reset the nominal energy value selected before subsequent treatment can be initiated; and

3. Irradiation shall not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location.

4. For equipment manufactured after July 9, 1997, the selection of energy shall be in compliance with International Electrotechnical Commission (IEC) Document 60601-2-1.

(16) Selection of stationary beam radiation therapy or moving beam radiation therapy. Therapeutic radiation machines capable of both stationary beam radiation therapy and moving beam radiation therapy shall meet the following requirements:

1. Irradiation shall not be possible until a selection of stationary beam radiation therapy or moving beam radiation therapy has been made at the treatment control panel;

2. The mode of operation shall be displayed at the treatment control panel;

3. An interlock system shall be provided to ensure that the equipment can operate only in the mode which has been selected;

4. An interlock system shall be provided to prevent irradiation if any selected parameter in the treatment room does not agree with the selected parameter at the treatment control panel;

5. Moving beam radiation therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental movement. For equipment manufactured after July 9, 1997:

- An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any ten degrees of rotation or one centimeter of linear motion differs by more than 20 percent from the selected value;
- Where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units delivered shall differ by less than 5 percent from the dose monitor unit value selected;
- An interlock shall be provided to prevent motion of more than five degrees or one centimeter beyond the selected limits during moving beam radiation therapy;
- An interlock shall be provided to require that a selection of direction be made at the treatment control panel in all units which are capable of both clockwise and counterclockwise moving beam radiation therapy.
- Moving beam radiation therapy shall be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement.

6. Where the beam monitoring system terminates the irradiation in moving beam radiation therapy, the termination of irradiation shall be as required by 41.3(18)*"a"*(10); and

7. For equipment manufactured after July 9, 1997, an interlock system shall be provided to terminate irradiation if movement:

- Occurs during stationary beam radiation therapy; or
- Does not start or stops during moving beam radiation therapy unless such stoppage is a preplanned function.

b. Facility design requirements for therapeutic radiation machines operating above 500 kV. In addition to shielding adequate to meet requirements of 41.3(19), the following design requirements are made:

(1) Protective barriers. All protective barriers shall be fixed, except for access doors to the treatment room or movable beam interceptors.

(2) Control panel. In addition to other requirements specified in 41.3(136C), the control panel shall also:

1. Be located outside the treatment room;

2. Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;

3. Provide an indication of whether radiation is being produced; and

4. Include an access control (locking) device which will prevent unauthorized use of the therapeutic radiation machine.

(3) Viewing systems. Windows, mirrors, closed-circuit television or an equivalent viewing system shall be provided to permit continuous observation of the patient following positioning and during irradiation and shall be so located that the operator may observe the patient from the treatment control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational.

(4) Aural communications. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel. The therapeutic radiation machine shall not be used for irradiation of patients unless continuous two-way aural communication is possible.

(5) Room entrances. Treatment room entrances shall be provided with warning lights in a readily observable position near the outside of all access doors, which will indicate when the useful beam is "ON" and when it is "OFF".

(6) Entrance interlocks. Interlocks shall be provided such that all access controls are activated before treatment can be initiated or continued. If the radiation beam is interrupted by any access control, it shall not be possible to restore the machine to operation without resetting the access control and reinitiating irradiation by manual action at the control panel.

(7) Beam interceptor interlocks. If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with 641—paragraphs 40.26(1)*"a"* and *"b,"* interlocks shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barrier(s).

(8) Emergency cutoff switches. At least one emergency power cutoff switch shall be located in the radiation therapy room and shall terminate all equipment electrical power including radiation and mechanical motion. This switch is in addition to the termination switch required by 41.3(18)*"a"*(11). All emergency power cutoff switches shall include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch.

(9) Safety interlocks. All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine.

(10) Surveys for residual radiation. Surveys for residual activity shall be conducted on all therapeutic radiation machines capable of generating photon and electron energies above 10 MV prior to machining, removing, or working on therapeutic radiation machine components which may have become activated due to photoneutron production.

(11) Possession of survey instrument(s). Each facility location authorized to use a therapeutic radiation machine in accordance with 41.3(18) shall have at its disposal appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 mrem (10 μSv) per hour to 1000 mrem (10 mSv) per hour. The survey instrument(s) shall be operable and calibrated at intervals not to exceed 12 months for the radiation measured.

c. Radiation therapy physicist support.

(1) The services of a radiation therapy physicist shall be required in facilities having therapeutic radiation machines with energies of 500 kV and above. The radiation therapy physicist shall be responsible for:

1. Full calibration(s) required by 41.3(18)*"e"* and protection surveys required by 41.3(16)*"a"*;

2. Supervision and review of dosimetry;

3. Beam data acquisition and transfer for computerized dosimetry, and supervision of its use;

4. Quality assurance, including quality assurance check review required by 41.3(18)*"f"*(5) of these regulations;

5. Consultation with the authorized user in treatment planning, as needed; and

6. Performing calculations/assessments regarding misadministrations.

(2) If the radiation therapy physicist is not a full-time employee of the registrant, the operating procedures required by 41.3(18)*"d"* shall also specifically address how the radiation therapy physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the radiation therapy physicist can be contacted.

d. Operating procedures.

(1) No individual, other than the patient, shall be in the treatment room during treatment or during any irradiation for testing or calibration purposes;

(2) Therapeutic radiation machines shall not be made available for medical use unless the requirements of 41.3(16)*"a,"* 41.3(18)*"e,"* and 41.3(18)*"f"* have been met;

(3) Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use;

(4) When adjustable beam-limiting devices are used, the position and shape of the radiation field shall be indicated by a light field;

(5) If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used; and

(6) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console.

e. Acceptance testing, commissioning, and full calibration measurements.

(1) Acceptance testing, commissioning, and full calibration of a therapeutic radiation machine subject to 41.3(18) shall be performed by, or under the direct supervision of, a radiation therapy physicist:

1. Acceptance testing and commissioning shall be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47," prepared by Radiation Therapy Task Group 45, and the manufacturer's contractual specifications and shall be conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine;

2. Full calibration shall include measurement of all parameters listed in Appendix D of 641—Chapter 41 and shall be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47," prepared by Radiation Therapy Task Group 45. Although it shall not be necessary to complete all elements of a full calibration at the same time, all parameters (for all energies) shall be completed at intervals not to exceed 12 calendar months, unless a more frequent interval is required by this agency.

3. The radiation therapy physicist shall perform all elements of a full calibration necessary to determine that all parameters are within acceptable limits:

- Whenever quality assurance check measurements indicate that the radiation output differs by more than 5 percent from the value obtained at the last full calibration and the difference cannot be reconciled. Therapeutic radiation machines with multienergy or multimode capabilities or both shall only require measurements for those modes or energies that are not within their acceptable range; and
- Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam. If the repair, replacement or modification does not affect all modes or energies, measurements shall be performed on the affected mode/energy that is in most frequent clinical use at the facility. The remaining energies/modes may be validated with quality assurance check procedures against the criteria in 41.3(18)*"e"*(1)"3."

(2) The registrant shall use the dosimetry system described in 41.3(16)*"c"* to measure the radiation output for one set of exposure conditions.

(3) The registrant shall maintain a record of each calibration in an auditable form for the duration of the registration. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine, and the signature of the radiation therapy physicist responsible for performing the calibration.

f. Periodic quality assurance checks.

(1) Periodic quality assurance checks shall be performed on all therapeutic radiation machines subject to 41.3(18) at intervals as specified in Appendix D of 641—Chapter 41;

(2) To satisfy the requirement of 41.3(18)*"f"*(1), quality assurance checks shall include determination of central axis radiation output and a representative sampling of periodic quality assurance checks contained in Appendix D of 641—Chapter 41. Representative sampling shall include all referenced periodic quality assurance checks at intervals not to exceed 12 consecutive calendar months;

(3) The registrant shall use a dosimetry system which has been intercompared within the previous 12 months with the dosimetry system described in 41.3(16)*"c"*(1) to make the periodic quality assurance checks required in 41.3(18)*"f"*(2);

(4) The registrant shall perform periodic quality assurance checks required by 41.3(18)*"f"*(1) in accordance with procedures established by the radiation therapy physicist;

(5) The registrant shall review the results of each periodic radiation output check according to the following procedures:

1. The authorized user and radiation therapy physicist shall be immediately notified if any parameter is not within its acceptable tolerance. The therapeutic radiation machine shall not be made available for subsequent medical use until the radiation therapy physicist has determined that all parameters are within their acceptable tolerances;

2. If all quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either the authorized user or radiation therapy physicist within three treatment days; and

3. The radiation therapy physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed one month.

(6) Therapeutic radiation machines subject to 41.3(18) shall have safety quality assurance checks of each external beam radiation therapy machine performed at intervals not to exceed one week;

(7) To satisfy the requirement of 41.3(18)*"f"*(6), safety quality assurance checks shall ensure proper operation of:

1. Electrical interlocks at each external beam radiation therapy room entrance;

2. Proper operation of the "BEAM-ON," interrupt and termination switches;

3. Beam condition indicator lights on the access doors, control console, and in the radiation therapy room;

4. Viewing systems;

5. Aural systems;

6. Electrically operated treatment room door(s) from inside and outside the treatment room;

7. At least one emergency power cutoff switch. If more than one emergency power cutoff switch is installed and not all switches are tested at once, each switch shall be tested on a rotating basis. Safety quality assurance checks of the emergency power cutoff switches may be conducted at the end of the treatment day in order to minimize possible stability problems with the therapeutic radiation machine;

(8) Rescinded IAB 4/11/07, effective 5/16/07.

(9) The registrant shall promptly repair any system identified in 41.3(18)*"f"*(7) that is not operating properly; and

(10) The registrant shall maintain a record of each quality assurance check required by 41.3(18)*"f"*(1) and 41.3(18)*"f"*(7) for three years. The record shall include the date of the quality assurance check, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the manufacturer's name, model number and serial number of the instrument(s) used to measure the radiation output of the therapeutic radiation machine, and the signature of the individual who performed the periodic quality assurance check.

41.3(19) Shielding and safety design requirements.

a. Each therapeutic radiation machine subject to 41.3(17) or 41.3(18) shall be provided with such primary or secondary barriers as are necessary to ensure compliance with 641—40.15(136C) and 641—40.26(136C).

b. Facility design information for all new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine of higher energy into a room not previously approved for that energy shall be submitted for agency approval prior to actual installation of the therapeutic radiation machine. The minimum facility design information that must be submitted is contained in Appendix E of 641—Chapter 41.

41.3(20) Calibration of survey instruments.

a. The registrant shall ensure that the survey instruments used to show compliance with 645—41.3(136C) have been calibrated before first use, at intervals not to exceed 12 months, and following repair.

b. To satisfy the requirements of 41.3(20), the registrant shall:

(1) Calibrate all required scale readings up to 1000 mrem (10 mSv) per hour with an appropriate radiation source that is traceable to the National Institute of Standards and Technology (NIST);

(2) Calibrate at least two points on each scale to be calibrated. These points should be at approximately 1/3 and 2/3 of full scale;

(3) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 10 percent; and

(4) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 20 percent if a correction factor or graph is conspicuously attached to the instrument.

c. The registrant shall retain a record of each calibration required in 41.3(20) for three years. The record shall include:

(1) A description of the calibration procedure; and

(2) A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

d. The registrant may obtain the services of individuals licensed by this agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state to perform calibrations of survey instruments. Records of calibrations that contain information required in 41.3(20) shall be maintained by the registrant.

641—41.4(136C) Radiation safety requirements for analytical X-ray equipment. Rescinded IAB 4/8/98, effective 7/1/98.

641—41.5(136C) Radiation safety requirements for wireline service operations and subsurface tracer studies. Rescinded IAB 4/8/98, effective 7/1/98.

641—41.6(136C) X-ray machines used for screening and diagnostic mammography.

41.6(1) *Definitions.* In addition to the definitions provided in 641—38.2(136C), 641—40.2(136C), and 641—41.1(136C), the following definitions shall be applicable to this rule.

"Accreditation body" means an entity that has been approved by FDA to accredit mammography facilities.

"Action limits" or *"action levels"* means the minimum and maximum values of a quality assurance measurement that can be interpreted as representing acceptable performance with respect to the parameter being tested. Values less than the minimum or greater than the maximum action limit or level indicate that corrective action must be taken by the facility. Action limits or levels are also sometimes called control limits or levels.

"Adverse event" means an undesirable experience associated with mammography activities. Adverse events include but are not limited to:

1. Poor image quality;

2. Failure to send mammography reports within 30 days to the referring physician or in a timely manner to the self-referred patient; and

3. Use of personnel who do not meet the applicable requirements of this chapter.

"Air kerma" means kerma in a given mass of air. The unit used to measure the quantity of air kerma is the Gray (Gy). For X-rays with energies less than 300 kiloelectronvolts (keV), 1 Gray of absorbed dose is delivered by 114 roentgens (R) of exposure.

"Annually" means within 10 to 14 months of previous occurrence.

"Artifact" means a substance or structure not naturally present in living tissue but of which an authentic image appears in a radiograph.

"Automatic exposure control systems" means automatic exposure control systems, often referred to as phototimers, which are designed to automatically determine and provide the exposure needed to produce an adequate density image by sampling the X-ray intensity after passage through the patient and image receptor.

"Average glandular dose" means the energy deposited per unit mass of glandular tissue averaged over all the glandular tissue in the breast, calculated from values of entrance exposure in air, the X-ray beam quality (half-value layer), and compressed breast thickness. For a 50 percent-50 percent adipose and glandular 4.2 centimeter breast, the average glandular dose shall not exceed 300 millirad (3 mGy). See also: "Dose."

"Breast implant" means a prosthetic device implanted in the breast.

"Calendar quarter" means any one of the following time periods during a given year: January 1 through March 31, April 1 through June 30, July 1 through September 30, or October 1 through December 31.

"Category 1" means medical education activities that have been designated as Category 1 by the Accreditation Council for Continuing Medical Education (ACCME), the American Osteopathic Association (AOA), a state medical society, or an equivalent organization.

"Certificate" means the certificate described in 41.6(2)*"a"*(2).

"Certification" means the process of approval of a facility by the FDA or this agency to provide mammography services.

"Clinical image" means a mammogram.

"Compression device" means a firm plastic paddle used to help hold the breast stationary and eliminate blurring due to motion, to help separate structures within the breast, and to decrease the thickness of breast tissue, minimizing the amount of radiation used and the amount of scattered radiation reaching the film.

"Computed radiography mammography" means a type of digital mammography in which the digital image receptor must be removed from the X-ray unit for the image to be read and processed by a separate image receptor reader.

"Consumer" means an individual who chooses to comment or complain in reference to a mammography examination, including the patient or representative of the patient (e.g., family member or referring physician).

"Contact hour" means an hour of training received through direct instruction.

"Continuing education unit" or *"continuing education credit"* means one contact hour of training.

"Craniocaudal view" means one of two routine views for mammography. The detector system is placed caudad to (below) the breast and the vertical X-ray beam is directed from cranial to caudad (downward) through the breast.

"Dedicated mammography equipment" means X-ray systems designed specifically for breast imaging, providing optimum imaging geometry, a device for breast compression and low dose exposure that can generate reproducible images of high quality.

"Direct detector technology" means a digital mammogram captured using a material which converts the X-ray energies directly to an electric signal.

"Direct instruction" means:

1. Face-to-face interaction between instructor(s) and student(s), as when the instructor provides a lecture, conducts demonstrations, or reviews student performance; or

2. The administration and correction of student examinations by an instructor(s) with subsequent feedback to the student(s).

"Direct supervision" means that:

1. During joint interpretation of mammograms, the supervising interpreting physician reviews, discusses, and confirms the diagnosis of the physician being supervised and signs the resulting report before it is entered into the patient's records; or

2. During the performance of a mammography examination or survey of the facility's equipment and quality assurance program, the supervisor is present to observe and correct, as needed, the performance of the individual being supervised who is performing the examination or conducting the survey.

"Dose" means the amount of energy deposited per unit mass of tissue due to X-radiation. The newer unit of absorbed dose is the Gray: 1 Gray=1 Joule of energy deposited per kilogram of tissue. The older unit of absorbed dose is the rad: 1 rad=0.01 Gray, 1 centiGray, or 10 milliGray.

"Exposure" means the amount of X-radiation, quantitated by measuring the amount of ionization in air caused by the radiation. The units of exposure are Coulombs of charge ionized per kilogram of air. The older unit of exposure is the Roentgen: 1 Roentgen=2.58 × 10E-4 Coulombs of charge per kilogram of air.

"Facility" means a hospital, outpatient department, clinic, radiology practice, mobile unit, office of a physician, or other facility that conducts mammography activities, including the following: operation of equipment to produce a mammogram, initial interpretation of the mammogram, and maintaining viewing conditions for that interpretation. This term does not include a facility of the Department of Veterans Affairs.

"FDA" means the Food and Drug Administration.

"First allowable time" means the earliest time a resident physician is eligible to take the diagnostic radiology boards from an FDA-designated certifying body. The "first allowable time" may vary with the certifying body.

"Full field digital mammography" means radiographic imaging of the breast using a digital image receptor with minimum dimensions of 18×23 cm to allow imaging the average size breast in a single exposure.

"Grids" means a set of thin lead strips spaced close to one another, interspaced by carbon fiber for mammographic grids. The grid is placed between the breast and the screen-film image receptor to reduce scattered radiation reaching the image receptor.

"Image noise." See "Radiographic noise."

"Image receptor support device" means, for mammography X-ray systems, that part of the system designed to support the image receptor during a mammographic examination and to provide a primary protective barrier.

"Interpreting physician" means a licensed radiologist who interprets mammograms and who meets the requirements set forth in 41.6(3)*"a."*

"Kerma" means the sum of the initial energies of all the charged particles liberated by uncharged ionizing particles in a material of given mass.

"Laterality" means the designation of either the right or left breast.

"Lead interpreting physician" means the interpreting physician assigned the general responsibility for ensuring that a facility's quality assurance program meets all of the requirements of this chapter. The administrative title and other supervisory responsibilities of the individual, if any, are left to the discretion of the facility.

"Mammogram" means a radiographic image produced through mammography.

"Mammographic modality" means a technology for radiography of the breast. Examples are screen-film mammography, xeromammography, and digital mammography.

"Mammography" means radiography of the breast but, for the purposes of 641—41.6(136C), does not include:

1. Radiography of the breast performed during invasive interventions for localization or biopsy procedures; or

2. Radiography of the breast performed with an investigational mammography device as part of a scientific study conducted in accordance with FDA investigational device exemption regulations; or

3. Radiography of the breast performed as part of either a breast localization procedure or a post-stereotactic clip placement localization procedure.

"Mammography equipment evaluation" means an on-site assessment of the mammography unit or image processor performance by a medical physicist for the purpose of making a preliminary determination as to whether the equipment meets all of the applicable standards.

"Mammography medical outcomes audit" means a systematic collection of mammography results and the comparison of those results with outcomes data.

"Mammography unit(s)" means an assemblage of components for the production of X-rays for use during mammography including, at a minimum: an X-ray generator, an X-ray control, a tube housing assembly, a beam limiting device, and the supporting structures for these components.

"Mean optical density" means the average of the optical densities measured using phantom thicknesses of 2, 4, and 6 centimeters with values of kilovolt peak (kVp) clinically appropriate for those thicknesses.

"Medical physicist" means a person trained in evaluating the performance of mammography equipment and facility quality assurance programs and who meets the qualifications for a medical physicist set forth in 41.6(3)*"c."*

"Mediolateral view" means one of the routine views for mammography in addition to the craniocaudal view. The detector system is placed lateral to the breast and the horizontal X-ray beam is directed from medial to lateral aspect through the breast.

"MQSA" means the Mammography Quality Standards Act of 1992.

"Multi-reading" means two or more physicians, at least one of whom is an interpreting physician, interpreting the same mammogram. A radiologist may count the current mammographic examination and one prior mammographic examination, provided the radiologist was not the interpreter of the prior mammographic examination. A separate tally shall be kept for the prior examinations.

"Oblique mediolateral view" means one of the standard two views of the breast. The detector system (cassette holder assembly) is angled 30-60 degrees from horizontal so that the cassette assembly is parallel to the pectoral muscle and the corner of the cassette holder fits comfortably into the axilla. The X-ray beam is directed from the supero-medial to the infero-lateral aspect of the breast.

"Patient" means any individual who undergoes a mammography evaluation in a facility, regardless of whether the person is referred by a physician or is self-referred.

"Phantom" means an artificial test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer.

"Phantom image" means a radiographic image of a phantom.

"Physical science" means physics, chemistry, radiation science (including medical physics and health physics), and engineering.

"Positive mammogram" means a mammogram that has an overall assessment of findings that are either "suspicious" or "highly suggestive of malignancy."

"Provisional certification" means the six-month certification time period in which a facility has to complete the accreditation/certification process.

"Qualified instructor" means individuals whose training and experience adequately prepare them to carry out specified training assignments. Interpreting physicians, radiologic technologists, or medical physicists who meet the requirements of 41.6(3) would be considered qualified instructors in their respective areas of mammography. Radiological technologists who meet the requirements of 41.6(3) and have passed a state-approved mammography examination such as the examination given by the American Registry of Radiography Technologists would be considered qualified instructors in their respective areas of mammography. The examination would include, but not necessarily be limited to: breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, and imaging of patients with breast implants. Other examples of individuals who may be qualified instructors for the purpose of providing training to meet the regulations of this chapter include, but are not limited to, instructors in a post-high school training institution and manufacturers' representatives.

"Quality control technologist" means an individual meeting the requirements of 41.6(5)*"a"*(4) who is responsible for those quality assurance responsibilities not assigned to the lead interpreting physician or to the medical physicist.

"Radiographic equipment" means X-ray equipment used for the production of static X-ray images.

"Radiologic technologist" means an individual specifically trained in the use of radiographic equipment and in the positioning of patients for radiographic examinations and who meets the requirements set forth in 41.6(3)*"b."*

"Radiologist continuing experience" means the number of mammograms interpreted by a radiologist in the past 24-month period. For the purpose of counting, a radiologist may count the current mammographic examination and one prior mammographic examination, provided the radiologist was not the interpreter of the prior mammographic examination. A separate tally shall be kept for the prior examinations.

"Reinstatement" means the process of recertification of a facility that has lost or voluntarily given up previous accreditation/certification.

"Screen-film mammography" means mammography performed with high-detailed intensifying screen(s) in close contact with the film.

"Screening mammography" means X-ray breast examination of asymptomatic individuals in an attempt to detect breast cancer when it is small, nonpalpable, and confined to the breast.

"Serious adverse event" means an adverse event that may significantly compromise clinical outcomes or an adverse event for which a facility fails to take appropriate corrective action in a timely manner.

"Serious complaint" means a report of a serious adverse event.

"Soft copy review workstation" means a configuration of two 5 megapixel monitors used for the interpretation of full field digital mammogram images.

"Standard breast" means a 4.2 centimeter (cm) thick compressed breast consisting of 50 percent glandular and 50 percent adipose tissue.

"Supplier" means the individual in control of a mammography facility whose basic responsibility is the overall quality of all mammograms conducted in that particular facility.

"Survey" means an on-site physics consultation and evaluation of a facility quality assurance program performed by a medical physicist.

"Time cycle" means the film development time.

"Traceable to a national standard" means an instrument is calibrated at either the National Institute of Standards and Technology (NIST) or at a calibration laboratory that participates in a proficiency program with NIST at least once every two years and the results of the proficiency test conducted within 24 months of calibration show agreement within ± 3 percent of the national standard in the mammography energy range.

"Written report" means interpreting physician's technical narrative of a mammography evaluation.

"Written statement" means interpreting physician's description of a mammography examination written in lay terms.

41.6(2) *Registration and application standards and requirements.*

a. Registration and certificates.

(1) Each radiation machine used to perform mammography shall be registered according to 641—subrule 39.3(2).

(2) A certificate issued by the FDA or this agency is required for lawful operation of all mammography facilities subject to the provisions of this subrule. To obtain a certificate from the FDA or this agency, facilities are required to meet the quality standards in 641—41.6(136C) and to be accredited and approved by an approved accreditation body.

b. Each facility wishing to perform mammography shall apply for agency approval by providing or verifying the following information for each mammography machine:

(1) The mammography unit meets the criteria for agency-approved mammography accreditation bodies.

(2) The mammography equipment and facility meet the general requirements of these rules for radiation machines.

(3) The radiation machine is specifically designed to perform mammography.

(4) The radiation machine is used according to these rules on patient radiation exposure and radiation dose levels.

(5) The radiation machine is operated by individuals meeting the requirements of this subrule.

(6) The entire mammography system is evaluated at least annually by a medical physicist.

(7) The equipment, personnel, procedures, and records are evaluated annually by a physician consultant.

(8) Provisional or reinstatement certification. A new facility beginning operation after September 30, 1994, is eligible to apply for provisional or reinstatement certification. This will enable the facility to perform mammography and to obtain the clinical images needed to complete the accreditation process. To apply for and receive provisional or reinstatement certification, a facility must meet the requirements of 641—41.6(136C). Provisional or reinstatement certification shall be effective for up to six months from the date of issuance and cannot be renewed. The facility may apply for one 90-day extension.

c. Suspension, revocation, or denial of mammography certification.

(1) Mammography certification may be suspended or revoked with cause if any facility or machine does not meet one or more of the standards of these rules, will not permit inspections or provide access to records or information in a timely fashion, or has been guilty of misrepresentation in obtaining the certification.

(2) The facility shall have opportunity for a hearing in connection with a denial, suspension or revocation of mammography certification in accordance with 641—Chapter 173.

(3) An emergency order suspending or revoking certification may be issued in accordance with 641—173.31(17A) if the agency finds the radiation unit or facility violates rules that seriously affect the health, safety, and welfare of the public. An opportunity for hearing shall be held within 20 working days after the issuance of the order. The order shall be effective during the proceedings.

(4) If certification is revoked, the radiation machine shall not be used for mammography until reinstated.

(5) If a facility's certification is revoked, no person who owned or operated that facility at the time the act occurred may own or operate a mammography facility in Iowa within two years of the date of revocation.

d. Reinstatement of mammography certification after revocation.

(1) An application for reinstatement shall be submitted and processed as an initial application. Appropriate corrective actions must be submitted with the application.

(2) The agency shall inspect the radiation machine within 60 days of the approved reinstatement application.

(3) A full certificate shall be issued only after the agency has inspected the radiation machine and determined that it meets the requirements of these rules.

e. Inspections. The agency shall conduct an inspection of each radiation machine no later than 14 months after initial mammography certification and at least annually thereafter.

f. The authorization of facilities is included in the accreditation process for facilities accredited by the state of Iowa. Determination of the quality of the mammograms produced by facilities accredited by the state of Iowa will be made. To make the determination, each facility will:

(1) Provide at the time of initial accreditation, new unit installation, or reaccreditation (at least every three years) thereafter, two original (not copies) mammography examinations which meet the following criteria for the clinical image review process by the agency:

1. One mammography examination, including craniocaudal and mediolateral oblique views of each breast, of a patient with predominantly fatty breast tissue,

2. One mammography examination, including craniocaudal and mediolateral oblique views of each breast, of a patient with predominantly glandular breast tissue, and

3. Each mammography examination must have been interpreted as a "negative" or "benign" examination.

(2) Provide randomly, at the request of agency mammography inspectors, two mammography examinations (mammograms) which meet the criteria in 41.6(2)*"f"*(1).

(3) Provide at the time of initial accreditation, new unit installation, or reaccreditation (at least every three years) thereafter, a phantom image taken with the unit being accredited within six months of the submission date for review by the agency.

(4) Be billed the fee for the quality review process as set forth in 641—subparagraph 38.8(1)*"b"*(2).

(5) Be provided with a written explanation of the results of the quality review process which will accompany the returned mammograms referred to in 41.6(2)*"f"*(3).

g. Facilities accredited by an approved accrediting body other than the state of Iowa must be authorized by the agency. Quality determination for these facilities will be made by the agency through a phantom image provided at the time of initial authorization, new unit authorization, or reauthorization (at least every three years) thereafter, taken with the unit being accredited within six months of the submission date.

h. Federal mammography regulations. All Iowa facilities performing mammography shall comply with the applicable regulations found in 21 CFR Part 900 which has an effective date of April 28, 1999. Persons certified to perform mammography in Iowa shall be responsible for ensuring compliance with the appropriate CFR regulations or Iowa administrative rules, whichever are more stringent.

i. Soft copy review workstation requirements. Soft copy review workstations used for final interpretation of mammogram images must be a configuration of two 5 megapixel monitors. The workstation must have a quality control program substantially the same as that outlined by the image receptor manufacturer's quality control manual or that outlined by the image receptor manufacturer's designated soft copy review workstation quality control manual.

41.6(3) *Mammography personnel.* The following requirements apply to all personnel involved in any aspect of mammography, including the production, processing, and interpretation of mammograms and related quality assurance activities:

a. Interpreting physicians. All radiologists interpreting mammograms shall meet the following qualifications:

(1) Initial qualifications. Unless the exemption in 41.6(3)*"a"*(3)"1" applies, before beginning to interpret mammograms independently, the interpreting radiologist shall:

1. Be licensed to practice medicine in Iowa;

2. Either:

- Be certified in an appropriate specialty area by a body determined by FDA to have procedures and requirements adequate to ensure that physicians certified by the body are competent to interpret radiological procedures, including mammography; or
- Have had at least three months of documented formal training in the interpretation of mammograms and in topics related to mammography. The training shall include instruction in radiation physics, including radiation physics specific to mammography, radiation effects, and radiation protection. The mammographic interpretation component shall be under the direct supervision of a radiologist who meets the requirements of 41.6(3)*"a"*; and

3. Have a minimum of 60 hours of documented medical education in mammography, which shall include: instruction in the interpretation of mammograms and education in basic breast anatomy, pathology, and physiology, technical aspects of mammography, and quality assurance and quality control in mammography. All 60 of these hours shall be Category 1 and at least 15 of the Category 1 hours shall have been acquired within the 36 months immediately prior to the date that the radiologist qualifies as an interpreting physician. Hours spent in residency specifically devoted to mammography will be considered as equivalent to Category 1 continuing medical education credits and will be accepted if documented in writing by the appropriate representative of the training institution;

4. Unless the exemption in 41.6(3)*"a"*(3)"2" applies, have interpreted or multi-read at least 240 mammographic examinations within the six-month period immediately prior to the date that the radiologist qualifies as an interpreting physician. This interpretation or multi-reading shall be under the direct supervision of an interpreting physician; and

5. Before an interpreting physician may begin independently interpreting mammograms produced by a new mammographic modality other than the modality in which the initial training was received, the interpreting physician shall have at least 8 hours of Category 1 continuing medical education credits in the new mammographic modality. An interpreting physician previously qualified to interpret full field digital mammography in another state will have six months to complete this requirement. The six-month time frame begins when the interpreting physician commences Iowa full field digital mammography interpretation.

(2) Continuing experience and education. All interpreting physicians shall maintain their qualifications by meeting the following requirements:

1. Following the second anniversary date of the end of the calendar quarter in which the requirements of 41.6(3)*"a"*(1) were completed, the interpreting physician shall have read or multi-read at least 960 mammographic examinations during the prior 24 months, during the 24-month period ending on the last day of the previous calendar quarter, or during any 24-month period between the two. The facility will choose one of these dates to determine the 24-month period.

2. Following the third anniversary date of the end of the calendar quarter in which the requirements of 41.6(3)*"a"*(1) were completed, the interpreting physician shall have taught or completed at least 15 Category 1 continuing education units in mammography during the prior 36 months, during the 36-month period ending on the last day of the previous calendar quarter, or during any 36-month period between the two. The facility will choose one of these dates to determine the 36-month period.

3. Units earned through teaching a specific course can be counted only once towards the 15 required by 41.6(3)*"a"*(2)"2" even if the course is taught multiple times during the previous 36 months.

4. Continuing qualifications must be met and a current state of Iowa medical license must be in effect whenever mammography interpretations are performed by the physician.

(3) Exemptions.

1. Those physicians who qualified as interpreting physicians under 41.6(3)*"a"* or FDA interim regulations prior to April 28, 1999, are considered to have met the initial requirements of 41.6(3)*"a."* They may continue to interpret mammograms provided they continue to meet the licensure requirements of 41.6(3)*"a"*(1)"1" and the continuing experience and education requirements of this subrule.

2. Physicians who have interpreted or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician in any six-month period during the last two years of a diagnostic radiology residency and who become appropriately board certified at the first allowable time, as defined by an eligible certifying body, are otherwise exempt from 41.6(3)*"a"*(1)"4."

(4) Reestablishing qualifications. Interpreting physicians who fail to maintain the required continuing experience or continuing education requirements shall reestablish their qualifications before resuming the independent interpretation of mammograms, as follows:

1. Interpreting physicians who fail to meet the continuing experience requirements of 41.6(3)*"a"*(2)"1" shall:

- Interpret or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician, or
- Interpret or multi-read a sufficient number of mammographic examinations, under the direct supervision of an interpreting physician, to bring the physician's total to at least 960 examinations for the prior 24 months, whichever is less. The interpretations required under 41.6(3)*"a"*(4)"1" shall be done within the six months immediately prior to resuming independent interpretation. Consecutive or back-to-back requalification of mammography personnel, due to failure to meet continuing education or experience requirements, will be allowed once without proof of extenuating circumstances. This agency will determine the validity of such proof and render a decision after review of all pertinent information. Those individuals who are denied requalification will be allowed to resubmit for requalification following a 90-day waiting period.

2. Interpreting physicians who fail to meet the continuing education requirements of 41.6(3)*"a"*(2)"2" shall obtain a sufficient number of additional Category 1 continuing medical education credits in mammography to bring their total up to the required 15 credits in the previous 36 months before resuming independent interpretation.

b. Radiologic technologists. All mammographic examinations shall be performed by general radiographers who meet the following general requirements, mammography requirements, and continuing education and experience requirements:

(1) General requirements. Be permitted to operate as a general radiographer in Iowa; and

(2) Mammography requirements. Have qualified as a radiologic technologist under 41.6(3)*"b"* before April 28, 1999, or have completed at least 40 contact hours of documented training specific to mammography under the supervision of a qualified instructor after successful completion of at least a two-year radiography program. The hours of documented training shall include, but not necessarily be limited to:

1. Training in breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, and imaging of patients with breast implants;

2. The performance of a minimum of 25 examinations under the direct supervision of an individual qualified under 41.6(3)*"b"*; and

3. Before a radiologic technologist may begin independently performing mammographic examinations using a mammographic modality other than one of those for which the technologist received training under 41.6(3)*"b"*(2)"3," the technologist shall have at least 8 hours of continuing education units in the new modality. The 8 hours may not be derived from the supervised examination of patients; and

(3) Continuing education requirements.

1. Following the third anniversary date of the end of the calendar quarter in which the requirements of 41.6(3)*"b"*(1) and (2) were completed, the radiologic technologist shall have taught or completed at least 15 continuing education units in mammography during the prior 36 months, during the 36-month period ending on the last day of the previous calendar quarter, or during any 36-month period between the two. The facility will choose one of these dates to determine the 36-month period.

2. Units earned through teaching a specific course can be counted only once towards the 15 required in 41.6(3)*"b"*(3)"1" even if the course is taught multiple times during the previous 36 months.

3. Requalification. A radiologic technologist who fails to meet the continuing education requirements of 41.6(3)*"b"*(3)"1" shall obtain a sufficient number of continuing education units in mammography to bring the total up to at least 15 in the previous 36 months. The continuing education for requalification cannot be obtained by performing supervised mammography examinations. The technologist may not resume performing unsupervised mammography examinations until the continuing education requirements are completed.

4. Continuing qualifications must be met and an Iowa permit to practice radiography must be in effect whenever mammogram procedures are performed by the radiologic technologist.

5. Only 50 percent of the total required mammography continuing education hours may be obtained through presenting, or acting as a trainer for, a continuing education or training program.

(4) Continuing experience requirements.

1. Following the second anniversary date on which the requirements of 41.6(3)*"b"*(1) and (2) were completed, the radiologic technologist shall have performed a minimum of 200 mammography examinations during the prior 24 months, during the 24-month period ending on the last day of the previous calendar quarter, or during any 24-month period between the two. The facility will choose one of these dates to determine the 24-month period.

2. Requalification. Radiologic technologists who fail to meet the continuing experience requirements of this subrule shall perform a minimum of 25 mammography examinations under the direct supervision of a qualified radiologic technologist before resuming the performance of unsupervised mammography examinations.

3. Continuing qualifications must be met and an Iowa permit to practice radiography must be in effect whenever mammogram procedures are performed by the radiologic technologist.

(5) Consecutive or back-to-back requalification of mammography personnel, due to failure to meet continuing education or experience requirements, will be allowed once without proof of extenuating circumstances. This agency will determine the validity of such proof and render a decision after review

of all pertinent information. Those individuals who are denied requalification will be allowed to resubmit for requalification following a 90-day waiting period.

c. Medical physicists. All medical physicists conducting surveys of mammography facilities and providing oversight of the facility quality assurance program under 41.6(3)*"c"*(2) shall meet the following:

(1) Initial qualifications.

1. Be Iowa approved; and

2. Have a master's degree or higher in a physical science from an accredited institution, with no less than 20 semester hours or 30 quarter hours of college undergraduate or graduate level physics;

3. Have 20 contact hours of documented specialized training in conducting surveys of mammography facilities; and

4. Have experience conducting surveys in at least one mammography facility and have a total of at least 10 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. After April 28, 1999, experience conducting surveys must be acquired under the direct supervision of a medical physicist who meets all the requirements of this subrule; or

(2) Alternative initial qualifications.

1. Have qualified as a medical physicist under FDA interim regulations and have retained that qualification by maintenance of the active status of any licensure, approval, or certification required under the interim regulations; and

2. Prior to April 28, 1999, have:

- A bachelor's degree or higher in a physical science from an accredited institution with no less than 10 semester hours or equivalent of college undergraduate or graduate level physics.
- Forty contact hours of documented specialized training in conducting surveys of mammography facilities.
- Experience conducting surveys in at least one mammography facility and have a total of at least 20 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. The training and experience requirements must be met after fulfilling the degree requirement.
- At least eight hours of training in surveying units of the new mammographic modality before independently performing mammographic surveys of a new mammographic modality other than one for which the physicist received training to qualify under this subrule.

(3) Continuing qualifications.

1. Continuing education. Following the third anniversary date on which the requirements of 41.6(3)*"c"*(1) or (2) were completed, the medical physicist shall have taught or completed at least 15 continuing education units in mammography during the prior 36 months, during the 36-month period ending on the last day of the previous calendar quarter, or during any 36-month period between the two. The facility shall choose one of these dates to determine the 36-month period. Units earned through teaching a specific course shall be counted only once towards the required 15 units in a 36-month period, even if the course is taught multiple times during the 36 months.

2. Continuing experience. Following the second anniversary date on which the requirements of this subrule were completed, the medical physicist shall have surveyed at least two mammography facilities and a total of at least 6 mammography units during the prior 24 months, during the 24-month period ending on the last day of the previous calendar quarter, or during any 24-month period between the two. The facility shall choose one of these dates to determine the 24-month period. No more than one survey of a specific facility within a 10-month period or a specific unit within a period of 60 days shall be counted towards this requirement.

3. Continuing qualifications must be met whenever medical physics services are provided by the medical physicist.

(4) Reestablishing qualifications. Medical physicists who fail to maintain the required continuing qualifications of this subrule may not perform the MQSA surveys without the supervision of a qualified

medical physicist. Before independently surveying another facility, medical physicists must reestablish their qualifications as follows:

1. Medical physicists who fail to meet the continuing education requirements of this subrule shall obtain a sufficient number of continuing education units to bring their total units up to the required 15 in the previous three years.

2. Medical physicists who fail to meet the continuing experience requirements of this subrule shall complete a sufficient number of surveys under the direct supervision of a medical physicist who meets the qualifications of this subrule to bring their total surveys up to the required two facilities and 6 units in the previous 24 months. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement.

d. *Retention of personnel records.* Facilities shall maintain records to document the qualifications of all personnel who worked at the facility as interpreting physicians, general radiographers, or medical physicists. These records must be available for review by the MQSA inspectors. Records of personnel no longer employed by the facility should not be discarded until the next annual inspection has been completed and the agency has determined that the facility is in compliance with the MQSA personnel requirements.

41.6(4) *Obtaining and preserving records.*

a. The facility performing the current mammography examination must make all reasonable efforts to obtain the patient's recent mammography records, including original images or films, copies of written reports prepared by interpreting physicians, and other relevant information pertinent to previous mammograms that might be available from other facilities, for comparison with the current mammography records.

b. The facility must make, for each patient, a written report of each mammography examination performed. This report shall include:

(1) The date the mammography procedure was performed.

(2) The date of the interpretation.

(3) The name of the interpreting physician.

(4) The name of the patient and an additional patient identifier.

(5) A description of the procedures performed.

(6) The name of the referring physician (if any) or other physician (if any) identified by the patient to receive the interpreting physician's written report.

(7) The date the interpreting physician's written report was sent to the appropriate physician or patient.

(8) A separate and distinct section entitled, "Assessment" with the appropriate assessment term. One of the following terms in quotations or an approved equivalent must be included in the assessment:

1. "Negative": Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained).

2. "Benign": Also a negative assessment.

3. "Probably benign": Finding(s) has a high probability of being benign.

4. "Suspicious": Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant.

5. "Highly suggestive of malignancy": Finding(s) has a high probability of being malignant.

6. "Incomplete: Need additional imaging evaluation" shall be assigned as an assessment in cases where no final assessment category can be assigned due to incomplete workup, and reasons why no assessment can be made shall be stated by the interpreting physician.

(9) Recommendations made to the health care provider about what additional actions, if any, should be taken. All clinical questions raised by the referring health care provider shall be addressed in the report to the extent possible, even if the assessment is negative or benign.

c. Preservation of records.

(1) The facility must provide satisfactory assurances (as documented in its medical records) that the images or films of the first and subsequent mammography procedures and the related written reports of the interpreting physician for each patient are either placed in the patient's medical record kept by the

facility or sent for placement in the patient's medical record as directed by the patient's physician or the patient.

(2) Records retained by the facility must be retained for at least 60 calendar months following the date of service, as long as the patient continues consecutive mammograms. If no additional mammograms of the patient are performed, the records must be retained for at least ten years.

(3) If the facility should cease to exist before the end of the retention period, the records must be transferred to the patient or patient's physician or other mammographic facility.

(4) The facility shall upon request by, or on behalf of, the patient, permanently or temporarily, transfer the original mammograms and copies of the patient's reports to a medical institution, or to a physician or health care provider of the patient, or to the patient directly.

(5) Any fee charged to the patient for providing the services in subparagraph (4) above shall not exceed the documented costs associated with this service.

d. Communication of results to the patient. Each facility shall maintain a system to ensure that the results of each mammographic examination are communicated in lay terms to each patient in a time period not to exceed 30 days from the date of the mammography examination. If assessments are "Suspicious" or "Highly suggestive of malignancy" and the patient has not named a health care provider, the facility shall make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.

(1) As soon as possible, but no later than 30 days from the date of the mammography examination, patients who do not name a health care provider to receive the mammography report shall be sent the report described in 41.6(4)*"e"*(1) in addition to a written notification of results in lay terms.

(2) Each facility that accepts patients who do not have a primary care provider shall maintain a system for referring such patients to a health care provider when clinically indicated.

e. Communication of results to health care providers. When the patient has a referring health care provider or the patient has named a health care provider, the facility shall:

(1) Provide a written report of the mammography examination, including all of the items listed in 41.6(4)*"b,"* to the health care provider as soon as possible, but no later than 30 days from the date of the examination, and

(2) If the assessment is "Suspicious" or "Highly suggestive of malignancy," make reasonable attempts to communicate with the health care provider as soon as possible or, if the health care provider is unavailable, to a responsible designee of the health care provider.

f. Mammographic image identification. Each mammographic image shall have the following information indicated on it in a permanent, legible, and unambiguous manner and placed so as not to obscure anatomic structures:

(1) Name of patient and an additional patient identifier.

(2) Date of examination.

(3) View and laterality. This information shall be placed on the image in a position near the axilla. Standardized codes specified by the accreditation body and approved by the FDA shall be used to identify view and laterality.

(4) Facility name and location. At a minimum, the location shall include the city, state, and ZIP code of the facility.

(5) Technologist identification.

(6) Cassette/screen identification.

(7) Mammography unit identification, if there is more than one unit in the facility.

41.6(5) *Quality assurance program.*

a. The facility shall ensure that the facility has an equipment quality assurance program specific to mammography and covering all components of the system to ensure consistently high-quality images with minimum patient exposure. Responsibility for the quality assurance program and for each of its elements shall be assigned to individuals who are qualified for their assignments and who shall be allowed adequate time to perform these duties.

(1) Lead interpreting physician. The facility shall identify a lead interpreting physician who shall have the general responsibility of ensuring that the quality assurance program meets all requirements

of these rules. No other individual shall be assigned or shall retain responsibility for quality assurance tasks unless the lead interpreting physician has determined that the individual's qualifications for, and performance of, the assignment are adequate.

(2) Interpreting physicians. All interpreting physicians interpreting mammograms for the facility shall:

1. Follow the facility procedures for corrective action when the images they are asked to interpret are of poor quality, and

2. Participate in the facility's medical outcomes audit program.

(3) Medical physicist. Each facility shall have the services of a medical physicist available to survey mammography equipment and oversee the equipment-related quality assurance practices of the facility. At a minimum, the medical physicist(s) shall be responsible for performing the surveys and mammography equipment evaluations and providing the facility with the applicable reports.

(4) Quality control technologist. Responsibility for all individual tasks within the quality assurance program not assigned to the lead interpreting physician or the medical physicist shall be assigned to a quality control technologist(s). The tasks are to be performed by the quality control technologist or by other personnel qualified to perform the tasks. When other personnel are utilized for these tasks, the quality control technologist shall ensure that the tasks are completed in such a way as to meet the requirements of 41.6(5)*"e"* through *"k."*

b. The facility shall ensure that a general review of the program is conducted at least annually and have available the services of a qualified medical physicist who is capable of establishing and conducting the program.

c. Under the direction of the lead interpreting physician, the medical physicist shall have responsibility for establishing and conducting the equipment quality assurance program. The program shall include:

(1) Conducting or training others to conduct equipment performance monitoring functions.

(2) Analyzing the monitoring results to determine if there are any problems requiring correction.

(3) Ensuring that the facility has procedures in place for carrying out or arranging for the necessary corrective actions as well as for the calibrations and other preventive maintenance.

d. Calibration of equipment. All variable parameters of the equipment shall be calibrated:

(1) When the equipment is first installed.

(2) After any major changes or replacement of parts.

(3) At least annually during use based on recommendations of the mammography imaging medical physicist.

(4) When quality assurance tests indicate that calibration is needed.

e. Performance monitoring. The supplier shall routinely ensure that the performance of the mammography system is monitored. The parameters to be monitored for film-screen mammography shall include but not be limited to:

(1) Processor performance (through daily sensitometric-densitometric means).

(2) Half-value layer.

(3) Output reproducibility and linearity.

(4) Automatic exposure control reproducibility and linearity.

(5) Adequacy of film storage (both before use and after exposure if processing does not occur immediately).

(6) Availability and use of technique charts that shall include an indication of the kV-target-filter combination to be used with each image receptor.

(7) Darkroom integrity, to be performed at least semiannually or when conditions have changed, shall include an inspection for light leaks, a fog test, and a safe light test.

(8) Image quality. The minimum image quality achieved at a mammography facility shall be the ability to observe the image of at least four 0.75-mm fibriles, three 0.32-mm speck groups, and three 0.75-mm masses from an FDA-approved phantom (or equivalent) on the standard mammographic film used at the facility. No mammograms shall be performed if this minimum is not met.

f. Frequency of monitoring.

(1) Processor performance shall be accomplished daily before processing patient films.

(2) Image quality shall be monitored at least weekly with a phantom and every time the unit is altered including the replacement of parts.

(3) All other parameters shall be proportional to the expected variability of each parameter, but at least annually.

g. Evaluation of monitoring results. Full field digital mammography units must comply with the quality control test requirements outlined by the performance criteria in the appropriate manufacturer's quality control manual.

(1) Standards of image quality giving acceptable ranges of values for each of the parameters tested shall be established to aid in the evaluation. The standards of image quality related to dose shall include a requirement that the mean glandular dose for one craniocaudal view of a 4.2 cm compressed breast (50 percent adipose/50 percent glandular) or equivalent phantom shall not exceed 100 millirad for film-screen units with no grids, 300 millirad for film-screen units with grids, or 300 millirad for full field digital units.

(2) The monitoring results shall be compared routinely by the facility staff to the standards of image quality in 41.6(5)*"k."* If the results fall outside the acceptable range, the test shall be repeated. For film-screen mammography, if the results continue to be unacceptable, the source of the problem shall be identified and corrected before further examinations are conducted. For full field digital mammography, if any test results fall outside the performance criteria range listed for the unit, specific actions as directed in the appropriate quality control manual shall be followed.

h. Retake analysis program—film-screen and full field digital.

(1) A program shall be established as a further aid in detecting and correcting problems affecting image quality or exposure.

(2) All retakes shall be logged including date, technologist's name and reason for retake. A retake analysis shall be performed every 250 patients or quarterly, whichever comes first. If more than 250 mammograms are performed in one week, weekly analysis is acceptable.

(3) If the total repeat or reject rate changes from the previously determined rate by more than 2.0 percent of the total films included in the analysis, the reason(s) for the change shall be determined. Any corrective actions shall be recorded and the results of these corrective actions shall be assessed.

i. Medical outcomes audit. Each facility shall establish a system for reviewing outcome data from all mammography performed, including follow-up on the disposition of positive mammograms and correlation of surgical biopsy results with the interpreting physician's findings. This program shall be designed to ensure the reliability, clarity, and accuracy of the interpretation of mammograms.

(1) Analysis of these outcome data shall be made individually and collectively for all interpreting physicians at the facility. In addition, any cases of breast cancer among women imaged at the facility that subsequently become known to the facility shall prompt the facility to initiate follow-up on surgical and pathology results, or both, and review of the mammograms taken prior to the diagnosis of a malignancy. Responsibility for each requirement for monitoring shall be assigned to qualified personnel and documented in the facility's records.

(2) Frequency of audit analysis. The facility's first audit analysis shall be initiated no later than 12 months after the date the facility becomes certified, or 12 months after April 28, 1999, whichever date is the latest. This audit analysis shall be completed within an additional 12 months to permit completion of diagnostic procedures and data collection. Subsequent audit analyses will be conducted at least once every 12 months.

(3) Reviewing interpreting physician. Each facility shall designate at least one interpreting physician to review the medical outcomes audit data at least once every 12 months. This individual shall record the dates of the audit period(s) and shall be responsible for analyzing results based on this audit. This individual shall also be responsible for documenting the results and notifying other interpreting physicians of the results and the facility aggregate results. If follow-up actions are taken, the reviewing interpreting physician shall also be responsible for documenting the nature of the follow-up. The reviewing physician shall sign the medical audit as proof of the evaluation of the data.

j. Quality assurance records. The lead interpreting physician, quality control technologist, and medical physicist shall ensure that records concerning employee qualifications to meet assigned quality

assurance tasks, mammography technique and procedures, quality control (including monitoring data, problems detected by analysis of that data, corrective actions, and the effectiveness of the corrective actions), safety, and protection are properly maintained and updated. These quality control records shall be kept for each test specified in these rules until the next annual inspection has been completed and the facility is in compliance with the quality assurance requirements or until the test has been performed two additional times at the required frequency, whichever is longer.

k. Quality assurance—equipment.

(1) Daily quality control tests. Film processors used to develop mammograms shall be adjusted and maintained to meet the technical development specifications for the mammography film in use. A processor performance test shall be performed on each day that clinical films are processed before any clinical films are processed that day. The test shall include an assessment of base plus fog density, mid-density, and density difference, using the mammography film used clinically at the facility.

1. The base plus fog density shall be below plus 0.03 of the established operating level.
2. The mid-density shall be within plus or minus 0.15 of the established operating level.
3. The density difference shall be within plus or minus 0.15 of the established operating level.

(2) Weekly quality control tests. Facilities with screen-film systems shall perform an image quality evaluation test, using an FDA-approved phantom, at least weekly.

1. The optical density of the film at the center of an image of a standard FDA-accepted phantom shall be at least 1.20 when exposed under a typical clinical condition.
2. The optical density of the film at the center of the phantom image shall not change by more than plus or minus 0.20 from the established operating level.
3. The phantom image shall achieve at least the minimum score established by the accreditation body and accepted by the FDA.
4. The density difference between the background of the phantom and an added test object used to assess image contrast shall be measured and shall not vary by more than plus or minus 0.05 from the established operating level.

(3) Quarterly quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least quarterly:

- Fixer retention in film. The residual fixer shall be no more than 5 micrograms per square centimeter.

(4) Semiannual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least semiannually:

1. Darkroom fog. The optical density attributable to darkroom fog shall not exceed 0.05 when a mammography film of the type used in the facility, which has a mid-density of no less than 1.2 OD, is exposed to typical darkroom conditions for two minutes while such film is placed on the countertop emulsion side up. If the darkroom has a safelight used for mammography film, it shall be on during this test.
2. Screen-film contact. Testing for screen-film contact shall be conducted using 40 mesh copper screen. All cassettes used in the facility for mammography shall be tested.
3. Compression device performance. The maximum compression force for the initial power drive shall be between 25 pounds (111 newtons) and 45 pounds (200 newtons).

(5) Annual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least annually:

1. Automatic exposure control (AEC) performance.

- The AEC shall be capable of maintaining film optical density (OD) within plus or minus 0.15 of the mean optical density when thickness of a homogenous material is varied over a range of 2 to 6 centimeters and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility.
- The optical density of the film in the center of the phantom image shall not be less than 1.20.

2. kVp accuracy and reproducibility.

- The kVp shall be accurate within plus or minus 5 percent of the indicated or selected kVp at the lowest clinical kVp that can be measured by a kVp test device, the most commonly used clinical kVp, and the highest available clinical kVp.
- At the most commonly used clinical settings of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02.

3. Focal spot condition. Facilities shall evaluate focal spot condition only by determining the system resolution.

- Each X-ray system used for mammography, in combination with the mammography screen-film combination used in the facility, shall provide a minimum resolution of 11 cycles/millimeters (mm) (line-pairs/mm) when a high contrast resolution bar test pattern is oriented with the bars perpendicular to the anode-cathode axis, and a minimum resolution of 13 line-pairs/mm when the bars are parallel to that axis.
- The bar pattern shall be placed 4.5 centimeters above the breast support surface, centered with respect to the chest wall edge of the image receptor, and with the edge of the pattern within 1 centimeter of the chest wall edge of the image receptor.
- When more than one target material is provided, the measurement above shall be made using the appropriate focal spot for each target material.
- When more than one SID is provided, the test shall be performed at the SID most commonly used clinically.
- Test kVp shall be set at the value used clinically by the facility for a standard breast and shall be performed in the AEC mode, if available. If necessary, a suitable absorber may be placed in the beam to increase exposure times. The screen-film cassette combination used by the facility shall be used to test for this requirement and shall be placed in the normal location used for clinical procedures.
- Focal spot dimensions. Measured values of the focal spot length (dimension parallel to the anode-cathode axis) and width (dimension perpendicular to the anode-cathode axis) shall be within tolerance limits specified in Table 1.

Table 1

Focal Spot Tolerance Limit Nominal Focal Spot Size (mm)	Maximum Measured Dimensions Width (mm)	Length (mm)
0.10	0.15	0.15
0.15	0.23	0.23
0.20	0.30	0.30
0.30	0.45	0.65
0.40	0.60	0.85
0.60	0.90	1.30

4. Beam quality and half-value layer (HVL). The HVL shall meet the specification of 41.1(4) and 41.1(6) for the minimum HVL. These values, extrapolated to the mammographic range, are shown in Table 2. Values not shown in Table 2 may be determined by linear interpolation or extrapolation.

Table 2

X-ray Tube Voltage (kilovolt peak) and Minimum HVL Designed Operating Range (kV) Below 50	
Measured Operating Voltage (kV)	Minimum HVL (millimeters of aluminum)
20	0.20
25	0.25
30	0.30

5. Breast entrance air kerma and AEC reproducibility. The coefficient of variation for both air kerma and mAs shall not exceed 0.05.

6. Dosimetry. The average glandular dose delivered during a single cranio-caudal view of an FDA-accepted phantom simulating a standard breast shall not exceed 0.3 rad (3.0 milligray (mGy)) per exposure. The dose shall be determined with technique factors and conditions used clinically for a standard breast.

7. X-ray field/light field/image receptor/compression paddle alignment.

- All systems shall have beam-limiting devices that allow the entire chest wall edge of the X-ray field to extend to the chest wall edge of the image receptor and provide means to ensure that the X-ray field does not extend beyond any edge of the image receptor by more than 2 percent of the SID.
- The chest wall edge of the compression paddle shall not extend beyond the chest wall edge of the image receptor by more than 1 percent of the SID when tested with the compression paddle placed above the breast support surface at a distance equivalent to standard breast thickness. The shadow of the vertical edge of the compression paddle shall be not be visible on the image.

8. Uniformity of screen speed. Uniformity of screen speed of all the cassettes in the facility shall be tested and the difference between the maximum and minimum optical densities shall not exceed 0.30. Screen artifacts shall also be evaluated during this test.

9. System artifacts. System artifacts shall be evaluated with a high-grade, defect-free sheet of homogeneous material large enough to cover the mammography cassette and shall be performed for all cassette sizes used in the facility using a grid appropriate for the cassette size being tested. System artifacts shall also be evaluated for all available focal spot sizes and target filter combinations used clinically.

10. Radiation output.

- The system shall be capable of producing a minimum output of 800 milliRoentgen (mR) per second (7.0 mGy air kerma per second) when operating at 28 kVp in the standard (moly/moly) mammography mode at any SID where the system is designed to operate and when measured by a detector with its center located 4.5 centimeters above the breast support surface with the compression paddle in place between the source and the detector.
- The system shall be capable of maintaining the required minimum radiation output averaged over a 3.0 second period.

11. Decompression. If the system is equipped with a provision for automatic decompression after completion of an exposure or interruption of power to the system, the system shall be tested to confirm that it provides:

- An override capability to allow maintenance of compression;
- A continuous display of the override status; and
- A manual emergency compression release that can be activated in the event of power or automatic release failure.

(6) Quality control tests—other modalities. For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in 41.6(5)*"k"*(5)"6."

(7) Use of test results.

1. After completion of the tests specified in 41.6(5)*"k,"* the facility shall compare the test results to the corresponding specified action limits; or, for non-screen-film modalities, to the manufacturer's recommended action limits; or, for post-move, preexamination testing of mobile units, to the limits established in the test method used by the facility.

2. If the test results fall outside the action limits, the source of the problem shall be identified, and corrective actions shall be taken before any further examinations are performed or any films are processed using the component of the mammography system that failed the test, if the failed test was that described in 41.6(5)*"k."*

3. Full field digital unit corrective actions shall be made as prescribed in the appropriate manufacturer's quality control manual or in accordance with the appropriate FDA-approved alternative requirements.

(8) Surveys.

1. At least once a year, each facility shall undergo a survey by a medical physicist or by an individual under the direct supervision of a medical physicist. At a minimum, this survey shall include the performance of tests to ensure that the facility meets the quality assurance requirements of the annual tests described in 41.6(5)*"k"*(5) and (6), the weekly phantom image quality test described in 41.6(5)*"k"*(2) and the quarterly retake analysis results described in 41.6(5)*"h."*

2. The results of all tests conducted by the facility in accordance with 41.6(5)*"k"*(1) through (7) for film-screen units, as well as written documentation of any corrective actions taken and their results, shall be evaluated for adequacy by the medical physicist performing the survey. Surveys of full field digital mammography units shall be conducted as described in the appropriate manufacturer's quality control manual. The results of the tests, any corrective actions taken and their results shall be evaluated for adequacy by the medical physicist performing the survey.

3. The medical physicist shall prepare a survey report that includes a summary of this review and recommendations for necessary improvements.

4. The survey report shall be sent to the facility within 30 days of the date of the survey.

5. The survey report shall be dated and signed by the medical physicist performing or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey report.

(9) Mammography equipment evaluations. Additional evaluations of mammography units or image processors or any other applicable mammography system ancillary parts shall be conducted at new installations, at disassembly, at reassembly, at the same or a new location, or when major components are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in 41.6(5) and 41.6(6). All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. The mammography equipment evaluation shall be performed by a medical physicist or by an individual under the direct supervision of an Iowa-approved medical physicist.

(10) Facility cleanliness.

1. The facility shall establish and implement adequate protocols for maintaining darkroom, screen, and viewbox cleanliness.

2. The facility shall document that all cleaning procedures are performed at the frequencies specified in the protocols.

(11) Calibration of air kerma measuring instruments. Instruments used by medical physicists in their annual survey to measure the air kerma or air kerma rate from a mammography unit shall be calibrated at least once every two years and each time the instrument is repaired. The instrument calibration must be traceable to a national standard and calibrated with an accuracy of plus or minus 6 percent (95 percent confidence level) in the mammography energy range.

(12) Infection control. Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. This system shall specify the methods for documenting facility compliance with the infection control procedures established and shall:

1. Comply with all applicable federal, state, and local regulations pertaining to infection control; and

2. Comply with the manufacturer's recommended procedures for the cleaning and disinfecting of the mammography equipment used in the facility; or

3. If adequate manufacturer's recommendations are not available, comply with generally accepted guidance on infection control, until such recommendations become available.

l. Mammography procedures and techniques for mammography of patients with breast implants.

(1) Each facility shall have a procedure to inquire whether or not the patient has breast implants prior to the actual mammographic examination.

(2) Except where contraindicated, or unless modified by a physician's directions, patients with breast implants undergoing mammography shall have mammographic views to maximize the visualization of breast tissue.

m. Consumer complaint mechanism. Each facility shall:

(1) Establish a written and documented system for collecting and resolving consumer complaints;

(2) Maintain a record of each serious complaint received by the facility for at least three years from the date the complaint was received;

(3) Provide the consumer with adequate directions for filing serious complaints with the facility's accreditation body and any other appropriate regulatory entity if the facility is unable to resolve a serious complaint to the consumer's satisfaction.

(4) Report unresolved serious complaints to the accreditation body in a manner and time frame specified by the accreditation body.

n. Clinical image quality. Clinical images produced by any certified facility must continue to comply with the standards for clinical image quality established by that facility's accreditation body.

o. Additional mammography review and patient notification.

(1) If the agency believes that mammography quality at a facility has been compromised and may present a serious risk to human health, the facility shall provide clinical images and other relevant information, as specified by the agency, for review by the accreditation body or other entity designated by the agency. This additional mammography review will help the agency to determine whether the facility is in compliance with rule 641—41.6(136C) and, if not, whether there is a need to notify affected patients, their physicians, or the public that the reliability, clarity, and accuracy of interpretation of mammograms has been compromised.

(2) If the agency determines that any activity related to the provision of mammography at a facility may present a serious risk to human health such that patient notification is necessary, the facility shall notify patients or their designees, their physicians, or the public of action that may be taken to minimize the effects of the risk. Such notification shall occur within a time frame and a manner specified by the agency.

41.6(6) *Equipment standards.* The equipment used to perform mammography shall meet the following standards:

a. Design: Be specifically designed for mammography. This prohibits systems that have been modified or equipped with special attachments for mammography.

b. Performance standards: Meet the Food and Drug Administration (FDA) performance standards for diagnostic X-ray systems and their major components found in 21 CFR 1020.30 and FDA standards for radiographic equipment in 21 CFR 1020.31.

c. Image receptor systems: Have image receptor systems and individual components which are appropriate for mammography and used according to the manufacturer's recommendations.

(1) Systems using screen-film image receptors shall provide, at a minimum, for operation for image receptors of 18 × 24 centimeters and 24 × 30 centimeters.

(2) Systems using screen-film image receptors shall be equipped with moving grids matched to all image receptor sizes provided.

(3) Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptor.

d. Light fields: For any system with a light beam that passes through the X-ray beam-limiting device, the light shall provide an average illumination of not less than 160 lux (15 foot candles) at 100 centimeters or the maximum source-image receptor distance (SID), whichever is less.

e. Magnification:

(1) Systems used to perform noninterventional problem-solving procedures shall have radiographic magnification capability available for use by the operator.

(2) Systems used for magnification procedures shall provide, at a minimum, at least one magnification value within the range of 1.4 to 2.0.

f. Tube-image receptor assembly:

(1) The assembly shall be capable of being fixed in any position where it is designed to operate. Once fixed in any such position, it shall not undergo unintended motion.

(2) The mechanism ensuring compliance with this subrule shall not fail in the event of power interruption.

g. Film/screen contact: Shall check film/screen contact when cassettes are first placed into use and semiannually thereafter.

h. Focal spot: The focal spot size, magnification factor and source to image receptor distance (SID) shall be appropriate for mammography and in the ranges shown below:

SID	Nominal Focal Spot Size
> 65 cm	< or = to 0.6 mm
50 to 65 cm	< or = to 0.5 mm
< 50 cm	< or = to 0.4 mm

(1) When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.

(2) When more than one target material is provided, the system shall indicate, prior to exposure, the preselected target material.

(3) When the target material or focal spot, or both, is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall display, after the exposure, the target material or focal spot, or both, actually used during the exposure.

i. Compression devices: Shall have compression devices parallel to the imaging plane and able to immobilize and compress the breast with a force of at least 25 pounds per square inch and shall be capable of maintaining this compression for at least three seconds. Effective October 28, 2002, each system shall provide:

(1) An initial power-driven compression activated by hands-free controls operable from both sides of the patient; and

(2) Fine adjustment compression controls operable from both sides of the patient.

(3) Systems shall be equipped with different sized compression paddles that match the sizes of all full field image receptors provided for the system. Compression paddles for special purposes, including those smaller than the full size of the image receptor (for "spot compression"), may be provided. Such compression paddles for special purposes are not subject to 41.6(6)*"i"*(6) and (7).

(4) Except as provided in 41.6(6)*"i"*(5), the compression paddle shall be flat and parallel to the breast support table and shall not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied.

(5) Equipment intended by the manufacturer's design not to be flat and parallel to the breast support table during compression shall meet the manufacturer's design specifications and maintenance requirements.

(6) The chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor.

(7) The chest wall edge may be bent upward to allow for patient comfort but shall not appear on the image.

j. Grids: Shall have the capability for using antiscatter grids.

k. AEC: Shall have automatic exposure control such that:

(1) Each screen-film system shall provide an AEC mode that is operable in all combinations of equipment configuration provided, e.g., grid, nongrid; magnification, nonmagnification; and various target-filter combinations.

(2) The positioning or selection of the detector shall permit flexibility in the placement of the detector under the target tissue.

- The size and available positions of the detector shall be clearly indicated at the X-ray input surface of the breast compression paddle.

- The selected position of the detector shall be clearly indicated.

(3) The system shall provide means for the operator to vary the selected optical density from the normal (zero) setting.

l. Control panel: Shall have a control panel that:

(1) Gives a positive indication when X-rays are being produced.

(2) Gives an audible signal indicating termination of exposure.

(3) Has manual selection of milliampere seconds (mAs) or at least one of its component parts (milliampere (mA) or time, or both).

(4) Has the technique factors (peak tube potential in kilovolts (kV) and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs) to be used during an exposure indicated before the exposure begins, except when AEC is used, in which case the technique factors that are set prior to the exposure shall be indicated.

(5) Has a system that, following AEC mode use, shall indicate the actual kilovoltage peak (kVp) and mAs used during the exposure.

m. mAs: Shall indicate, or provide a means of determining, the mAs resulting from each exposure made with automatic exposure control.

n. Viewboxes: Shall have a viewbox that is checked periodically to ensure optimal conditions. When the mammogram is placed on the viewbox, the area surrounding the film must be masked to exclude extraneous light which may reduce image contrast.

o. X-ray film: Shall use X-ray film that has been designated by the film manufacturer as appropriate for mammography and that is matched to the screen's spectral output as specified by the manufacturer.

p. Intensifying screens: Shall use intensifying screens that have been designated by the screen manufacturer as appropriate for mammography.

q. Chemicals: Shall use chemical solutions for processing mammography films that are capable of developing the films in a manner equivalent to the minimum requirements specified by the film manufacturer.

r. Hot-lights: Shall make special lights for film illumination, i.e., hot-lights, capable of producing light levels greater than that provided by the viewbox, available to the interpreting physicians.

s. Masking devices: Shall ensure that film masking devices that can limit the illuminated area to a region equal to or smaller than the exposed portion of the film are available to all interpreting physicians interpreting for the facility.

t. Mobile units and vans—film-screen.

(1) A phantom image shall be produced, processed, and evaluated after each relocation and prior to examinations being conducted.

(2) If processing is not available, a check of the radiation output shall be made and compared to a preset standard for quality. Equipment shall be recalibrated as necessary to maintain quality of phantom image.

u. Mobile units and vans—full field digital. Appropriate manufacturer's quality control manual procedures and criteria shall be met.

41.6(7) *Safety standards for mammography equipment.*

a. Proper safety precautions shall be maintained and shall include, but not be limited to, adequate shielding for patients, personnel, and facilities. The equipment shall be operated only from a shielded position.

b. Equipment operators shall be monitored in accordance with 641—40.37(136C).

c. Annual inspections shall be conducted by an inspector from the agency to ensure compliance with these rules. Identified hazards shall be promptly corrected.

d. Equipment shall be shockproof and grounded to protect against electrical hazards.

e. Records of all inspections, reports, and consultations shall be maintained for at least seven years.

RULE 41.6(136C)—APPENDIX I
Rescinded IAB 4/5/00, effective 5/10/00

RULE 41.6(136C)—APPENDIX II
Glandular Dose (in mrad) for 1 Roentgen Entrance Exposure
4.5-cm Breast Thickness—50% Adipose/50% Glandular Breast Tissue*

	Mo/Mo Target Filter X-Ray Voltage (kVp)											W/Al Target Filter Combination
HVL	23	24	25	26	27	28	29	30	31	32	33	
0.23	109											
0.24	113	116										
0.25	117	120	122									
0.26	121	124	126	128								
0.27	126	128	130	132	134							
0.28	130	132	134	136	138	139						
0.29	135	137	139	141	142	143	144					
0.30	139	141	143	145	146	147	148	149				170
0.31	144	146	147	149	150	151	152	153	154			175
0.32	148	150	151	153	154	155	156	158	159	160	160	180
0.33	153	154	155	157	158	159	160	162	163	164	164	185
0.34	157	159	160	161	162	163	164	166	167	168	168	190
0.35		163	164	166	167	168	169	170	171	172	172	194
0.36			168	170	171	172	173	174	175	176	176	199
0.37				174	175	176	177	178	178	179	180	204
0.38					179	180	181	182	182	183	184	208
0.39						184	185	186	186	187	188	213
0.40							189	190	191	192	192	217
0.41								194	195	196	196	221
0.42										200	200	225
0.43											204	230
0.44												234
0.45												238

To convert from entrance exposure in air in Roentgen to mean glandular breast dose in millirads, multiply the entrance exposure by the factor shown in the table for the appropriate kVp and beam quality (HVL) combination. For example, a measured entrance exposure of 0.50 Roentgen from a Mo/Mo Target Filter system at 30 kVp with a measured HVL of 0.36-mm aluminum yields an average glandular dose of (0.50 R) × (174 mrad/R) = 87 mrad or 0.87 mGy.

*Wu X. Breast dosimetry in screen-film mammography. In: Barnes GT, Frey GD (eds), Screen film mammography: Imaging considerations and medical physics responsibilities. Madison, WI: Medical Physics Publishing; 159-175, 1991. W/Al conversion factors are derived from fits to data from Stanton L et al. Dosage evaluation in mammography. Radiology 1984; 150:577-584.

641—41.7(136C) X-ray machines used for stereotactically guided breast biopsy.

41.7(1) *Definitions.* In addition to the definitions provided in rules 641—38.2(136C), 641—40.2(136C), and 641—41.1(136C), the following definitions are applicable to this rule.

"Collaborative setting" means a setting in which a qualified radiologist and surgeon (under 41.7(3)*"a"* or 41.7(3)*"c"*) are working together in consultation and in performing stereotactically guided breast biopsies with a common goal of the patient's benefit.

"Procedure" means a stereotactically guided breast biopsy performed on a patient for diagnostic purposes.

"Qualified training physician" means a physician who is qualified under 41.7(3) to perform stereotactically guided breast biopsies and who has performed at least 24 procedures.

"Stereotactically guided breast biopsy" means a breast biopsy procedure performed with the utilization of a dedicated system which emits ionizing radiation and is designed specifically for that procedure.

"Supervising physician" means the physician designated by the facility/owner to:

1. Evaluate the equipment, personnel, procedures, and records annually; and
2. Establish and conduct the quality assurance program.

41.7(2) *Registration and application standards and requirements.*

a. Each radiation machine used to perform stereotactically guided breast biopsies shall be registered according to 641—subrule 39.3(2).

b. Each facility wishing to perform stereotactically guided breast biopsies shall apply to the agency for authorization by providing or verifying the following information for each machine:

(1) The stereotactically guided breast biopsy equipment and facility meet the general requirements of these rules for radiation machines.

(2) The radiation machine is specifically designed to perform stereotactically guided breast biopsies.

(3) The radiation machine is used according to these rules on patient radiation exposure and radiation dose levels.

(4) The radiation machine is operated by individuals meeting the requirements of this rule.

(5) The entire stereotactically guided breast biopsy system is evaluated annually by a medical physicist who meets the requirements of this rule.

(6) The equipment, personnel, procedures and records are evaluated annually by the supervising physician.

c. Suspension, revocation, or denial of authorization.

(1) Authorization may be suspended or revoked with cause if any machine does not meet one or more of the standards of these rules.

(2) The facility shall have an opportunity for a hearing in connection with a denial,suspension, or revocation of authorization.

(3) An emergency order suspending or revoking authorization may be issued if the agency finds the radiation machine or facility violates rules that seriously affect the health, safety and welfare of the public. An opportunity for hearing shall be held within 20 working days after the issuance of the order. The order shall be effective during the proceedings.

(4) If authorization is revoked, the radiation machine shall not be used until reinstated.

d. Reinstatement of authorization.

(1) An application for reinstatement shall be submitted and processed the same as an initial application.

(2) The agency shall inspect the radiation machine within 60 days of the approved reinstatement application. If the reinstatement is after a revocation, appropriate corrective action shall be submitted with the application.

(3) A full reinstatement shall be issued only after the agency has inspected the radiation machine and facility and determined that they meet the requirements of these rules.

e. Inspections. The agency shall conduct an inspection of each radiation machine no later than 14 months after initial authorization and at least annually thereafter.

41.7(3) *Physicians.* Physicians must be qualified according to the setting and their role in performing stereotactically guided breast biopsies as outlined below.

a. Requirements for a radiologist in a collaborative setting are as follows:

(1) Initial training and qualifications.

1. Must be qualified according to 41.6(3)*"a."*

2. Shall have performed at least 12 stereotactically guided breast biopsies prior to July 1, 1998, or at least 3 hands-on stereotactically guided breast biopsies under a physician who is qualified under 41.7(3) and has performed at least 24 stereotactically guided breast biopsies.

3. Shall have at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy.

4. Shall be responsible for mammographic interpretation, be experienced as noted in 41.7(3)*"a"*(1)"2" above and be experienced in the specific recommendations for each biopsy and lesion identification at time of each biopsy performed by that physician.

5. Shall be responsible for the supervision of the radiologic technologist during the procedure.

(2) Maintenance of proficiency and CME requirements.

1. Perform at least 12 stereotactically guided breast biopsies per year . If experience is not maintained, the physician must requalify by performing 3 procedures under direct supervision of a qualified training physician or an agency-approved manufacturer applications specialist before resuming unsupervised procedures.

2. Obtain at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy every 36 months. If education is not maintained, the physician must requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months before resuming unsupervised procedures. These CMEs cannot be obtained by the performance of supervised procedures.

3. Continuing qualifications must be met and a current state of Iowa medical license must be in effect whenever procedures are performed independently by the physician.

b. Requirements for a physician other than a qualified radiologist in a collaborative setting are as follows:

(1) Initial training and qualifications.

1. Must be licensed to practice medicine in Iowa.

2. Must have at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy which includes instruction on triangulation for lesion location.

3. Must have performed at least 12 stereotactically guided breast biopsies prior to May 9, 2001, or at least 3 hands-on stereotactically guided breast biopsy procedures under a physician who is both qualified to perform stereotactic biopsy procedures according to 41.7(3) and has performed at least 24 stereotactically guided breast biopsies.

4. Shall be responsible for post-biopsy management of the patient.

5. Shall be responsible for supervision of the radiologic technologist during the procedure.

(2) Maintenance of proficiency and CME requirements.

1. Perform or participate in at least 12 stereotactically guided breast biopsies per year or requalify by performing 3 procedures under direct supervision of a qualified training physician or an agency–approved manufacturer applications specialist before resuming unsupervised procedures.

2. Obtain at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy every 36 months. If education is not maintained, the physician must requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months before resuming unsupervised procedures. These CMEs cannot be obtained by the performance of supervised procedures.

3. Continuing qualifications must be met and a current state of Iowa medical license must be in effect whenever unsupervised procedures are performed by the physician.

c. Requirements for a radiologist performing stereotactically guided breast biopsy independently are as follows:

(1) Initial training and requirements.

1. Must be qualified according to 41.6(3)*"a."*

2. Initially, must have at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy.

3. Initially, must obtain at least 15 hours of CME in breast imaging including benign and malignant breast diseases.

4. Must have performed at least 12 stereotactically guided breast biopsies prior to July 1, 1998, or at least 3 hands-on stereotactically guided breast biopsy procedures under a physician who is both qualified according to 41.7(3) and has performed at least 24 stereotactically guided breast biopsies.

5. Must be responsible for mammographic interpretation.

6. Must be responsible for patient selection.

7. Must be responsible for the supervision of the radiologic technologist during the procedure.

8. Must be responsible for post-biopsy management of the patient which may include referral to a surgeon for a follow-up on certain lesions.

(2) Maintenance of proficiency and CME requirements.

1. Perform at least 12 stereotactically guided breast biopsies per year or requalify by performing 3 procedures under direct supervision of a qualified training physician or an agency-approved manufacturer applications specialist.

2. Obtain at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy every 36 months which includes post-biopsy management of the patient. If education is not maintained, the physician must requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months before resuming unsupervised procedures. These CMEs cannot be obtained by the performance of supervised procedures.

3. Continuing qualifications must be met and a current state of Iowa medical license must be in effect whenever unsupervised procedures are performed by the physician.

d. Requirements for a physician other than a qualified radiologist (under 41.7(3)*"c"*) performing stereotactically guided breast biopsy independently are as follows:

(1) Initial training and requirements.

1. Must be licensed to practice medicine in Iowa.

2. Must have evaluated at least 480 mammograms in the prior 24 monthsin consultation with a physician who is qualified according to 41.6(3)*"a."*

3. Initially, must have at least 15 hours of Category 1 CME or 15 hours of training approved by the agency in stereotactically guided breast imaging and biopsy or three years' experience having performed at least 36 stereotactically guided breast biopsies.

4. Must have four hours of Category 1 CME in medical radiation physics.

5. Must have performed at least 12 stereotactically guided breast biopsies prior to May 9, 2001, or at least 3 hands-on stereotactically guided breast biopsy procedures under a physician who is both qualified according to 41.7(3)and has performed at least 24 stereotactically guided breast biopsies.

6. Must be responsible for patient selection.

7. Must be responsible for the supervision of the radiologic technologist during the procedure.

8. Must be responsible for post-biopsy management of the patient.

(2) Maintenance of proficiency and CME requirements.

1. Continue to evaluate at least 480 mammograms every 24 months in consultation with a physician who is qualified according to 41.6(3)*"a."*

2. Perform at least 12 stereotactically guided breast biopsies per year or requalify by performing 3 procedures under direct supervision of a qualified training physician or an agency-approved manufacturer applications specialist.

3. Obtain at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy every 36 months. If education is not maintained, the physician must requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months before resuming unsupervised procedures. The CME credits for requalification cannot be obtained by performing procedures.

4. Continuing qualifications must be met and a current state of Iowa medical license must be in effect whenever unsupervised procedures are performed by the physician.

41.7(4) *Medical physicist.*

a. Must be qualified according to 41.6(3)*"c."*

b. Must have performed three hands-on stereotactically guided breast biopsy system physics surveys prior to July 1, 1998; or one hands-on stereotactically guided breast biopsy system physics survey under the guidance of a medical physicist qualified through 41.7(4)*"a"* and 41.7(4)*"b."*

c. Maintenance of proficiency and continuing education requirements.

(1) Have performed at least one stereotactically guided breast biopsy system physics survey per year after the initial qualifications are met or requalify by performing one survey supervised by a qualified medical physicist; and

(2) Following the third anniversary in which the requirements of this subrule were met, have obtained at least three hours of continuing education in stereotactically guided breast biopsy system physics during the previous 36 months or requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months.

41.7(5) *Radiologic technologist.*

a. Must be qualified according to 41.6(3)*"b."*

b. Must meet the following initial requirements:

(1) Five hands-on stereotactically guided breast biopsy procedures on patients under the supervision of a physician or technologist qualified under rule 641— 41.7(136C).

(2) Three hours of continuing education in stereotactically guided breast biopsy. The required continuing education cannot be obtained through the performance of supervised stereotactically guided breast biopsy procedures.

c. Maintenance of proficiency and continuing education and experience requirements.

(1) Following the first anniversary in which the requirements of this subrule were met, have performed at least 12 stereotactically guided breast biopsies per year or requalify by performing 3 stereotactically guided breast biopsies under the supervision of a physician or radiologic technologist qualified under 41.7(3) or 41.7(5)..

(2) Following the third anniversary in which the requirements of this subrule were met, have at least three hours of continuing education in stereotactically guided breast biopsy system physics during the previous 36 months or requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months. The CMEs cannot be obtained by the performance of supervised procedures.

(3) If a stereotactic radiologic technologist performs only stereotactic procedures, the radiologic technologist must perform at least 100 stereotactic procedures during the prior 24 months.during the 24-month period ending on the last day of the previous calendar quarter, or any 24-month period between the two. In this case, all requirements for radiologic technologists must be met with the exception of 41.6(3)*"b"*(4)"1."

(4) Only 50 percent of the total required stereotactic continuing education hours may be obtained through presenting or acting as a trainer for a continuing education or training program.

41.7(6) *Obtaining and preserving records.*

a. The facility must make, for each procedure, a record of the service provided including:

(1) The date of the procedure.

(2) The name of the patient and one additional patient identifier.

(3) The name of the radiologic technologists and physicians performing the procedure.

(4) A description of the service provided.

(5) The name of the referring physician, if any.

b. Records retained by the medical facility must be retained for at least ten years.

41.7(7) *Quality assurance program.*

a. The facility shall have an equipment quality assurance program specific to stereotactically guided breast biopsy systems and covering all components of the system to ensure high-quality images with minimum patient exposure.

b. The facility shall ensure that a general review of the program is conducted at least annually and have available the services of a qualified medical physicist who is capable of establishing and conducting the program.

c. The facility shall name a supervising stereotactic biopsy physician who shall be responsible for:

(1) Quality assurance activities including the medical audit,

(2) Oversight of the quality control program, and

(3) Supervision of the radiologic technologist(s) and the medical physicist.

d. Under the direction of the supervising physician, the medical physicist shall have the responsibility for establishing and conducting the equipment quality assurance program. The program shall include:

(1) Conducting equipment performance monitoring functions, initially and then at least annually, to include:

1. Evaluation of biopsy unit assembly. Any failed items must be corrected within 30 days of the survey unless the medical physicist deems that the failure poses a serious injury risk to the patient, at which time the failure needs to be corrected before further procedures are performed.

2. Collimation.

- Digital – X-ray field must not extend beyond the image receptor by more than 5 mm on any side.
- Film-screen – On all sides other than the chest wall side, the X-ray field must be within the image receptor. The chest wall side must not extend beyond the image receptor by more than 2 percent.
- Any failures must be corrected within 30 days of the survey.

3. Evaluation of focal spot.

- Digital – Focal spot must not degrade from initial measurement. If reduction in lp/mm is found, focal spot must be corrected within 30 days of survey.
- Film-screen – Film-screen must show 13 lp/mm parallel to the anode-cathode axis and 11 lp/mm perpendicular to the anode-cathode axis. Failure to meet the performance criteria must be corrected within 30 days of survey.

4. kVp accuracy/reproducibility. kVp accuracy/reproducibility must be accurate to within +/- 5% of nominal kVp setting. Failures must be corrected before further procedures are performed.

5. Half-value layer measurement. HVL shall be greater than kVp/100 (in units of mm Al). Failures must be corrected before further procedures are performed.

6. Exposure reproducibility. Exposure must be reproducible to within +/- 15% of mean exposure. Failures must be corrected before further procedures are performed.

7. Breast entrance exposure, average glandular dose. Average glandular dose must be less than 300 millirad (3 milliGray) per exposure of a 50 percent glandular/50 percent adipose 4.5 centimeter breast. Failures must be corrected before further procedures are performed.

8. Image quality evaluation.

- Digital – Phantom image must meet the criteria of 5 fibers, 4 speck groups and 3 masses for the ACR accreditation phantom or 3 fibers, 3 speck groups and 2.5 masses for the mini phantom unless otherwise stated by the phantom manufacturer.
- Film-screen – Phantom image must meet the criteria of 4 fibers, 3 speck groups and 3 masses for the ACR phantom or 2 fibers, 2 speck groups and 2 masses for the mini phantom unless otherwise stated by the phantom manufacturer. The background density must be within +/- .20 of the established aim, and the density differences must be within +/- .05 of the established aim.
- Failures must be corrected before further procedures are performed.

9. Artifact evaluation. Any significant black or white artifacts seen in the image detector field must be corrected within 30 days of the survey.

10. Digital field uniformity. For units with region of interest (ROI) capability, the SNR in each corner must be within +/- 15% of the SNR in the center. Failures must be corrected within 30 days of the survey.

11. Localization simulation (gelatin phantom) test. Localization accuracy must be within 1 mm of target, and the test must include a portion of the test "lesion" in the sample chamber. Failures must be corrected before further procedures are performed.

(2) Analyzing the monitoring results to determine if there are any problems requiring correction.

(3) Ensuring that the facility has procedures in place for carrying out or arranging for the necessary corrective actions as well as for the calibrations and other preventative maintenance.

e. The supervising physician shall have the responsibility for establishing and conducting the quality control program in a facility with a fixed unit. In the case of a mobile stereotactic unit, the owner or designee shall assume the responsibility for establishing and conducting the quality assurance program. The program shall include:

(1) Localization accuracy (daily before use and before using the localization unit after it is adjusted). Each coordinate must be within manufacturer specifications for the intended target value. Failures must be corrected before further procedures are performed.

(2) Visual checklist (monthly). Any failed items must be corrected within 30 days.

(3) Phantom image (weekly).

1. Digital – Phantom image must meet the criteria of 5 fibers, 4 speck groups and 3 masses for the ACR accreditation phantom or 3 fibers, 3 speck groups and 2.5 masses for the mini phantom unless otherwise stated by the phantom manufacturer.

2. Film-screen – Phantom image must meet the criteria of 4 fibers, 3 speck groups and 3 masses for the ACR phantom or 2 fibers, 2 speck groups and 2 masses for the mini phantom unless otherwise stated by the phantom manufacturer. The background density must be within +/- .20 of the established aim, and the density difference must be within +/- .05 of the established aim.

3. Failures must be corrected before further procedures are performed.

(4) Compression (semiannually). The maximum auto drive compression force shall not exceed 45 pounds. Failures must be corrected within 30 days.

(5) Processor sensitometry (daily before use with systems utilizing film).

f. Each facility shall establish a medical audit program to ensure the accuracy and appropriateness of the procedures performed. This program shall include an imaging-pathology correlation for each biopsy performed, an ongoing analysis of biopsy results and periodic review of the utilization of the procedure. The program must include the number of biopsies performed, the number of cancers found, the number of benign lesions found, and the number of biopsies repeated.

g. Additional medical physicist evaluations of stereotactic units shall be conducted whenever a new unit is installed, a unit is disassembled and reassembled at the same or a new location, or major components of a stereotactic unit are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in 41.7(7). All problems shall be corrected before the new or changed equipment is put into service for examinations. The stereotactic equipment evaluation shall be performed by a medical physicist qualified under 41.7(4) or by an individual under the direct supervision of a medical physicist qualified under 41.7(4).

41.7(8) *Equipment standards.*

a. Be specifically designed for stereotactically guided breast biopsy.

b. Meet the Food and Drug Administration (FDA) standards found in 21 CFR.

41.7(9) *Safety standards.*

a. Proper safety precautions shall be maintained and shall include, but not be limited to, adequate shielding for patients, personnel and facilities. The equipment shall be operated only from a shielded position.

b. Equipment operators shall wear personnel monitors to monitor their radiation exposure.

c. Annual inspections shall be conducted by an inspector from the agency to ensure compliance with these rules. Identified hazards shall be promptly corrected.

d. Equipment shall be shockproof and grounded to protect against electrical hazards.

e. Records of all inspections, reports and consultations shall be maintained for at least seven years.

This rule is intended to implement Iowa Code chapter 136C.

CHAPTER 41—APPENDIX A

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS (EXCLUDING THERAPY MACHINES)

In order for the agency to provide an evaluation and verification that national standards have been met on shielding requirements for a radiation installation, the following information shall be submitted.

1. The plans should show, as a minimum, the following:

(a) The normal location of the X-ray system's radiation port; the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; the location of the operator's booth; and the location of the X-ray control panel.

(b) The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

(c) The dimensions of the room(s) concerned.

(d) The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

(e) The make and model of the X-ray equipment, the energy waveform (single phase, three phase, etc.) and the maximum technique factors.

(f) The type of examination(s) or treatment(s) which will be performed with the equipment.

2. Information on the anticipated workload of the X-ray system(s) in mA-minutes per week.

3. If the services of a qualified expert have been utilized to determine the shielding requirements, a report, including all basic assumptions used, shall be submitted with the plans.

CHAPTER 41—APPENDIX B

DESIGN REQUIREMENTS FOR AN OPERATOR'S BOOTH

1. Space requirements:

(a) The operator shall be allotted not less than 7.5 square feet (0.697 m) of unobstructed floor space in the booth.

(b) The operator's booth may be any geometric configuration with no dimension of less than 2 feet (0.61 m).

(c) The space shall be allotted excluding any encumbrance by the X-ray control panel, such as overhang, cables, or other similar encroachments.

(d) The booth shall be located or constructed such that unattenuated direct scatter radiation originating on the examination table or at the wall cassette will not reach the operator's station in the booth.

2. Structural requirements:

(a) The booth walls shall be permanently fixed barriers of at least 7 feet (2.13 m) high.

(b) When a door or movable panel is used as an integral part of the booth structure, it must have an interlock which will prevent an exposure when the door or panel is not closed.

(c) Shielding shall be provided to meet the requirements of 641—Chapter 40.

3. X-ray control placement:

The X-ray control for the system shall be fixed within the booth; and

(a) Shall be at least 40 inches (1.02 m) from any point subject to direct scatter, leakage or primary beam radiation.

(b) Shall allow the operator to use the majority of the available viewing windows or mirrors.

4. Viewing system requirements:

(a) Each booth shall have at least one viewing device which will:

(1) Be so placed that the operator can view the patient during any exposure, and

(2) The device shall be so placed that the operator can have full view of any occupant of the room and should be so placed that the operator can view any entry into the room. If any door which allows access to the room cannot be seen from the booth, then outside that door there shall be an "X-ray" warning sign that will be lighted anytime the rotor of the X-ray tube is activated. Alternatively, that door must have an interlock controlling the exposure which will prevent the exposure if the door is not closed.

(b) When the viewing system is a window, the following requirements also apply:

(1) The viewing area shall be at least 1 square foot (0.0929 m^2).

(2) Regardless of size or shape, at least 0.09 m^2 (1 sq ft) of window area must be centered no less than 0.6 m (2 feet) from the open edge of the booth and no less than 1.5 m (5.0 feet) from the floor.

(3) The material constituting the window shall have the same lead equivalence as that required in the booth's wall in which it is mounted.

(c) When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the general requirements of Appendix B, 4(a).

(d) When the viewing system is by electronic means:

(1) The camera shall be so located as to accomplish the general requirements of Appendix B, 4(a), and

(2) There shall be an alternate viewing system as a backup for the primary system.

CHAPTER 41—APPENDIX C

INFORMATION TO BE SUBMITTED BY PERSONS PROPOSING TO CONDUCT HEALING ARTS SCREENING

Persons requesting that the agency approve a healing arts screening program shall submit the following information and evaluation:

1. Name and address of the applicant and, where applicable, the names and addresses of agents within this state.
2. Diseases or conditions for which the X-ray examinations are to be used in diagnoses.
3. A detailed description of the X-ray examinations proposed in the screening program.
4. Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information. Any person conducting a screening program for cardiac scoring shall conduct screening only on either women over age 45 or men over age 50 who meet any two of the following criteria: family history, smoker, high blood pressure, high cholesterol, obesity (at least 20 pounds overweight), diabetes.
5. An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used instead of the X-ray examinations.
6. An evaluation by a qualified expert of the X-ray system(s) to be used in the screening program. The evaluation by the qualified expert shall show that such system(s) does satisfy all requirements of these regulations. The evaluation shall include a measurement of patient exposures from the X-ray examinations to be performed.
7. A description of the diagnostic film quality control program.
8. A copy of the technique chart for the X-ray examination procedures to be used.
9. The qualifications of each individual who will be operating the X-ray system(s).
10. The qualifications of the individual who will be supervising the operators of the X-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified.
11. The name and address of the physician who will interpret the radiograph(s) and a copy of the physician's license to practice in Iowa.
12. A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated.
13. A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the X-ray examinations.
14. An indication of the frequency of screening and the duration of the entire screening program.
15. Documentation justifying the reason for the screening. The applicant must submit data which supports the efficacy of the screening test in diagnosing the disease or condition being screened. Data which will be acceptable to the department includes, but is not limited to, the following: (1) the recommendation of a nationally recognized certifying medical or government body; (2) the recommendation of one of the following national organizations: American Cancer Association, American Lung Association, American Heart Association; or (3) medical literature from peer-reviewed journals supporting the screening.
16. The procedures for preventing pregnant individuals from participating in the screening or justification for allowing pregnant individuals to participate.
17. The dates of the screening to include beginning and ending dates.
18. A copy of IRB for a research project or information justifying the research project.

APPENDIX D

QA for Therapeutic Radiation Machines

Frequency	Procedure	Tolerance[a]
Daily	Dosimetry	
	X-ray output constancy	3%
	Electron output constancy[b]	3%
	Mechanical	
	Localizing lasers	2mm
	Distance indicator (ODI)	2mm
	Safety	
	Door interlocks	functional
	Audiovisual monitors	functional
Monthly	Dosimetry	
	X-ray output constancy[c]	2%
	Electron output constancy[c]	2%
	Backup monitor constancy	2%
	X-ray central axis dosimetry parameter (PDD, TAR) constancy	2%
	Electron central axis dosimetry parameter constancy (PDD)	2mm @ therapeutic depth
	X-ray beam flatness constancy	2%
	Electron beam flatness constancy	3%
	X-ray and electron symmetry	3%
	Safety Interlocks	
	Wedge, electron cone interlocks	functional
	Mechanical	
	Light/radiation field coincidence	2mm or 1% on a side[d]
	Gantry/collimator angle indicators	1 degree
	Wedge position	2mm (or 2% change in transmission factor)
	Tray position	2mm
	Applicator position	2mm
	Field size indicators	2mm
	Cross-hair centering	2mm diameter
	Treatment couch position indicators	2mm/1deg
	Latching of wedges, blocking tray	functional
	Jaw symmetry[e]	2mm
	Field Light intensity	functional
Annual	Dosimetry	
	X-ray/electron output calibration constancy	2%
	Field size dependence of X-ray output constancy	2%

[a] The tolerances listed in the tables should be interpreted to mean that if a parameter either: (1) exceeds the tabulated value (e.g., the measured isocenter under the gantry exceeds 2 mm diameter); or (2) that the change in the parameter exceeds the nominal value (e.g., the output changes by more than 2%), then an action is required. The distinction is emphasized by the use of the term constancy for the latter case. Moreover, for constancy, percent values ± the deviation of the parameter with respect to its nominal value; distances are referenced to the isocenter or nominal SSD.

[b] All electron energies need not be checked daily, but all electron energies are to be checked at least twice weekly.

[c] A constancy check with a field instrument using temperature pressure corrections.

[d] Whichever is greater. Should also be checked after change of light field source.

[e] Jaw symmetry is defined as the difference in distance of each jaw from the isocenter.

Frequency	Procedure	Tolerance[a]
	Output factor constancy for electron applicators	2%
	Central axis parameter constancy (PDD, TAR)	2%
	Off-axis factor constancy	2%
	Transmission factor constancy for all treatment accessories	2%
	Wedge transmission factor constancy[f]	2%
	Monitor chamber linearity	1%
	X-ray output constancy vs. gantry angle	2%
	Electron output constancy vs. gantry angle	2%
	Off-axis factor constancy vs. gantry angle	2%
	Arc mode	Mfrs. specs.
	Safety Interlocks	
	Follow manufacturer's test procedures	functional
	Mechanical	
	Collimator rotation isocenter	2mm diameter
	Gantry rotation isocenter	2mm diameter
	Couch rotation isocenter	2mm diameter
	Coincidence of collimetry, gantry, couch axes with isocenter	2mm diameter
	Coincidence of radiation and mechanical isocenter	2mm diameter

[f] Most wedges' transmission factors are field size and depth dependent.

[a] The tolerances listed in the tables should be interpreted to mean that if a parameter either: (1) exceeds the tabulated value (e.g., the measured isocenter under the gantry exceeds 2 mm diameter); or (2) that the change in the parameter exceeds the nominal value (e.g., the output changes by more than 2%), then an action is required. The distinction is emphasized by the use of the term constancy for the latter case. Moreover, for constancy, percent values ± the deviation of the parameter with respect to its nominal value; distances are referenced to the isocenter or nominal SSD.

APPENDIX E

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS FOR THERAPY MACHINES

I. All therapeutic radiation machines.

A. Basic facility information including: name, telephone number and agency registration number of the individual responsible for preparation of the shielding plan; name and telephone number of the facility supervisor; and the street address (including room number if applicable) of the external beam radiation therapy facility. The plan should also indicate whether this is a new structure or a modification to existing structure(s).

B. All wall, floor, and ceiling areas struck by the useful beam shall have primary barriers.

C. Secondary barriers shall be provided in all wall, floor, and ceiling areas not having primary barriers.

II. Therapeutic machines up to 150 kV (photons only).

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities which produce only photons with a maximum energy less than or equal to 150 kV shall submit shielding plans which contain, as a minimum, the following additional information:

A. Equipment specifications, including the manufacturer and model number of the therapeutic radiation machine, as well as the maximum technique factors.

B. Maximum design workload for the facility including total weekly radiation output (expressed in gray (rad) or air kerma at one meter), total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week.

C. A facility blueprint/drawing indicating: scale (0.25 inch = 1 foot is typical); direction of north; normal location of the therapeutic radiation machine's radiation port(s); the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; and the location of the therapeutic radiation machine control panel. If the control panel is located inside the external beam radiation therapy treatment room, the location of the operator's booth shall be noted on the plan and the operator's station at the control panel shall be behind a protective barrier sufficient to ensure compliance with 641—40.15(136C).

D. The structural composition and thickness or lead/concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

F. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition (i.e., primary and secondary leakage barriers, restricted and unrestricted areas, entry door(s)) and shielding material in the facility.

(1) If commercial software is used to generate shielding requirements, identify the software used and the version/revision date.

(2) If the software used to generate shielding requirements is not in the open literature, submit quality control sample calculations to verify the result obtained with the software.

III. Therapeutic radiation machines over 150 kV.

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities which produce photons or electrons with a maximum energy in excess of 150 kV or electrons shall submit shielding plans which contain, as a minimum, the following additional information:

A. Equipment specifications including the manufacturer and model number of the therapeutic radiation machine, and gray (rad) at the isocenter and the energy(s) and type(s) of radiation produced (i.e., photon, electron). The target to isocenter distance shall be specified.

B. Maximum design workload for the facility including total weekly radiation output (expressed in gray (rad) at one meter), total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week.

C. Facility blueprint/drawing (including both floor plan and elevation views) indicating relative orientation of the therapeutic radiation machine, scale (0.25 inch = 1 foot is typical), type(s), thickness and minimum density of shielding material(s), direction of north, the locations and size of all penetrations through each shielding barrier (ceiling, walls and floor), as well as details of the door(s) and maze.

D. The structural composition and thickness or concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

F. Description of all assumptions that were in shielding calculations including, but not limited to, design energy (i.e., room may be designed for 6 MV unit although only a 4 MV unit is currently proposed), workload, presence of integral beam-stop in unit, occupancy and use(s) of adjacent areas, fraction of time that useful beam will intercept each permanent barrier (walls, floor and ceiling) and "allowed" radiation exposure in both restricted and unrestricted areas.

G. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition (i.e., primary and secondary leakage barriers, restricted and unrestricted areas, small angle scatter, entry door(s) and maze) and shielding material in the facility.

(1) If commercial software is used to generate shielding requirements, also identify the software used and the version/revision date.

(2) If the software used to generate shielding requirements is not in the open literature, submit quality control sample calculations to verify the result obtained with the software.

IV. Neutron shielding.

In addition to the requirements listed in Section III above, therapeutic radiation machine facilities which are capable of operating above 10 MV shall submit shielding plans which contain, as a minimum, the following additional information:

A. The structural composition, thickness, minimum density and location of all neutron shielding material.

B. Description of all assumptions that were used in neutron shielding calculations including, but not limited to, neutron spectra as a function of energy, neutron fluency rate, absorbed dose and dose equivalent (due to neutrons) in both restricted and unrestricted areas.

C. At least one example calculation which shows the methodology used to determine the amount of neutron shielding required for each physical condition (i.e., restricted and unrestricted areas, entry door(s) and maze) and neutron shielding material utilized in the facility.

(1) If commercial software is used to generate shielding requirements, also identify the software used and the version/revision date.

(2) If the software used to generate shielding requirements is not in the open literature, submit quality control sample calculations to verify the result obtained with the software.

D. The method(s) and instrumentation which will be used to verify the adequacy of all neutron shielding installed in the facility.

V. References.

A. NCRP Report 49, "Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma Rays of Energies Up to 10 MeV" (1976).

B. NCRP Report 51, "Radiation Protection Design Guidelines for 0.1-100 MeV Particle Accelerator Facilities" (1977).

C. NCRP Report 79, "Neutron Contamination from Medical Electron Accelerator" (1984).

D. NCRP Report 144, "Radiation Protection for Particle Accelerator Facilities" (2003).

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◊ Two or more ARCs

CHAPTER 131
EMERGENCY MEDICAL SERVICES
PROVIDER EDUCATION/TRAINING/CERTIFICATION

641—131.1(147A) Definitions. For the purpose of these rules, the following definitions shall apply:

"Automated external defibrillator" or *"AED"* means an external semiautomatic device that determines whether defibrillation is required.

"Basic care" means treatment interventions, appropriate to certification level, that provide minimum care to the patient including, but not limited to, CPR, bandaging, splinting, oxygen administration, spinal immobilization, oral airway insertion and suctioning, antishock garment, vital sign assessment and administration of over-the-counter drugs.

"Candidate" means an individual who has successfully completed a course of study as a first responder, EMT-basic, EMT-intermediate, EMT-paramedic, paramedic specialist or other level certified by the department and who has been recommended by a training program for a state-approved certification examination.

"CECBEMS" means the continuing education coordinating board for emergency medical services.

"CEH" means "continuing education hour" which is based upon a minimum of 50 minutes of training per hour.

"Certification period" means the length of time an EMS provider certificate is valid. The certification period shall be for two years from initial issuance or from renewal, unless otherwise specified on the certificate or unless sooner suspended or revoked.

"Certification status" means a condition placed on an individual certificate for identification as active, deceased, denied, dropped, expired, failed, hold, idle, inactive, incomplete, pending, probation, retired, revoked, surrendered, suspended, or temporary.

"Continuing education" means training approved by the department which is obtained by a certified emergency medical care provider to maintain, improve, or expand relevant skills and knowledge and to satisfy renewal of certification requirements.

"Course completion date" means the date of the final classroom session of an emergency medical care provider course.

"Course coordinator" means an individual who has been assigned by the training program to coordinate the activities of an emergency medical care provider course.

"CPR" means training and successful course completion in cardiopulmonary resuscitation, AED, and obstructed airway procedures for all age groups according to recognized national standards.

"Critical care paramedic (CCP)" means a currently certified paramedic specialist who has successfully completed a critical care course of instruction approved by the department and has received endorsement from the department as a critical care paramedic.

"Current course completion" means written recognition given for training and successful course completion of CPR with an expiration date or a recommended renewal date that exceeds the current date.

"Department" means the Iowa department of public health.

"Director" means the director of the Iowa department of public health.

"DOT" means the United States Department of Transportation.

"Emergency medical care" means such medical procedures as:

1. Administration of intravenous solutions.
2. Intubation.
3. Performance of cardiac defibrillation and synchronized cardioversion.
4. Administration of emergency drugs as provided by protocol.
5. Any medical procedure authorized by 131.3(3).

"Emergency medical care provider" means an individual who has been trained to provide emergency and nonemergency medical care at the first responder, EMT-basic, EMT-intermediate, EMT-paramedic, paramedic specialist or other certification levels recognized by the department before 1984 and who has been issued a certificate by the department.

"Emergency medical services" or *"EMS"* means an integrated medical care delivery system to provide emergency and nonemergency medical care at the scene or during out-of-hospital patient transportation in an ambulance.

"Emergency medical technician-ambulance (EMT-A)" means an individual who has successfully completed the 1984 United States Department of Transportation's Emergency Medical Technician-Ambulance curriculum, passed the department's approved written and practical examinations, and is currently certified by the department as an EMT-A.

"Emergency medical technician-basic (EMT-B)" means an individual who has successfully completed the current United States Department of Transportation's Emergency Medical Technician-Basic curriculum and department enhancements, passed the department's approved written and practical examinations, and is currently certified by the department as an EMT-B.

"Emergency medical technician-defibrillation (EMT-D)" means an individual who has successfully completed an approved program which specifically addresses manual or automated defibrillation, passed the department's approved written and practical examinations, and is currently certified by the department as an EMT-D.

"Emergency medical technician-intermediate (EMT-I)" means an individual who has successfully completed an EMT-intermediate curriculum approved by the department, passed the department's approved written and practical examinations, and is currently certified by the department as an EMT-I.

"Emergency medical technician-paramedic (EMT-P)" means an individual who has successfully completed the current United States Department of Transportation's EMT-Intermediate curriculum or the 1985 or earlier DOT EMT-P curriculum, passed the department's approved written and practical examinations, and is currently certified by the department as an EMT-P.

"Emergency rescue technician (ERT)" means an emergency medical care provider trained in various rescue techniques including, but not limited to, extrication from vehicles and agricultural rescue, and who has successfully completed a curriculum approved by the department in cooperation with the department of public safety.

"EMS advisory council" means a council appointed by the director, pursuant to Iowa Code chapter 147A, to advise the director and develop policy recommendations concerning regulation, administration, and coordination of emergency medical services in the state.

"EMS evaluator (EMS-E)" means an individual who has successfully completed an EMS evaluator curriculum approved by the department and is currently endorsed by the department as an EMS-E.

"EMS instructor (EMS-I)" means an individual who has successfully completed an EMS instructor curriculum approved by the department and is currently endorsed by the department as an EMS-I.

"Endorsement" means providing approval in an area related to emergency medical care including, but not limited to, emergency rescue technician and emergency medical services-instructor.

"First responder (FR)" means an individual who has successfully completed the current United States Department of Transportation's first responder curriculum and department enhancements, passed the department's approved written and practical examinations, and is currently certified by the department as an FR.

"First responder-defibrillation (FR-D)" means an individual who has successfully completed an approved program that specifically addresses defibrillation, passed the department's approved written and practical examinations, and is currently certified by the department as an FR-D.

"Good standing" means a student or candidate in compliance with these rules and training program requirements.

"Idle" means the status of a lower certification level when a higher level is held.

"Inactive" means the status of a certification level when an individual moves from a higher certification level to a lower certification level that was previously idle or requests inactive status.

"Intermediate" means an emergency medical technician-intermediate.

"NCA" means North Central Association of Colleges and Schools.

"NREMT" means National Registry of Emergency Medical Technicians.

"Out-of-state student" means any individual enrolled in an approved out-of-state training program and participating in clinical or field experience portions.

"Out-of-state training program" means an EMS program located outside the state of Iowa that is approved by the authorizing agency of the program's home state to conduct initial EMS training for first responder, EMT-basic, EMT-intermediate, EMT-paramedic, paramedic specialist or other level certified by the department.

"Outreach course coordinator" means an individual who has been assigned by the training program to coordinate the activities of an emergency medical care provider course held outside the training program facilities.

"Paramedic (EMT-P)" means an emergency medical technician-paramedic.

"Paramedic specialist (PS)" means an individual who has successfully completed the current United States Department of Transportation's EMT-Paramedic curriculum or equivalent, passed the department's approved written and practical examinations, and is currently certified by the department as a paramedic specialist.

"Patient" means an individual who is sick, injured, or otherwise incapacitated.

"Physician" means an individual licensed under Iowa Code chapter 148, 150, or 150A.

"Physician assistant (PA)" means an individual licensed pursuant to Iowa Code chapter 148C.

"Physician designee" means a registered nurse licensed under Iowa Code chapter 152, or any physician assistant licensed under Iowa Code chapter 148C and approved by the board of physician assistant examiners. The physician designee acts as an intermediary for a supervising physician in accordance with written policies and protocols in directing the care provided by emergency medical care providers.

"Preceptor" means an individual who has been assigned by the training program, clinical facility or service program to supervise students while the students are completing their clinical or field experience. A preceptor must be an emergency medical care provider certified at the level at which the preceptor is providing supervision or a higher level, or must be licensed as a registered nurse, physician assistant or physician.

"Primary instructor" means an individual who is responsible for teaching the majority of an emergency medical care provider course.

"Protocols" means written directions and orders, consistent with the department's standard of care, that are to be followed by an emergency medical care provider in emergency and nonemergency situations. Protocols must be approved by the service program's medical director and address the care of both adult and pediatric patients.

"Registered nurse (RN)" means an individual licensed pursuant to Iowa Code chapter 152.

"Service program" or *"service"* means any medical care ambulance service or nontransport service that has received authorization by the department.

"Service program area" means the geographic area of responsibility served by any given ambulance or nontransport service program.

"Student" means any individual enrolled in a training program and participating in the didactic, clinical, or field experience portions.

"Training program" means an NCA-approved Iowa college or an Iowa hospital approved by the department to conduct emergency medical care training.

"Training program director" means an appropriate health care professional (full-time educator or practitioner of emergency or critical care) assigned by the training program to direct the operation of the training program.

"Training program medical director" means a physician licensed under Iowa Code chapter 148, 150, or 150A who is responsible for directing an emergency medical care training program.

641—131.2(147A) Emergency medical care providers—requirements for enrollment in training programs. To be enrolled in an EMS training program course leading to certification by the department, an applicant shall:

1. Be at least 17 years of age at the time of enrollment.
2. Have a high school diploma or its equivalent if enrolling in an EMT-I, EMT-P, or PS course.
3. Be able to speak, write and read English.

4. Hold a current course completion card in CPR if enrolling in an EMT-B, EMT-I, EMT-P, or PS course.

5. Be currently certified, as a minimum, as an EMT-B, if enrolling in an EMT-I, EMT-P, or PS course. If currently certified in another state as an EMT-B, the applicant must submit an endorsement application to the department within two weeks of the course start date.

6. Be a current EMS provider, RN, PA, or physician and submit a recommendation in writing from an approved EMS training program if enrolling in an EMS instructor course.

7. Be currently certified as a PS if enrolling in a CCP course.

641—131.3(147A) Emergency medical care providers—EMS provider authority.

131.3(1) Authority of emergency medical care personnel. An emergency medical care provider who holds an active certification issued by the department may:

a. Render, via on-line medical direction, emergency and nonemergency medical care in those areas for which the emergency medical care provider is certified as part of an authorized service program:

(1) At the scene of an emergency;

(2) During transportation to a hospital;

(3) While in the hospital emergency department;

(4) Until patient care is directly assumed by a physician or by authorized hospital personnel; and

(5) During transfer from one medical care facility to another or to a private home.

b. Function in any hospital or any other entity in which health care is ordinarily provided only when under the direct supervision of a physician when:

(1) Enrolled as a student in, and approved by, a training program;

(2) Fulfilling continuing education requirements;

(3) Employed by or assigned to a hospital or other entity in which health care is ordinarily provided only when under the direct supervision of a physician as a member of an authorized service program, or in an individual capacity, by rendering lifesaving services in the facility in which employed or assigned pursuant to the emergency medical care provider's certification and under direct supervision of a physician, physician assistant, or registered nurse. An emergency medical care provider shall not routinely function without the direct supervision of a physician, physician assistant, or registered nurse. However, when the physician, physician assistant, or registered nurse cannot directly assume emergency care of the patient, the emergency medical care provider may perform, without direct supervision, emergency medical care procedures for which certified, if the life of the patient is in immediate danger and such care is required to preserve the patient's life;

(4) Employed by or assigned to a hospital or other entity in which health care is ordinarily provided only under the direct supervision of a physician, as a member of an authorized service program, or in an individual capacity, to perform nonlifesaving procedures for which certified and designated in a written job description. Such procedures may be performed after the patient is observed by and when the emergency medical care provider is under the supervision of the physician, physician assistant, or registered nurse, including when the registered nurse is not acting in the capacity of a physician designee, and where the procedure may be immediately abandoned without risk to the patient.

131.3(2) When emergency medical care personnel are functioning in a capacity identified in subrule 131.3(1), paragraph *"a,"* they may perform emergency and nonemergency medical care without contacting a supervising physician or physician designee if written protocols have been approved by the service program medical director which clearly identify when the protocols may be used in lieu of voice contact.

131.3(3) Scope of practice.

a. Emergency medical care providers shall provide only those services and procedures as are authorized within the scope of practice for which they are certified.

b. Scope of Practice for Iowa EMS Providers (April 2009) is incorporated and adopted by reference for EMS providers. For any differences that may occur between the adopted references and these administrative rules, the administrative rules shall prevail.

c. The department may grant a variance for changes to the Scope of Practice that have not yet been adopted by these rules. A variance to these rules may be granted by the department pursuant to 641—subrule 132.14(1).

d. Scope of Practice for Iowa EMS Providers is available through the Iowa Department of Public Health, Bureau of EMS, Lucas State Office Building, Des Moines, Iowa 50319- 0075, or the bureau of EMS Web site (www.idph.state.ia.us/ems).

131.3(4) The department may approve other emergency medical pilot project(s) on a limited basis. Requests for a pilot project application shall be made to the department.

131.3(5) An emergency medical care provider who has knowledge of an emergency medical care provider, service program or training program that has violated Iowa Code chapter 147A or these rules shall report such information to the department within 30 days.

[**ARC 8230B**, IAB 10/7/09, effective 11/11/09]

641—131.4(147A) Emergency medical care providers—certification, renewal standards, procedures, continuing education, and fees.

131.4(1) *Student application and candidate examination.*

a. Applicants shall complete the EMS Student Registration at the beginning of the course. EMS Student Registration shall be completed via the bureau of EMS Web site at www.idph.state.ia.us/ems.

b. EMS Student Registration shall be completed within 14 days after the course start date.

c. Upon satisfactory completion of the course and all training program requirements, including payment of appropriate fees, the candidate shall be recommended by the training program to take the state-approved certification examinations. A candidate recommended for state certification is not eligible to continue functioning as a student in the clinical and field setting. State certification must be obtained to perform appropriate skills.

d. The practical examination shall be administered using the standards and forms provided by the department. The training program shall notify the department at least four weeks prior to the administration of a practical examination.

e. Rescinded IAB 8/1/07, effective 9/5/07.

f. Candidates eligible to take the state written examination shall submit an EMS Certification Application form to the department. EMS Certification Application forms are provided by the department.

g. When a student's EMS Student Registration or a candidate's EMS Certification Application is referred to the department for investigation, or when a student or candidate is otherwise under investigation by the department, the individual shall not be eligible for certification, and the practical examination results will not be confirmed with the NREMT, until the individual is approved by the department.

h. The written certification examination shall be administered at times and places determined by the department.

i. No oral certification examinations shall be permitted; however, candidates may be eligible for appropriate accommodations. The candidate should contact the Iowa Department of Public Health, Bureau of Emergency Medical Services, Lucas State Office Building, Des Moines, Iowa 50319-0075 at least four weeks prior to the test date.

j. Certifying examination fees shall be approved by the department.

k. The fee for certification as an emergency medical care provider is $30, payable to the Iowa Department of Public Health. This nonrefundable fee shall be paid prior to a candidate's receiving certification.

l. A candidate who fails the practical certification examination shall be required to repeat only those stations that were failed and shall have two additional opportunities to attain a passing score. A candidate failing the practical certification examination on three full attempts must repeat the entire EMS training program to be eligible for certification.

(1) An FR or EMT-B candidate will test all practical stations and have three opportunities to pass those stations. The candidate's first attempt at all stations will constitute the first full attempt. Each retest of failed stations will constitute an additional full attempt.

(2) A full attempt for an EMT-I, EMT-P or PS candidate will consist of completing all skills and two retesting opportunities, if eligible. The candidate must provide documentation of remediation before taking a second or third full attempt.

m. The practical examination remains valid for a 12-month period from the date it was successfully completed. Required passing practical scores for FR, EMT-B, EMT-I, EMT-P, and PS shall be based on criteria established by the department.

n. A candidate who fails to attain the appropriate overall score on the written certification examination shall have two additional opportunities to complete the entire examination and attain a passing score. Required passing written scores for FR, EMT-B, EMT-I, EMT-P, and PS shall be based on criteria established by the department.

o. A candidate who fails to pass the written certification examination on the third attempt and who wishes to pursue certification must submit, at a minimum, written verification from an approved training program of successful completion of an appropriate refresher course or equivalent. Candidates failing the examination on six attempts must repeat the entire EMT training program to be eligible for certification.

p. All examination attempts shall be completed within two years of the initial course completion date. If an individual is unable to complete the testing within two years due to medical reasons or military obligation, an extension may be granted upon submission of a signed statement from an appropriate medical/military authority and approval by the department.

q. Examination scores shall be confidential except that they may be released to the training program that provided the training or to other appropriate state agencies, or released in a manner which does not permit the identification of an individual.

r. To be eligible to take the practical examination, FR candidates shall have a current course completion card in CPR.

s. Applicants for EMS-I endorsement shall successfully complete an EMS-Instructor curriculum approved by the department.

t. Applicants for ERT endorsement shall successfully complete an ERT curriculum approved by the department in cooperation with the department of public safety.

u. Payment of all appropriate certification/examination fees shall be made prior to the candidate's receiving certification.

131.4(2) *Multiple certificates and renewal.*

a. The department shall consider the highest level of certification attained to be active. Any lower levels of certification shall be considered idle.

b. A lower level certificate may be issued if the individual fails to renew the higher level of certification or voluntarily chooses to move from a higher level to a lower level. To be issued a certificate in these instances, an individual shall:

(1) Complete all applicable continuing education requirements for the lower level during the certification period and submit a change of status request, available through the Iowa Department of Public Health, Bureau of EMS, Lucas State Office Building, Des Moines, Iowa 50319-0075, or the bureau of EMS Web site (www.idph.state.ia.us/ems).

(2) Complete and submit to the department an EMS Affirmative Renewal of Certification Application and the applicable fee.

(3) Complete the reinstatement process in 131.4(3)*"f"* if renewal of the higher level is requested later.

c. A citation and warning, denial, probation, suspension or revocation imposed upon an individual certificate holder by the department shall be considered applicable to all certificates issued to that individual by the department.

131.4(3) *Renewal of certification.*

a. A certificate shall be valid for two years from issuance unless specified otherwise on the certificate or unless sooner suspended or revoked.

b. All continuing education requirements shall be completed during the certification period prior to the certificate's expiration date. Failure to complete the continuing education requirements prior to the expiration date shall result in an expired certification.

c. The EMS Affirmative Renewal of Certification Application shall be submitted to the department within 90 days prior to the expiration date. Failure to submit a renewal application to the department within 90 days prior to the expiration date (based upon the postmark date) shall cause the current certification to expire.

d. Emergency medical care providers shall not function on an expired certification.

e. An individual who completes the required continuing education during the certification period, but fails to submit the EMS Affirmative Renewal of Certification Application within 90 days prior to the expiration date, shall be required to submit a late fee of $30 (in addition to the renewal fee) and complete the audit process pursuant to 131.4(4)*"i"* to obtain renewal of certification.

f. An individual who has not completed the required continuing education during the certification period or who is seeking to reinstate an expired, inactive, or retired certificate shall:

(1) Complete a refresher course or equivalent approved by the department.

(2) Meet all applicable eligibility requirements.

(3) Submit an EMS Reinstatement Application and the applicable fees to the department.

(4) Pass the appropriate practical and written certification examinations.

g. Rescinded IAB 4/7/10, effective 5/12/10.

h. An individual may request an inactive or retired status for a certificate. The request must be made by submitting a change of status request, available through the Iowa Department of Public Health, Bureau of EMS, Lucas State Office Building, Des Moines, Iowa 50319-0075, or the bureau of EMS Web site (www.idph.state.ia.us/ems). Reinstatement of an inactive or retired certificate shall be made pursuant to 131.4(3)*"f."* A request for inactive or retired status, when accepted in connection with a disciplinary investigation or proceeding, has the same effect as an order of revocation.

i. An individual shall be deemed to have complied with the continuing education requirements during periods that the individual serves honorably on active duty in the military services or for periods that the individual is a government employee working as an emergency medical care provider and assigned to duty outside the United States. The individual must submit the Affirmative Renewal Application, all appropriate fees and documentation of assignment.

131.4(4) *Continuing education renewal standards.* To be eligible for renewal through continuing education, the following standards shall apply:

a. The applicant shall sign and submit an Affirmative Renewal of Certification Application provided by the department and submit the applicable fee within 90 days prior to the certificate's expiration date.

b. The applicant shall complete the continuing education requirements, including current course completion in CPR, during the certification period for the following EMS provider levels:

(1) FR, FR-D—12 hours of approved continuing education.

(2) EMT-A, EMT-B, EMT-D—24 hours of approved continuing education.

(3) EMT-I—36 hours of approved continuing education.

(4) EMT-P—48 hours of approved continuing education.

(5) PS—60 hours of approved continuing education.

(6) EMS-I—Attend at least one EMS-I workshop sponsored by the department.

(7) CCP—8 hours of approved CCP core curriculum topics.

c. At least 50 percent of the required hours for renewal shall be formal continuing education including, but not limited to, refresher programs, seminars, lecture programs, scenario-based programs, conferences, and Internet-delivered courses approved by CECBEMS and shall meet the criteria established in paragraph 131.4(6)*"d."*

d. Up to 50 percent of the required continuing education hours may be made up of any of the following:

(1) Nationally recognized EMS-related courses;

(2) EMS self-study courses;

(3) Medical director or designee case reviews;

(4) Clinical rounds with medical team (grand rounds);

(5) Rescinded IAB 8/1/07, effective 9/5/07.

(6) Working with students as an EMS field preceptor;

(7) Hospital or nursing home clinical performance;

(8) Skills workshops/maintenance;

(9) Community public information education projects;

(10) Emergency driver training;

(11) EMS course audits;

(12) Injury prevention or wellness initiatives;

(13) EMS service operations, e.g., management programs, continuous quality improvement;

(14) EMS system development meetings to include county, regional and state;

(15) Disaster preparedness;

(16) Emergency runs/responses as a volunteer member of an authorized EMS service program (primary attendant).

e. Additional hours may be allowed for any of the following (maximum):

(1) CPR—2 hours;

(2) Disaster drill—4 hours;

(3) Rescue—4 hours;

(4) Hazardous materials—8 hours;

(5) Practical examination evaluator—4 hours;

(6) Topics outside the provider's core curriculum—8 hours.

f. With training program approval, persons who are not enrolled in an emergency medical care provider course may audit those courses for CEHs.

g. Certificate holders must notify the department within 30 days of a change in address.

h. The certificate holder shall maintain a file containing documentation of continuing education hours accrued during each certification period for four years from the end of each certification period.

i. A group of individual certificate holders will be audited for each certification period. Certificate holders to be audited will be chosen in a random manner or at the discretion of the bureau of EMS. Falsifying reports or failure to comply with the audit request may result in formal disciplinary action. Certificate holders who are audited will be required to submit verification of continuing education compliance within 45 days of the request. If audited, the certificate holders must provide the following information:

(1) Date of program.

(2) Program sponsor number.

(3) Title of program.

(4) Number of approved hours.

(5) Appropriate supervisor signatures if clinical or practical evaluator hours are claimed.

j. Instructors of EMS initial or continuing education courses may use those courses for renewal as approved under subrule 131.4(6).

131.4(5) *Renewal by testing.*

a. To be eligible for renewal by testing, candidates shall meet the following standards:

(1) Submit a request to renew by testing to the department six months prior to the certificate's expiration date. Any testing fees will be in addition to renewal fees.

(2) Complete a Renewal by Testing Application provided by the department and schedule a test date with an EMS training program.

(3) Successfully complete the practical and written examinations.

b. Candidates who are unsuccessful by testing may renew under the continuing education standards in subrule 131.4(4); however, renewal must be completed prior to the certificate's expiration date.

c. Candidates who are unsuccessful by testing or who do not complete the continuing education requirements prior to the expiration date shall reinstate an expired certificate pursuant to 131.4(3)*"f"* if active certification is sought.

131.4(6) *Continuing education approval.* The following standards shall be applied for approval of continuing education:

a. Required CEHs identified in 131.4(4)*"c"* shall be approved by the department, CECBEMS, or an authorized EMS training program, using a sponsor number assignment system approved by the department.

b. Optional CEHs identified in 131.4(4)*"d"* and 131.4(4)*"e"* require no formal sponsor number; however, CEHs awarded shall be verified by an authorized EMS training program, a national EMS continuing education accreditation entity, a service program medical director, an appropriate community sponsor, or the department. Documentation of CEHs awarded shall include program or event, date and title, number of hours approved, and applicable signatures.

c. Courses in physical, social or behavioral sciences offered by accredited colleges and universities are approved for CEHs and need no further approval.

d. Courses approved as formal education must meet the following criteria:

(1) Involve live interaction with an instructor or be an Internet-delivered course approved by CECBEMS; and

(2) Be based on the appropriate department curricula for EMS providers and include one or more of the following topic areas: airway, patient assessment, trauma assessment and management, medical assessment and management, behavioral emergencies, obstetrics, gynecology, pediatrics, or patient care record documentation.

e. Programs developed and delivered by the department may be approved for formal education.

131.4(7) *Out-of-state continuing education.* Out-of-state continuing education courses will be accepted for CEHs if they meet the criteria in subrule 131.4(4) and have been approved for emergency medical care personnel in the state in which the courses were held. A copy of course completion certificates (or other verifying documentation) shall, upon request, be submitted to the department with the EMS Affirmative Renewal of Certification Application.

131.4(8) *Fees.* The following fees shall be collected by the department and shall be nonrefundable:

a. FR, EMT-B, EMT-I, EMT-P, and PS certification fee—$30.

b. Certification renewal fees:

(1) FR and EMT-B—no fee.

(2) Renewal of EMT-I certification fee—$10.

(3) Renewal of EMT-P and PS certification fee—$25.

This fee is refundable if the applicant's certification renewal status is not posted on the bureau of EMS Web site in the certification database within ten working days from the date the department receives the completed renewal application.

c. Endorsement certification fee—$50.

d. Reinstatement fee—$30.

e. Late fee—$30.

f. Rescinded IAB 12/3/08, effective 1/7/09.

g. Duplicate/replacement card—$10.

h. Returned check—$20.

i. Extension fee—$50.

131.4(9) *Certification through endorsement.* An individual currently certified by another state or a registrant of the National Registry of EMTs must also possess a current Iowa certificate to be considered certified in this state. The department shall contact the state of certification or the National Registry of EMTs to verify certification or registry and good standing.

a. To receive Iowa certification, the individual shall:

(1) Complete and submit the EMS Endorsement Application available from the department.

(2) Provide verification of current certification in another state or registration with the National Registry of EMTs.

(3) Provide verification of current course completion in CPR.

(4) Pass the appropriate Iowa practical and written certification examinations in accordance with subrule 131.4(1) within one year of the department's approval of the endorsement candidate's application. Current National Registry endorsement candidates are exempt from testing.

(5) Meet all other applicable eligibility requirements necessary for Iowa certification pursuant to these rules.

(6) Submit all applicable fees to the department.

b. An individual certified through endorsement shall satisfy the renewal and continuing education requirements set forth in subrule 131.4(3) to renew Iowa certification.

131.4(10) *Temporary certification through endorsement.* Upon written request, the endorsement applicant may be issued a temporary FR or EMT-B certification by the department. Temporary certification shall not exceed 12 months per application.

131.4(11) *National registration in lieu of continuing education.*

a. An individual who is certified in Iowa and is registered with the NREMT may renew the individual's certification by meeting the NREMT reregistration requirements.

b. The individual shall submit the NREMT Registration in Lieu of Continuing Education Application, available through the Iowa Department of Public Health, Bureau of EMS, Lucas State Office Building, Des Moines, Iowa 50319-0075, or the bureau of EMS Web site (www.idph.state.ia.us/ems), to the department, with proof of NREMT registration exceeding the current certification expiration date, within 90 days prior to the expiration date.

131.4(12) *Extension of certification.*

a. If an individual is unable to complete the required continuing education during the certification period due to a medical reason, an extension of certification may be issued upon submission of a signed statement from an appropriate medical provider and approval by the department. The letter must include information concerning the reason the individual could not complete the continuing education requirements, the time period affected, and the length of time requested for extension.

b. If an individual is unable to attain all continuing education requirements within the certification period, a 45-day extension may be granted. To complete the extension process, the individual shall:

(1) Submit a Request for Extension Application, available through the Iowa Department of Public Health, Bureau of EMS, Lucas State Office Building, Des Moines, Iowa 50319-0075, or the bureau of EMS Web site (www.idph.state.ia.us/ems), at least 7 days prior to the expiration date, but no more than 90 days prior to the expiration date, and a $50 extension fee.

(2) Be given 45 days from the current expiration date to complete continuing education requirements.

(3) Submit the EMS Affirmative Renewal of Certification Application, with all applicable renewal fees, to the department prior to the extended expiration date (based on the postmark date).

(4) Not use continuing education completed during the extension period in the subsequent renewal.

[**ARC 8660B**, IAB 4/7/10, effective 5/12/10]

641—131.5(147A) Training programs—standards, application, inspection and approval.

131.5(1) *Curricula.*

a. The training program shall use the following course curricula approved by the department for certification.

(1) EMS provider curricula and course length:

1. First responder—Current DOT FR curriculum plus department enhancements, 50 to 60 hours.

2. EMT-B—Current DOT EMT-B curriculum plus department enhancements, 120 to 130 hours, clinical time or field time or both as necessary to complete objectives.

3. EMT-I—Iowa curriculum, 54 to 60 didactic hours, clinical and field time as necessary to complete objectives.

4. EMT-P—Current DOT EMT-I curriculum, 280 to 310 didactic hours, clinical and field time as necessary to complete objectives.

5. PS—Current DOT EMT-P curriculum, 600 to 660 didactic hours, clinical and field time as necessary to complete objectives.

6. Training programs that hold current accreditation by the Commission of Accreditation of Allied Health Education Programs for the EMT-P are exempt from the minimum and maximum didactic hours for the EMT-P and PS courses.

(2) Specialty curricula:

1. EMS-I—Current DOT curriculum plus department enhancements.

2. ERT—Iowa curriculum.

3. CCP—Iowa curriculum, 80 to 90 didactic hours, clinical and field time as necessary to complete objectives.

4. EMS-E—Iowa curriculum.

b. Curriculum enhancements are available from the Iowa Department of Public Health, Bureau of EMS, Lucas State Office Building, Des Moines, Iowa 50319-0075.

c. The training program may waive portions of the required EMS provider training for individuals certified or licensed in other health care professions including, but not limited to, nursing, physician assistant, respiratory therapist, dentistry, and military. The training program shall document equivalent training and what portions of the course have been waived for equivalency.

131.5(2) *Clinical or field experience resources.* If clinical or field experience resources are located outside the framework of the training program, written agreements for such resources shall be obtained by the training program.

131.5(3) *Facilities.*

a. There shall be adequate classroom, laboratory, and practice space to conduct the training program. A library with reference materials on emergency and critical care shall also be available.

b. Opportunities for the student to accomplish the appropriate skill competencies in the clinical environment shall be ensured. The following hospital units shall be available for clinical experience for each training program as required in approved curricula pursuant to subrule 131.5(1):

(1) Emergency department;

(2) Intensive care unit or coronary care unit or both;

(3) Operating room and recovery room;

(4) Intravenous or phlebotomy team, or other method to obtain IV experience;

(5) Pediatric unit;

(6) Labor and delivery suite, and newborn nursery; and

(7) Psychiatric unit.

c. Opportunities for the student to accomplish the appropriate skill competencies in the field environment shall be ensured. The training program shall use an appropriate emergency medical care service program to provide field experience as required in approved curricula pursuant to subrule 131.5(1).

d. The training program shall have liability insurance and shall offer liability insurance to students while they are enrolled in a training program.

131.5(4) *Staff.*

a. The training program medical director shall be a physician licensed under Iowa Code chapter 148, 150, or 150A. It is recommended that the training program medical director complete a medical director workshop sponsored by the department.

b. A training program director shall be appointed who is an appropriate health care professional. This individual shall be a full-time educator or a practitioner in emergency or critical care. Current EMS instructor endorsement is also recommended, but not mandatory.

c. Course coordinators, outreach course coordinators, and primary instructors used by the training program shall be currently endorsed as EMS instructors.

d. The instructional staff shall be comprised of physicians, nurses, pharmacists, emergency medical care personnel, or other health care professionals who have appropriate education and

experience in emergency and critical care. Current EMS instructor endorsement is also recommended, but not mandatory.

e. Preceptors shall be assigned in each of the clinical units in which emergency medical care students are obtaining clinical experience and field experience. The preceptors shall supervise student activities to ensure the quality and relevance of the experience. Student activity records shall be kept and reviewed by the immediate supervisor(s) and by the program director and course coordinator.

f. If a training program's medical director resigns, the training program director shall report this to the department and provide a curriculum vitae for the medical director's replacement. A new course shall not be started until a qualified medical director has been appointed.

g. The training program shall maintain records for each instructor used which include, as a minimum, the instructor's qualifications.

h. The training program is responsible for ensuring that each course instructor is experienced in the area being taught and adheres to the course curricula.

i. The training program shall ensure that each practical examination evaluator and mock patient is familiar with the practical examination requirements and procedures. Practical examination evaluators shall attend a workshop sponsored by the department.

131.5(5) *Advisory committee.* There shall be an advisory committee, which includes training program representatives, and other groups such as affiliated medical facilities, local medical establishments, and ambulance, rescue and first response service programs.

131.5(6) *Student records.* The training program shall maintain an individual record for each student. Training program policy and department requirements will determine contents. These requirements may include:

a. Application;

b. Current certifications and endorsements;

c. Student record or transcript of hours and performance (including examinations) in classroom, clinical, and field experience settings.

131.5(7) *Selection of students.* There may be a selection committee to select students using, as a minimum, the prerequisites outlined in rule 641—131.2(147A).

131.5(8) *Students.*

a. A student may perform any procedures and skills for which the student has received training, if the student is under the direct supervision of a physician or physician designee, or under the remote supervision of a physician or physician designee, with direct field supervision by an appropriately certified emergency medical care provider.

b. A student shall not be substituted for personnel of any affiliated medical facility or service program, but may be employed while enrolled in the training program.

c. A student is not eligible to continue functioning as a student of the training program in the clinical or field setting if the student is not in good standing with the training program, once the the student has met the training program requirements, or once the student has been approved for certification testing.

131.5(9) *Financing and administration.*

a. There shall be sufficient funding available to the training program to ensure that each class started can be completed.

b. Tuition charged to students shall be accurately stated.

c. Advertising for training programs shall be appropriate.

d. The training program shall provide to each student, no later than the first session of the course, a guide that outlines, as a minimum:

(1) Course objectives.

(2) Required hours for completion.

(3) Minimum acceptable scores on interim testing.

(4) Attendance requirements.

(5) Grievance procedure.

(6) Disciplinary actions that may be invoked, the grounds for such actions, and the process provided.

(7) Requirements for certification.

131.5(10) *Training program application, inspection and approval.*

a. An applicant seeking initial or renewal training program approval shall use the EMS Training Program Application provided by the department. The application shall include, as a minimum:

(1) Names of appropriate officials of the applicant;

(2) Evidence of availability of clinical resources;

(3) Evidence of availability of physical facilities;

(4) Evidence of qualified faculty;

(5) Qualifications and major responsibilities of each faculty member;

(6) Policies used for selection, promotion, and graduation of trainees;

(7) Practices followed in safeguarding the health and well-being of trainees and of patients receiving emergency medical care within the scope of the training program; and

(8) Level(s) of EMS certification to be offered.

b. New training programs shall submit a needs assessment which justifies the need for the training program.

c. Applications shall be reviewed in accordance with the 2005 Standards and Guidelines for the Accreditation of Educational Programs in the Emergency Medical Services Professions, published by the Commission on Accreditation of Allied Health Education Programs. Failure to comply with the standards may lead to disciplinary action as described in rule 641—131.8(152C).

d. An on-site inspection of the applicant's facilities and clinical resources will be performed. The purpose of the inspection is to examine educational objectives, patient care practices, facilities and administrative practices, and to prepare a written report for review and action by the department.

e. The department shall inspect each training program at least once every five years. The department without prior notification may make additional inspections at times, places and under such circumstances as it deems necessary to ensure compliance with Iowa Code chapter 147A and these rules.

f. No person shall interfere with the inspection activities of the department or its agents. Interference with or failure to allow an inspection may be cause for disciplinary action regarding training program approval.

g. Representatives of the applicant may be required by the department to meet with the department at the time the application and inspection report are discussed.

h. A written report of department action accompanied by the department inspection report shall be sent to the applicant.

i. Training program approval shall not exceed five years.

j. The training program shall notify the department, in writing, of any change in ownership or control within 30 days.

k. Temporary variances. If during a period of authorization there is some occurrence that temporarily causes a training program to be in noncompliance with these rules, the department may grant a temporary variance. Temporary variances to these rules (not to exceed six months in length per any approved request) may be granted by the department to a currently authorized training program. Requests for temporary variances shall apply only to the training program requesting the variance and shall apply only to those requirements and standards for which the department is responsible. To request a variance, the training program shall:

(1) Notify the department verbally (as soon as possible) of the need to request a temporary variance. The program shall submit to the department, within ten days after having given verbal notification to the department, a written explanation for the temporary variance request. The address is Iowa Department of Public Health, Bureau of Emergency Medical Services, Lucas State Office Building, Des Moines, Iowa 50319-0075.

(2) Cite the rule from which the variance is requested.

(3) State why compliance with the rule cannot be maintained.

(4) Explain the alternative arrangements that have been or will be made regarding the variance request.

(5) Estimate the period of time for which the variance will be needed.

l. Training program applications and on-site inspection reports are public information.

131.5(11) *Out-of-state training program application and approval.*

a. An out-of-state training program shall apply to the department for approval.

b. An applicant seeking department approval shall use the out-of-state training program application provided by the department. The application shall include, as a minimum:

(1) Verification of approval to conduct initial EMS training by the authorizing agency within the applicant's home state;

(2) Evidence of physician medical direction oversight;

(3) Evidence of qualified faculty;

(4) Evidence of curriculum utilized;

(5) Evidence of written contracts between the out-of-state training program and clinical and field sites being utilized within Iowa; and

(6) Description of practices followed in safeguarding the health and well-being of trainees and of patients receiving emergency medical care within the scope of the training program.

c. An out-of-state training program shall provide the department with a roster of students who will be participating in the clinical or field experience within the state of Iowa and, for each program, the sites where they will be participating.

d. An out-of-state training program shall not be authorized to provide initial EMS training within the state of Iowa.

e. An out-of-state training program shall be limited to utilization of clinical or field sites or both within Iowa.

f. Representatives of the applicant may be required by the department to meet with the department at the time the application is discussed.

g. An out-of-state training program approval shall not exceed five years.

h. An out-of-state training program shall notify the department, in writing, of any change in ownership, control, or approval status by the out-of-state training program's authorizing state agency within 30 days.

131.5(12) *Out-of-state students.*

a. An out-of-state student shall be a registered student in good standing of an approved out-of-state training program.

b. An out-of-state student may perform any procedure and skills that the student is training for provided that the skill is within the Iowa scope of practice policy of a comparable Iowa EMS provider. The student must be under the direct supervision of a physician or physician designee, or under the remote supervision of a physician or physician designee, with direct supervision by an appropriately certified emergency medical care provider.

c. An out-of-state student shall not be substituted for personnel of any affiliated medical facility or service program, but may be employed while enrolled in the training program.

d. An out-of-state student participating in the clinical or field setting within the state of Iowa shall provide documentation of liability insurance.

e. An out-of-state student is not eligible to continue functioning as a student of the approved out-of-state training program in the clinical or field setting if the student is not in good standing with the approved out-of-state training program, once the student has met the training program's requirements, or once the student has been approved for certification testing.

f. An out-of-state student shall not be eligible for Iowa EMS certification without meeting the requirements for certification through endorsement in 131.4(9).

641—131.6(147A) Continuing education providers—approval, record keeping and inspection.

131.6(1) Continuing education courses for emergency medical care personnel may be approved by the department, EMS training program or a national EMS continuing education accreditation entity.

131.6(2) A training program may conduct continuing education courses (utilizing appropriate instructors) pursuant to subrule 131.4(4).

a. Each training program shall assign a sponsor number to each appropriate continuing education course using an assignment system approved by the department.

b. Course approval shall be made prior to the course's being offered.

c. Each training program shall maintain a participant record that includes, as a minimum:

(1) Name.

(2) Address.

(3) Certification number.

(4) Course sponsor number.

(5) Course instructor.

(6) Date of course.

(7) CEHs awarded.

d. Each training program shall submit to the department on a quarterly basis a completed Approved EMS Continuing Education form.

131.6(3) Record keeping and record inspection.

a. The department may request additional information or inspect the records of any continuing education provider who is currently approved or who is seeking approval to ensure compliance or to verify the validity of any training program application.

b. No person shall interfere with the inspection activities of the department or its agents. Interference with or failure to allow an inspection may be cause for disciplinary action regarding training program approval.

641—131.7(147A) Complaints and investigations—denial, citation and warning, probation, suspension, or revocation of emergency medical care personnel certificates or renewal.

131.7(1) This rule is not subject to waiver or variance pursuant to 641—Chapter 178 or any other provision of law.

131.7(2) The department may deny an application for issuance or renewal of an emergency medical care provider certificate, including endorsement, impose a civil penalty not to exceed $1000, place on probation, issue a citation and warning, suspend, revoke, or otherwise discipline the certificate when it finds that the applicant or certificate holder has committed any of the following acts or offenses:

a. Negligence in performing emergency medical care.

b. Failure to follow the directions of supervising physicians or their designees.

c. Rendering treatment not authorized under Iowa Code chapter 147A.

d. Fraud in procuring certification or renewal including, but not limited to:

(1) An intentional perversion of the truth in making application for a certification to practice in this state;

(2) False representations of a material fact, whether by word or by conduct, by false or misleading allegations, or by concealment of that which should have been disclosed when making application for a certification in this state; or

(3) Attempting to file or filing with the Iowa department of public health or training program any false or forged diploma or certificate or affidavit or identification or qualification in making an application for a certification in this state.

e. Professional incompetency. Professional incompetency includes, but is not limited to:

(1) A substantial lack of knowledge or ability to discharge professional obligations within the scope of practice.

(2) A substantial deviation from the standards of learning or skill ordinarily possessed and applied by other EMS providers in the state of Iowa acting in the same or similar circumstances.

(3) A failure to exercise the degree of care which is ordinarily exercised by the average EMS provider acting in the same or similar circumstances.

(4) Failure to conform to the minimal standard of acceptable and prevailing practice of certified EMS providers in this state.

f. Knowingly making misleading, deceptive, untrue or fraudulent representations in the practice of the profession or engaging in unethical conduct or practice harmful or detrimental to the public. Proof of actual injury need not be established. Acts which may constitute unethical conduct include, but are not limited to:

(1) Verbally or physically abusing a patient or coworker.

(2) Improper sexual contact with or making suggestive, lewd, lascivious or improper remarks or advances to a patient or coworker.

(3) Betrayal of a professional confidence.

(4) Engaging in a professional conflict of interest.

(5) Falsification of medical records.

g. Engaging in any conduct that subverts or attempts to subvert a department investigation.

h. Failure to comply with a subpoena issued by the department or failure to cooperate with an investigation of the department.

i. Failure to comply with the terms of a department order or the terms of a settlement agreement or consent order.

j. Failure to report another EMS provider to the department for any violations listed in these rules, pursuant to Iowa Code chapter 147A.

k. Knowingly aiding, assisting or advising a person to unlawfully practice EMS.

l. Representing oneself as an EMS provider when one's certification has been suspended or revoked, or when one's certification is lapsed or has been placed on inactive status.

m. Permitting the use of a certification by a noncertified person for any purpose.

n. Mental or physical inability reasonably related to and adversely affecting the EMS provider's ability to practice in a safe and competent manner.

o. Being adjudged mentally incompetent by a court of competent jurisdiction.

p. An EMS provider shall not sexually harass a patient, student, or supervisee. Sexual harassment includes sexual advances, sexual solicitation, requests for sexual favors, and other verbal or physical conduct of a sexual nature.

q. Habitual intoxication or addiction to drugs.

(1) The inability of an EMS provider to practice with reasonable skill and safety by reason of the excessive use of alcohol on a continuing basis.

(2) The excessive use of drugs which may impair an EMS provider's ability to practice with reasonable skill or safety.

(3) Obtaining, possessing, attempting to obtain or possess, or administering controlled substances without lawful authority.

r. Fraud in representation as to skill, ability or certification.

s. Willful or repeated violations of Iowa Code chapter 147A or these rules.

t. Violating a statute of this state, another state, or the United States, without regard to its designation as either a felony or misdemeanor, which relates to the provision of emergency medical care, including but not limited to a crime involving dishonesty, fraud, theft, embezzlement, controlled substances, substance abuse, assault, sexual abuse, sexual misconduct, or homicide. A copy of the record of conviction or plea of guilty is conclusive evidence of the violation.

u. Having certification to practice emergency medical care suspended or revoked, or having other disciplinary action taken by a licensing or certifying authority of this state or another state, territory or country. A copy of the record or order of suspension, revocation or disciplinary action is conclusive or prima facie evidence.

v. Falsifying certification renewal reports or failure to comply with the renewal audit request.

w. Acceptance of any fee by fraud or misrepresentation.

x. Repeated failure to comply with standard precautions for preventing transmission of infectious diseases as issued by the Centers for Disease Control and Prevention of the United States Department of Health and Human Services.

y. Privacy and confidentiality. An EMS provider shall not disclose or be compelled to disclose patient information unless required or authorized by law.

z. Discrimination. An EMS provider shall not practice, condone, or facilitate discrimination against a patient, student, or supervisee on the basis of race, ethnicity, national origin, color, sex, sexual orientation, age, marital status, political belief, religion, mental or physical disability, diagnosis, or social or economic status.

aa. Practicing emergency medical services or using a designation of certification or otherwise holding oneself out as practicing emergency medical services at a certain level of certification when the EMS provider is not certified at such level.

ab. Failure to respond within 30 days of receipt, unless otherwise specified, of communication from the department which was sent by registered or certified mail.

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641—131.8(147A) Complaints and investigations—denial, citation and warning, probation, suspension, or revocation of training program or continuing education provider approval or renewal.

131.8(1) This rule is not subject to waiver or variance pursuant to 641—Chapter 178 or any other provision of law.

131.8(2) The department may deny an application for approval or renewal, or issue a citation and warning, or place on probation, or suspend or revoke the approval or renewal when it finds that the applicant has failed to meet the applicable provisions of these rules or has committed any of the following acts or offenses:

a. Fraud in procuring approval or renewal.

b. Falsification of training or continuing education records.

c. Suspension or revocation of approval to provide emergency medical care training or other disciplinary action taken pursuant to Iowa Code chapter 147A. A certified copy of the record or order of suspension, revocation or disciplinary action is conclusive or prima facie evidence.

d. Engaging in any conduct that subverts or attempts to subvert a department investigation.

e. Failure to respond within 30 days of receipt of communication from the department which was sent by registered or certified mail.

f. Failure to comply with a subpoena issued by the department or failure to cooperate with an investigation of the department.

g. Failure to comply with the terms of a department order or the terms of a settlement agreement or consent order.

h. Submission of a false report of continuing education or failure to submit the quarterly report of continuing education.

i. Knowingly aiding, assisting or advising a person to unlawfully practice EMS.

j. Representing itself as an approved training program or continuing education provider when approval has been suspended or revoked or when approval has lapsed or has been placed on inactive status.

k. Using an unqualified individual as an instructor or evaluator.

l. Allowing verbal or physical abuse of a student or coworker.

m. A training program provider or continuing education provider shall not sexually harass a patient, student, or supervisee. Sexual harassment includes sexual advances, sexual solicitation, requests for sexual favors, and other verbal or physical conduct of a sexual nature.

n. Betrayal of a professional confidence.

o. Engaging in a professional conflict of interest.

p. A training program or continuing education provider shall not practice, condone, or facilitate discrimination against a patient, student, or supervisee on the basis of race, ethnicity, national origin, color, sex, sexual orientation, age, marital status, political belief, religion, mental or physical disability, diagnosis, or social or economic status.

q. Failure to comply with the 2005 Standards and Guidelines for the Accreditation of Educational Programs in the Emergency Medical Services Professions, published by the Commission on Accreditation of Allied Health Education Programs.

641—131.9(147A) Reinstatement of certification.

131.9(1) Any person whose certification to practice has been revoked or suspended may apply to the department for reinstatement in accordance with the terms and conditions of the order of revocation or suspension, unless the order of revocation provides that the certification is permanently revoked.

131.9(2) If the order of revocation or suspension did not establish terms and conditions upon which reinstatement might occur, or if the certification was voluntarily surrendered, an initial application for reinstatement may not be made until one year has elapsed from the date of the order or the date of the voluntary surrender.

131.9(3) All proceedings for reinstatement shall be initiated by the respondent, who shall file with the department an application for reinstatement of the certification. Such application shall be docketed in the original case in which the certification was revoked, suspended, or relinquished. All proceedings upon the application for reinstatement shall be subject to the same rules of procedure as other cases before the department.

131.9(4) An application for reinstatement shall allege facts which, if established, will be sufficient to enable the department to determine that the basis for the revocation or suspension of the respondent's certification no longer exists and that it will be in the public interest for the certification to be reinstated. The burden of proof to establish such facts shall be on the respondent.

131.9(5) An order denying or granting reinstatement shall be based upon a decision which incorporates findings of facts and conclusions of law. The order shall be published as provided for in this chapter.

641—131.10(147A) Certification denial.

131.10(1) An applicant who has been denied certification by the department may appeal the denial and request a hearing on the issues related to the licensure denial by serving a notice of appeal and request for hearing upon the department not more than 20 days following the date of mailing of the notification of certification denial to the applicant. The request for hearing shall specifically delineate the facts to be contested at hearing.

131.10(2) All hearings held pursuant to this rule shall be held pursuant to the process outlined in this chapter.

641—131.11(147A) Emergency adjudicative proceedings. To the extent necessary to prevent or avoid immediate danger to the public health, safety, or welfare, and consistent with the Constitution and other provisions of law, the department may issue a written order in compliance with Iowa Code section 17A.18 to suspend a certificate in whole or in part, order the cessation of any continuing activity, order affirmative action, or take other action within the jurisdiction of the department by emergency adjudicative order.

131.11(1) Before issuing an emergency adjudicative order, the department shall consider factors including, but not limited to, the following:

a. Whether there has been a sufficient factual investigation to ensure that the department is proceeding on the basis of reliable information;

b. Whether the specific circumstances which pose immediate danger to the public health, safety or welfare have been identified and determined to be continuing;

c. Whether the individual required to comply with the emergency adjudicative order may continue to engage in other activities without posing immediate danger to the public health, safety or welfare;

d. Whether imposition of monitoring requirements or other interim safeguards would be sufficient to protect the public health, safety or welfare; and

e. Whether the specific action contemplated by the department is necessary to avoid the immediate danger.

131.11(2) Issuance of order.

a. An emergency adjudicative order shall contain findings of fact, conclusions of law, and policy reasons to justify the determination of an immediate danger in the department's decision to take immediate action. The order is a public record.

b. The written emergency adjudicative order shall be immediately delivered to the individual who is required to comply with the order by utilizing one or more of the following procedures:

(1) Personal delivery.

(2) Certified mail, return receipt requested, to the last address on file with the department.

(3) Fax. Fax may be used as the sole method of delivery if the service program required to comply with the order has filed a written request that agency orders be sent by fax and has provided a fax number for that purpose.

c. To the degree practicable, the department shall select the procedure for providing written notice that best ensures prompt, reliable delivery.

d. Unless the written emergency adjudicative order is provided by personal delivery on the same day that the order issues, the department shall make reasonable immediate efforts to contact by telephone the individual who is required to comply with the order.

e. After the issuance of an emergency adjudicative order, the department shall proceed as quickly as feasible to complete any proceedings that would be required if the matter did not involve an immediate danger.

f. Issuance of a written emergency adjudicative order shall include notification of the date on which department proceedings are scheduled for completion. After issuance of an emergency adjudicative order, continuance of further department proceedings to a later date will be granted only in compelling circumstances upon application in writing unless the service program that is required to comply with the order is the party requesting the continuance.

641—131.12(147A) Complaints, investigations and appeals.

131.12(1) This rule is not subject to waiver or variance pursuant to 641—Chapter 178 or any other provision of law.

131.12(2) All complaints regarding emergency medical care personnel, training programs or continuing education providers, or those purporting to be or operating as the same, shall be reported to the department in writing. The address is Iowa Department of Public Health, Bureau of Emergency Medical Services, Lucas State Office Building, Des Moines, Iowa 50319-0075.

131.12(3) An emergency medical care provider who has knowledge of an emergency medical care provider or service program that has violated Iowa Code chapter 147A, 641—Chapter 132 or these rules shall report such information to the department.

131.12(4) Complaint investigations may result in the department's issuance of a notice of denial, citation and warning, probation, suspension or revocation.

131.12(5) A determination of mental incompetence by a court of competent jurisdiction automatically suspends a certificate for the duration of the certificate unless the department orders otherwise.

131.12(6) Notice of denial, issuance of a citation and warning, probation, suspension or revocation shall be effected in accordance with the requirements of Iowa Code section 17A.12. Notice to the alleged violator of denial, probation, suspension or revocation shall be served by certified mail, return receipt requested, or by personal service.

131.12(7) Any request for a hearing concerning the denial, citation and warning, probation, suspension or revocation shall be submitted by the aggrieved party in writing to the department by certified mail, return receipt requested, within 20 days of the receipt of the department's notice to take action. The address is Iowa Department of Public Health, Bureau of Emergency Medical Services, Lucas State Office Building, Des Moines, Iowa 50319-0075. If the request is made within the 20-day time period, the notice to take action shall be deemed to be suspended pending the hearing. Prior to or at the hearing, the department may rescind the notice upon satisfaction that the reason for the denial, citation and warning, probation, suspension or revocation has been or will be removed. If no request for a hearing is received within the 20-day time period, the department's notice of denial, citation and warning, probation, suspension or revocation shall become the department's final agency action.

131.12(8) Upon receipt of a request for hearing, the department shall forward the request within five working days to the department of inspections and appeals pursuant to the rules adopted by that agency

regarding the transmission of contested cases. The information upon which the adverse action is based and any additional information which may be provided by the aggrieved party shall also be provided to the department of inspections and appeals.

131.12(9) The hearing shall be conducted according to the procedural rules of the department of inspections and appeals found in 481—Chapter 10.

131.12(10) When the administrative law judge makes a proposed decision and order, it shall be served by certified mail, return receipt requested, or delivered by personal service. That proposed decision and order then becomes the department's final agency action without further proceedings ten days after it is received by the aggrieved party unless an appeal to the director is taken as provided in subrule 131.12(11).

131.12(11) Any appeal to the director for review of the proposed decision and order of the administrative law judge shall be filed in writing and mailed to the director by certified mail, return receipt requested, or delivered by personal service within ten days after the receipt of the administrative law judge's proposed decision and order by the aggrieved party. A copy of the appeal shall also be mailed to the administrative law judge. Any request for an appeal shall state the reason for appeal.

131.12(12) Upon receipt of an appeal request, the administrative law judge shall prepare the record of the hearing for submission to the director. The record shall include the following:

a. All pleadings, motions, and rules.

b. All evidence received or considered and all other submissions by recording or transcript.

c. A statement of all matters officially noticed.

d. All questions and offers of proof, objections and rulings on them.

e. All proposed findings and exceptions.

f. The proposed decision and order of the administrative law judge.

131.12(13) The decision and order of the director becomes the department's final agency action upon receipt by the aggrieved party and shall be delivered by certified mail, return receipt requested, or by personal service.

131.12(14) It is not necessary to file an application for a rehearing to exhaust administrative remedies when appealing to the director or the district court as provided in Iowa Code section 17A.19. The aggrieved party to the final agency action of the department who has exhausted all administrative remedies may petition for judicial review of that action pursuant to Iowa Code chapter 17A.

131.12(15) Any petition for judicial review of a decision and order shall be filed in the district court within 30 days after the decision and order becomes final. A copy of the notice of appeal shall be sent to the department by certified mail, return receipt requested, or by personal service. The address is Iowa Department of Public Health, Bureau of Emergency Medical Services, Lucas State Office Building, Des Moines, Iowa 50319-0075.

131.12(16) The party who appeals a final agency action to the district court shall pay the cost of the preparation of a transcript of the contested case hearing for the district court.

131.12(17) Final decisions of the department relating to disciplinary proceedings may be transmitted to the appropriate professional associations, the news media or employer.

These rules are intended to implement Iowa Code chapter 147A.

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CHAPTER 132
EMERGENCY MEDICAL SERVICES—SERVICE PROGRAM AUTHORIZATION

[Joint Rules pursuant to 147A.4]
[Prior to 7/29/87, Health Department[470] Ch 132]

641—132.1(147A) Definitions. For the purpose of these rules, the following definitions shall apply:

"Ambulance" means any privately or publicly owned ground vehicle specifically designed, modified, constructed, equipped, staffed and used regularly to transport the sick, injured or otherwise incapacitated.

"Ambulance service" means any privately or publicly owned service program which utilizes ambulances in order to provide patient transportation and emergency medical services.

"Automated defibrillator" means any external semiautomatic device that determines whether defibrillation is required.

"Automated external defibrillator" or *"AED"* means an external semiautomated device that determines whether defibrillation is required.

"Basic ambulance service" means an ambulance service that provides patient treatment at the basic care level.

"Basic care" means treatment interventions, appropriate to certification level, that provide minimum care to the patient including, but not limited to, CPR, bandaging, splinting, oxygen administration, spinal immobilization, oral airway insertion and suctioning, antishock garment, vital sign assessment and administration of over-the-counter drugs.

"CEH" means "continuing education hour" which is based upon a minimum of 50 minutes of training per hour.

"Continuous quality improvement (CQI)" means a program that is an ongoing process to monitor standards at all EMS operational levels including the structure, process, and outcomes of the patient care event.

"CPR" means training and successful course completion in cardiopulmonary resuscitation, AED and obstructed airway procedures for all age groups according to recognized national standards.

"Critical care paramedic (CCP)" means a currently certified paramedic specialist who has successfully completed a critical care course of instruction approved by the department and has received endorsement from the department as a critical care paramedic.

"Critical care transport (CCT)" means specialty care patient transportation when medically necessary, for a critically ill or injured patient needing critical care paramedic (CCP) skills, between medical care facilities, and provided by an authorized ambulance service that is approved by the department to provide critical care transportation and staffed by one or more critical care paramedics or other health care professional in an appropriate specialty area.

"Current course completion" means written recognition given for training and successful course completion of CPR with an expiration date or a recommended renewal date that exceeds the current date.

"Deficiency" means noncompliance with Iowa Code chapter 147A or these rules.

"Department" means the Iowa department of public health.

"Director" means the director of the Iowa department of public health.

"Direct supervision" means services provided by an EMS provider in a hospital setting or other health care entity in which health care is ordinarily performed when in the personal presence of a physician or under the direction of a physician who is immediately available or under the direction of a physician assistant or registered nurse who is immediately available and is acting consistent with adopted policies and protocols of a hospital or other health care entity.

"Emergency medical care" means such medical procedures as:

1. Administration of intravenous solutions.
2. Intubation.
3. Performance of cardiac defibrillation and synchronized cardioversion.
4. Administration of emergency drugs as provided by protocol.

5. Any medical procedure authorized by 131.3(3).

"Emergency medical care provider" means an individual who has been trained to provide emergency and nonemergency medical care at the first responder, EMT-basic, EMT-intermediate, EMT-paramedic, paramedic specialist or other certification levels recognized by the department before 1984 and who has been issued a certificate by the department.

"Emergency medical services" or *"EMS"* means an integrated medical care delivery system to provide emergency and nonemergency medical care at the scene or during out-of-hospital patient transportation in an ambulance.

"Emergency medical technician-basic (EMT-B)" means an individual who has successfully completed the current United States Department of Transportation's Emergency Medical Technician-Basic curriculum and department enhancements, passed the department's approved written and practical examinations, and is currently certified by the department as an EMT-B.

"Emergency medical technician-intermediate (EMT-I)" means an individual who has successfully completed an EMT-intermediate curriculum approved by the department, passed the department's approved written and practical examinations, and is currently certified by the department as an EMT-I.

"Emergency medical technician-paramedic (EMT-P)" means an individual who has successfully completed the current United States Department of Transportation's EMT-intermediate curriculum or the 1985 or earlier DOT EMT-P curriculum, passed the department's approved written and practical examinations, and is currently certified by the department as an EMT-P.

"Emergency medical transportation" means the transportation, by ambulance, of sick, injured or otherwise incapacitated persons who require emergency medical care.

"EMS advisory council" means a council appointed by the director to advise the director and develop policy recommendations concerning regulation, administration, and coordination of emergency medical services in the state.

"EMS contingency plan" means an agreement or dispatching policy between two or more ambulance service programs that addresses how and under what circumstances patient transportation will be provided in a given service area when coverage is not possible due to unforeseen circumstances.

"EMS system" is any specific arrangement of emergency medical personnel, equipment, and supplies designed to function in a coordinated fashion.

"Endorsement" means providing approval in an area related to emergency medical care including, but not limited to, CCP and emergency medical services.

"First responder (FR)" means an individual who has successfully completed the current United States Department of Transportation's First Responder curriculum and department enhancements, passed the department's approved written and practical examinations, and is currently certified by the department as an FR.

"First response vehicle" means any privately or publicly owned vehicle which is used solely for the transportation of emergency medical care personnel and equipment to and from the scene of a medical or nonmedical emergency.

"Hospital" means any hospital licensed under the provisions of Iowa Code chapter 135B.

"Inclusion criteria" means criteria determined by the department and adopted by reference to determine which patients are to be included in the Iowa EMS service program registry or the trauma registry.

"Intermediate" means an emergency medical technician-intermediate.

"Iowa EMS Patient Registry Data Dictionary" means reportable data elements for all ambulance service responses and definitions determined by the department and adopted by reference.

"Medical direction" means direction, advice, or orders provided by a medical director, supervising physician, or physician designee (in accordance with written parameters and protocols) to emergency medical care personnel.

"Medical director" means any physician licensed under Iowa Code chapter 148, 150, or 150A who shall be responsible for overall medical direction of the service program and who has completed a medical director workshop, sponsored by the department, within one year of assuming duties.

"Mutual aid" means an agreement, preferably in writing, between two or more services that addresses how and under what circumstances each service will respond to a request for assistance in situations that exhaust available resources.

"Nonemergency transportation" means transportation that may be provided for those persons determined to need transportation only.

"Nontransport service" means any privately or publicly owned rescue or first response service program which does not provide patient transportation (except when no ambulance is available or in a disaster situation) and utilizes only rescue or first response vehicles to provide emergency medical care at the scene of an emergency.

"Off-line medical direction" means the monitoring of EMS providers through retrospective field assessments and treatment documentation review, critiques of selected cases with the EMS personnel, and statistical review of the system.

"On-line medical direction" means immediate medical direction provided directly to service program EMS providers, in accordance with written parameters and protocols, by the medical director, supervising physician or physician designee either on-scene or by any telecommunications system.

"Paramedic (EMT-P)" means an emergency medical technician-paramedic.

"Paramedic specialist (PS)" means an individual who has successfully completed the current United States Department of Transportation's EMT-Paramedic curriculum or equivalent, passed the department's approved written and practical examinations, and is currently certified by the department as a paramedic specialist.

"Patient" means any individual who is sick, injured, or otherwise incapacitated.

"Patient care report (PCR)" means a computerized or written report that documents the assessment and management of the patient by the emergency care provider in the out-of-hospital setting.

"Physician" means any individual licensed under Iowa Code chapter 148, 150, or 150A.

"Physician assistant (PA)" means an individual licensed pursuant to Iowa Code chapter 148C.

"Physician designee" means any registered nurse licensed under Iowa Code chapter 152, or any physician assistant licensed under Iowa Code chapter 148C and approved by the board of physician assistant examiners. The physician designee acts as an intermediary for a supervising physician in accordance with written policies and protocols in directing the care provided by emergency medical care providers.

"Preceptor" means an individual who has been assigned by the training program, clinical facility or service program to supervise students while the students are completing their clinical or field experience. A preceptor must be an emergency medical care provider certified at the level being supervised or higher, or must be licensed as a registered nurse, physician's assistant or physician.

"Protocols" means written directions and orders, consistent with the department's standard of care, that are to be followed by an emergency medical care provider in emergency and nonemergency situations. Protocols must be approved by the service program's medical director and address the care of both adult and pediatric patients.

"Registered nurse (RN)" means an individual licensed pursuant to Iowa Code chapter 152.

"Reportable patient data" means data elements and definitions determined by the department and adopted by reference to be reported to the Iowa EMS service program registry or the trauma registry or a trauma care facility on patients meeting the inclusion criteria.

"Rescue vehicle" means any privately or publicly owned vehicle which is specifically designed, modified, constructed, equipped, staffed and used regularly for rescue or extrication purposes at the scene of a medical or nonmedical emergency.

"Service director" means an individual who is responsible for the operation and administration of a service program.

"Service program" or *"service"* means any medical care ambulance service or nontransport service that has received authorization by the department.

"Service program area" means the geographic area of responsibility served by any given ambulance or nontransport service program.

"Student" means any individual enrolled in a training program and participating in the didactic, clinical, or field experience portions.

"Supervising physician" means any physician licensed under Iowa Code chapter 148, 150, or 150A. The supervising physician is responsible for medical direction of emergency medical care personnel when such personnel are providing emergency medical care.

"Tiered response" means a rendezvous of service programs to allow the transfer of patient care.

"Training program" means an NCA-approved Iowa college, the Iowa law enforcement academy or an Iowa hospital approved by the department to conduct emergency medical care training.

"Transport agreement" means a written agreement between two or more service programs that specifies the duties and responsibilities of the agreeing parties to ensure appropriate transportation of patients in a given service area.

[**ARC 8661B**, IAB 4/7/10, effective 5/12/10]

641—132.2(147A) Authority of emergency medical care provider.

132.2(1) Rescinded IAB 2/7/01, effective 3/14/01.

132.2(2) An emergency medical care provider who holds an active certification issued by the department may:

a. Render via on-line medical direction emergency and nonemergency medical care in those areas for which the emergency medical care provider is certified, as part of an authorized service program:

(1) At the scene of an emergency;

(2) During transportation to a hospital;

(3) While in the hospital emergency department;

(4) Until patient care is directly assumed by a physician or by authorized hospital personnel; and

(5) During transfer from one medical care facility to another or to a private home.

b. Function in any hospital or any other entity in which health care is ordinarily provided only when under the direct supervision of a physician when:

(1) Enrolled as a student in and approved by a training program;

(2) Fulfilling continuing education requirements;

(3) Employed by or assigned to a hospital or other entity in which health care is ordinarily provided only when under the direct supervision of a physician as a member of an authorized service program, or in an individual capacity, by rendering lifesaving services in the facility in which employed or assigned pursuant to the emergency medical care provider's certification and under direct supervision of a physician, physician assistant, or registered nurse. An emergency medical care provider shall not routinely function without the direct supervision of a physician, physician assistant, or registered nurse. However, when the physician, physician assistant, or registered nurse cannot directly assume emergency care of the patient, the emergency medical care personnel may perform, without direct supervision, emergency medical care procedures for which certified, if the life of the patient is in immediate danger and such care is required to preserve the patient's life;

(4) Employed by or assigned to a hospital or other entity in which health care is ordinarily provided only when under the direct supervision of a physician, as a member of an authorized service program, or in an individual capacity, to perform nonlifesaving procedures for which certified and designated in a written job description. Such procedures may be performed after the patient is observed by and when the emergency medical care provider is under the supervision of the physician, physician assistant, or registered nurse, including when the registered nurse is not acting in the capacity of a physician designee, and where the procedure may be immediately abandoned without risk to the patient.

132.2(3) When emergency medical care personnel are functioning in a capacity identified in subrule 132.2(2), paragraph *"a,"* they may perform emergency and nonemergency medical care without contacting a supervising physician or physician designee if written protocols have been approved by the service program medical director which clearly identify when the protocols may be used in lieu of voice contact.

132.2(4) Scope of practice.

a. Emergency medical care providers shall provide only those services and procedures as are authorized within the scope of practice for which they are certified.

b. Scope of Practice for Iowa EMS Providers (April 2009) is incorporated and adopted by reference for EMS providers. For any differences that may occur between the adopted references and these administrative rules, the administrative rules shall prevail.

c. The department may grant a variance for changes to the Scope of Practice that have not yet been adopted by these rules. A variance to these rules may be granted by the department pursuant to 132.14(1).

d. Scope of Practice for Iowa EMS Providers is available through the Iowa Department of Public Health, Bureau of EMS, Lucas State Office Building, Des Moines, Iowa 50319-0075, or the bureau of EMS Web site (www.idph.state.ia.us/ems).

132.2(5) The department may approve other emergency medical care skills on a limited pilot project basis. Requests for a pilot project application shall be made to the department.

132.2(6) An emergency medical care provider who has knowledge of an emergency medical care provider, service program or training program that has violated Iowa Code chapter 147A or these rules shall report such information to the department within 30 days.

[**ARC 8230B**, IAB 10/7/09, effective 11/11/09]

641—132.3(147A) Emergency medical care providers—requirements for enrollment in training programs. Rescinded IAB 2/9/00, effective 3/15/00.

641—132.4(147A) Emergency medical care providers—certification, renewal standards and procedures, and fees. Rescinded IAB 2/9/00, effective 3/15/00.

641—132.5(147A) Training programs—standards, application, inspection and approval. Rescinded IAB 2/9/00, effective 3/15/00.

641—132.6(147A) Continuing education providers—approval, record keeping and inspection. Rescinded IAB 2/9/00, effective 3/15/00.

641—132.7(147A) Service program—authorization and renewal procedures, inspections and transfer or assignment of certificates of authorization.

132.7(1) *General requirements for authorization and renewal of authorization.*

a. An ambulance or nontransport service in this state that desires to provide emergency medical care, in the out-of-hospital setting, shall apply to the department for authorization to establish a program utilizing certified emergency medical care providers for delivery of care at the scene of an emergency or nonemergency, during transportation to a hospital, during transfer from one medical care facility to another or to a private home, or while in the hospital emergency department and until care is directly assumed by a physician or by authorized hospital personnel. Application for authorization shall be made on forms provided by the department. Applicants shall complete and submit the forms to the department at least 30 days prior to the anticipated date of authorization.

b. To renew service program authorization, the service program shall continue to meet the requirements of Iowa Code chapter 147A and these rules. The renewal application shall be completed and submitted to the department at least 30 days before the current authorization expires.

c. Applications for authorization and renewal of authorization may be obtained upon request to: Iowa Department of Public Health, Bureau of Emergency Medical Services, Lucas State Office Building, Des Moines, Iowa 50319-0075, or the bureau of EMS Web site (www.idph.state.ia.us/ems).

d. The department shall approve an application when the department is satisfied that the program proposed by the application will be operated in compliance with Iowa Code chapter 147A and these administrative rules.

e. Service program authorization is valid for a period of three years from its effective date unless otherwise specified on the certificate of authorization or unless sooner suspended or revoked.

f. Service programs shall be fully operational upon the effective date and at the level specified on the certificate of authorization and shall meet all applicable requirements of Iowa Code chapter 147A and these rules. Deficiencies that are identified shall be corrected within a time frame determined by the department.

g. The certificate of authorization shall be issued to the service program based in the city named in the application. Any ambulance service or nontransport service that operates from more than one city shall apply for and, if approved, shall receive an inclusive authorization for each city of operation that is listed in the application.

h. Any service program owner in possession of a certificate of authorization as a result of transfer or assignment shall continue to meet all applicable requirements of Iowa Code chapter 147A and these rules. In addition, the new owner shall apply to the department for a new certificate of authorization within 30 days following the effective date of the transfer or assignment.

i. Service programs that acquire and maintain current status with a nationally recognized EMS service program accreditation entity that meets or exceeds Iowa requirements may be exempted from the service application/inspection process. A copy of the state service application and accreditation inspection must be filed with the department for approval.

132.7(2) *Out-of-state service programs.*

a. Service programs located in other states which wish to provide emergency medical care in Iowa must meet all requirements of Iowa Code chapter 147A and these rules and must be authorized by the department except when:

(1) Transporting patients from locations within Iowa to destinations outside of Iowa;

(2) Transporting patients from locations outside of Iowa to destinations within Iowa;

(3) Transporting patients to or from locations outside of Iowa that requires travel through Iowa;

(4) Responding to a request for mutual aid in this state; or

(5) Making an occasional EMS response to locations within Iowa and then transporting the patients to destinations within Iowa.

b. An out-of-state service program that meets any of the exception criteria established in 132.7(2) shall be authorized to provide emergency medical care by the state in which the program resides and shall provide the department with verification of current state authorization upon request.

132.7(3) *Air ambulances.* Rescinded IAB 4/7/10, effective 5/12/10.

132.7(4) *Service program inspections.*

a. The department shall inspect each service program at least once every three years. The department without prior notification may make additional inspections at times, places and under such circumstances as it deems necessary to ensure compliance with Iowa Code chapter 147A and these rules.

b. The department may request additional information from or may inspect the records of any service program which is currently authorized or which is seeking authorization to ensure continued compliance or to verify the validity of any information presented on the application for service program authorization.

c. The department may inspect the patient care records of a service program to verify compliance with Iowa Code chapter 147A and these rules.

d. No person shall interfere with the inspection activities of the department or its agents pursuant to Iowa Code section 135.36.

e. Interference with or failure to allow an inspection by the department or its agents may be cause for disciplinary action in reference to service program authorization.

132.7(5) *Temporary service program authorization.*

a. A temporary service program authorization may be issued to services that wish to operate during special events that may need emergency medical care coverage at a level other than basic care. Temporary authorization is valid for a period of 30 days unless otherwise specified on the certificate of authorization or unless sooner suspended or revoked. Temporary authorization shall apply to those requirements and standards for which the department is responsible. Applicants shall complete and submit the necessary forms to the department at least 30 days prior to the anticipated date of need.

b. The service shall meet applicable requirement of these rules, but may apply for a variance using the criteria outlined in rule 641—132.14(147A).

c. The service shall submit a justification which demonstrates the need for the temporary service program authorization.

d. The service shall submit a report, to the department, within 30 days after the expiration of the temporary authorization which includes as a minimum:

(1) Number of patients treated;

(2) Types of treatment rendered;

(3) Any operational or medical problems.

132.7(6) *Conditional service program authorization.* Rescinded IAB 2/6/02, effective 3/13/02.

[**ARC 8661B**, IAB 4/7/10, effective 5/12/10]

641—132.8(147A) Service program levels of care and staffing standards.

132.8(1) A service program seeking ambulance authorization shall:

a. Apply for authorization at one of the following levels:

(1) EMT-B.

(2) EMT-I.

(3) EMT-P.

(4) PS.

b. Maintain an adequate number of ambulances and personnel to provide 24-hour-per-day, 7-day-per-week coverage. Ambulances shall comply with paragraph 132.8(1)*"d."* The number of ambulances and personnel to be maintained shall be determined by the department, and shall be based upon, but not limited to, the following:

(1) Number of calls;

(2) Service area and population; and

(3) Availability of other services in the area.

c. Provide as a minimum, on each ambulance call, the following staff:

(1) One currently certified EMT-B.

(2) One currently licensed driver. The service shall document each driver's training in CPR (AED training not required), in emergency driving techniques and in the use of the service's communications equipment. Training in emergency driving techniques shall include:

1. A review of Iowa laws regarding emergency vehicle operations.

2. A review of the service program's driving policy for first response vehicles, ambulances, rescue vehicles or personal vehicles of an emergency medical care provider responding as a member of the service. The policy shall include, at a minimum:

- Frequency and content of driver's training requirements.
- Criteria for response with lights or sirens or both.
- Speed limits when responding with lights or sirens or both.
- Procedure of approaching intersections with lights or sirens or both.
- Notification process in the event of a motor vehicle collision involving a first response vehicle, ambulance, rescue vehicle or personal vehicle of an emergency medical care provider responding as a member of the service.

3. Behind-the-wheel driving of the service's first response vehicles, ambulances and rescue vehicles.

d. Submit an EMS contingency plan that will be put into operation when coverage pursuant to the 24/7 rule in paragraph 132.8(1)*"b"* is not possible due to unforeseen circumstances.

e. Report frequency of use of the contingency plan to the department upon request.

f. Seek approval from the department to provide nontransport coverage in addition to or in lieu of ambulance authorization.

g. Advertise or otherwise imply or hold itself out to the public as an authorized ambulance service only to the level of care maintained 24 hours per day, seven days a week.

h. Apply to the department to receive approval to provide critical care transportation based upon appropriately trained staff and approved equipment.

i. Unless otherwise established by protocol approved by the medical director, the emergency medical care provider with the highest level of certification (on the transporting service) shall attend the patient.

132.8(2) A service program seeking nontransport authorization shall:

a. Apply for authorization at one of the following levels:

(1) Basic care.

(2) First responder.

(3) EMT-B.

(4) EMT-I.

(5) EMT-P.

(6) PS.

b. For staffing purposes provide, as a minimum, a transport agreement.

c. Advertise or otherwise hold itself out to the public as an authorized nontransport service program only to the level of care maintained 24 hours per day, seven days a week.

d. Not be prohibited from transporting patients in an emergency situation when lack of transporting resources would cause an unnecessary delay in patient care.

132.8(3) Service program operational requirements. Ambulance and nontransport service programs shall:

a. Complete and maintain a patient care report concerning the care provided to each patient. Ambulance services shall provide, at a minimum, a PCR verbal report upon delivery of a patient to a receiving facility and shall provide a complete PCR within 24 hours to the receiving facility.

b. Utilize department protocols as the standard of care. The service program medical director may make changes to the department protocols provided the changes are within the EMS provider's scope of practice and within acceptable medical practice. A copy of the changes shall be filed with the department.

c. Ensure that personnel duties are consistent with the level of certification and the service program's level of authorization.

d. Maintain current personnel rosters and personnel files. The files shall include the names and addresses of all personnel and documentation that verifies EMS provider credentials including, but not limited to:

(1) Current provider level certification.

(2) Current course completions/certifications/endorsements as may be required by the medical director.

(3) PA and RN exception forms for appropriate personnel and verification that PA and RN personnel have completed the appropriate EMS level continuing education.

e. If requested by the department, notify the department in writing of any changes in personnel rosters.

f. Have a medical director and 24-hour-per-day, 7-day-per-week on-line medical direction available.

g. Ensure that the appropriate service program personnel respond as required in this rule and that they respond in a reasonable amount of time.

h. Notify the department in writing within seven days of any change in service director or ownership or control or of any reduction or discontinuance of operations.

i. Select a new or temporary medical director if for any reason the current medical director cannot or no longer wishes to serve in that capacity. Selection shall be made before the current medical director relinquishes the duties and responsibilities of that position.

j. Within seven days of any change of medical director, notify the department in writing of the selection of the new or temporary medical director who must have indicated in writing a willingness to serve in that capacity.

k. Not prevent a registered nurse or physician assistant from supplementing the staffing of an authorized service program provided equivalent training is documented pursuant to Iowa Code sections 147A.12 and 147A.13.

l. Not be authorized to utilize a manual defibrillator (except paramedic, paramedic specialist).

m. Implement a continuous quality improvement program that provides a policy to include as a minimum:

(1) Medical audits.

(2) Skills competency.

(3) Follow-up (loop closure/resolution).

n. Require physician assistants and registered nurses providing care pursuant to Iowa Code sections 147A.12 and 147A.13 to meet CEH requirements approved by the medical director.

o. Document an equipment maintenance program to ensure proper working condition and appropriate quantities.

p. Ensure a response to requests for assistance when dispatched by a public safety answering point within the primary service area identified in the service program's authorization application.

132.8(4) Equipment and vehicle standards. The following standards shall apply:

a. Ambulances placed into service after July 1, 2002, shall meet, as a minimum, the National Truck and Equipment Association's Ambulance Manufacture Division (AMD) performance specifications.

b. All EMS service programs shall carry equipment and supplies in quantities as determined by the medical director and appropriate to the service program's level of care and available certified EMS personnel and as established in the service program's approved protocols.

c. Pharmaceutical drugs and over-the-counter drugs may be carried and administered upon completion of training and pursuant to the service program's established protocols approved by the medical director.

d. All drugs shall be maintained in accordance with the rules of the state board of pharmacy examiners.

e. Accountability for drug exchange, distribution, storage, ownership, and security shall be subject to applicable state and federal requirements. The method of accountability shall be described in the written pharmacy agreement. A copy of the written pharmacy agreement shall be submitted to the department.

f. Each ambulance service program shall maintain a telecommunications system between the emergency medical care provider and the source of the service program's medical direction and other appropriate entities. Nontransport service programs shall maintain a telecommunications system between the emergency medical care provider and the responding ambulance service and other appropriate entities.

g. All telecommunications shall be conducted in an appropriate manner and on a frequency approved by the Federal Communications Commission and the department.

132.8(5) Preventative maintenance. Each ambulance service program shall document a preventative maintenance program to make certain that:

a. Vehicles are fully equipped and maintained in a safe operating condition. In addition:

(1) All ground ambulances shall be housed in a garage or other facility that prevents engine, equipment and supply freeze-up and windshield icing. An unobstructed exit to the street shall also be maintained;

(2) The garage or other facility shall be adequately heated or each response vehicle shall have permanently installed auxiliary heating units to sufficiently heat the engine and patient compartment; and

(3) The garage or other facility shall be maintained in a clean, safe condition free of debris or other hazards.

b. The exterior and interior of the vehicles are kept clean. The interior and equipment shall be cleaned after each use as necessary. When a patient with a communicable disease has been transported or treated, the interior and any equipment or nondisposable supplies coming in contact with the patient shall be thoroughly disinfected.

c. All equipment stored in a patient compartment is secured so that, in the event of a sudden stop or movement of the vehicle, the patient and service program personnel are not injured by moving equipment.

d. All airway, electrical and mechanical equipment is kept clean and in proper operating condition.

e. Compartments provided within the vehicles and the medical and other supplies stored therein are kept in a clean and sanitary condition.

f. All linens, airway and oxygen equipment or any other supplies or equipment coming in direct patient contact is of a single-use disposable type or cleaned, laundered or disinfected prior to reuse.

g. Freshly laundered blankets and linen or disposable linens are used on cots and pillows and are changed after each use.

h. Proper storage is provided for clean linen.

i. Soiled supplies shall be appropriately disposed of according to current biohazard practices.

132.8(6) Service program—incident and accident reports.

a. Incidents of fire or other destructive or damaging occurrences or theft of a service program ambulance, equipment, or drugs shall be reported to the department within 48 hours following the occurrence of the incident.

b. A copy of the motor vehicle accident report required under Iowa Code subsection 321.266(2), relating to the reporting of an accident resulting in personal injury, death or property damage, shall be submitted to the department within seven days following an accident involving a service program vehicle.

c. A service program must report the termination of an emergency medical care provider due to negligence, professional incompetency, unethical conduct or substance use to the department within ten days following the termination.

132.8(7) Adoption by reference. The Iowa EMS Patient Registry Data Dictionary identified in 641—paragraph 136.2(1)*"c"* is adopted and incorporated by reference for inclusion criteria and reportable patient data. For any differences which may occur between the adopted reference and this chapter, the administrative rules shall prevail.

a. The Iowa EMS Patient Registry Data Dictionary identified in 641—paragraph 136.2(1)*"c"* is available through the Iowa Department of Public Health, Bureau of Emergency Medical Services, Lucas State Office Building, Des Moines, Iowa 50319-0075, or the EMS bureau Web site (www.idph.state.ia.us/ems).

b. The department shall prepare compilations for release or dissemination on all reportable patient data entered into the EMS service program registry during the reporting period. The compilations shall include, but not be limited to, trends and patient care outcomes for local, regional, and statewide evaluations. The compilations shall be made available to all service programs submitting reportable patient data to the registry.

c. Access and release of reportable patient data and information.

(1) The data collected by and furnished to the department pursuant to this subrule are confidential records of the condition, diagnosis, care, or treatment of patients or former patients, including outpatients, pursuant to Iowa Code section 22.7. The compilations prepared for release or dissemination from the data collected are not confidential under Iowa Code section 22.7, subsection 2. However, information which individually identifies patients shall not be disclosed, and state and federal law regarding patient confidentiality shall apply.

(2) The department may approve requests for reportable patient data for special studies and analysis provided the request has been reviewed and approved by the deputy director of the department with respect to the scientific merit and confidentiality safeguards, and the department has given administrative approval for the proposal. The confidentiality of patients and the EMS service program shall be protected.

(3) The department may require entities requesting the data to pay any or all of the reasonable costs associated with furnishing the reportable patient data.

d. To the extent possible, activities under this subrule shall be coordinated with other health data collection methods.

e. Quality assurance.

(1) For the purpose of ensuring the completeness and quality of reportable patient data, the department or authorized representative may examine all or part of the patient care report as necessary to verify or clarify all reportable patient data submitted by a service program.

(2) Review of a patient care report by the department shall be scheduled in advance with the service program and completed in a timely manner.

f. The director, pursuant to Iowa Code section 147A.4, may grant a variance from the requirements of these rules for any service program, provided that the variance is related to undue hardships in complying with this chapter.

132.8(8) The patient care report is a confidential document and shall be exempt from disclosure pursuant to Iowa Code subsection 22.7(2) and shall not be accessible to the general public. Information contained in these reports, however, may be utilized by any of the indicated distribution recipients and may appear in any document or public health record in a manner which prevents the identification of any patient or person named in these reports.

132.8(9) Implementation. The director may grant exceptions and variances from the requirements of this chapter for any ambulance or nontransport service. Exceptions or variations shall be reasonably related to undue hardships which existing services experience in complying with this chapter. Services requesting exceptions and variances shall be subject to other applicable rules adopted pursuant to Iowa Code chapter 147A. Nothing in this chapter shall be construed to require any nontransport service to provide a level of care beyond minimum basic care standards.

[**ARC 8661B**, IAB 4/7/10, effective 5/12/10]

641—132.9(147A) Service program—off-line medical direction.

132.9(1) The medical director shall be responsible for providing appropriate medical direction and overall supervision of the medical aspects of the service program and shall ensure that those duties and responsibilities are not relinquished before a new or temporary replacement is functioning in that capacity.

132.9(2) The medical director's duties include, but need not be limited to:

a. Developing, approving and updating protocols to be used by service program personnel that meet or exceed the minimum standard protocols developed by the department.

b. Developing and maintaining liaisons between the service, other physicians, physician designees, hospitals, and the medical community served by the service program.

c. Monitoring and evaluating the activities of the service program and individual personnel performance, including establishment of measurable outcomes that reflect the goals and standards of the EMS system.

d. Assessing the continuing education needs of the service and individual service program personnel and assisting them in the planning of appropriate continuing education programs.

e. Being available for individual evaluation and consultation to service program personnel.

f. Performing or appointing a designee to complete the medical audits required in subrule 132.9(4).

g. Developing and approving an applicable continuous quality improvement policy demonstrating type and frequency of review, including an action plan and follow-up.

h. Informing the medical community of the emergency medical care being provided according to approved protocols in the service program area.

i. Helping to resolve service operational problems.

j. Approving or removing an individual from service program participation.

132.9(3) Supervising physicians, physician designees, or other appointees as defined in the continuous quality improvement policy referenced in 132.9(2)*"g"* may assist the medical director by:

a. Providing medical direction.

b. Reviewing the emergency medical care provided.

c. Reviewing and updating protocols.

d. Providing and assessing continuing education needs for service program personnel.

e. Helping to resolve operational problems.

132.9(4) The medical director or other qualified designees shall randomly audit (at least quarterly) documentation of calls where emergency medical care was provided. The medical director shall randomly review audits performed by the qualified appointee. The audit shall be in writing and shall include, but need not be limited to:

a. Reviewing the patient care provided by service program personnel and remedying any deficiencies or potential deficiencies that may be identified regarding medical knowledge or skill performance.

b. Response time and time spent at the scene.

c. Overall EMS system response to ensure that the patient's needs were matched to available resources including, but not limited to, mutual aid and tiered response.

d. Completeness of documentation.

132.9(5) Rescinded IAB 2/6/02, effective 3/13/02.

132.9(6) On-line medical direction when provided through a hospital.

a. The medical director shall designate in writing at least one hospital which has established a written on-line medical direction agreement with the department. It shall be the medical director's responsibility to notify the department in writing of changes regarding this designation.

b. Hospitals signing an on-line medical direction agreement shall:

(1) Ensure that the supervising physicians or physician designees will be available to provide on-line medical direction via telecommunications on a 24-hour-per-day basis.

(2) Identify the service programs for which on-line medical direction will be provided.

(3) Establish written protocols for use by supervising physicians and physician designees who provide on-line medical direction.

(4) Administer a quality assurance program to review orders given. The program shall include a mechanism for the hospital and service program medical directors to discuss and resolve any identified problems.

c. A hospital which has a written medical direction agreement with the department may provide medical direction for any or all service program authorization levels and may also agree to provide backup on-line medical direction for any other service program when that service program is unable to contact its primary source of on-line medical direction.

d. Only supervising physicians or physician designees shall provide on-line medical direction. However, a physician assistant, registered nurse or EMT (of equal or higher level) may relay orders to emergency medical care personnel, without modification, from a supervising physician. A physician designee may not deviate from approved protocols.

e. The hospital shall provide, upon request to the department, a list of supervising physicians and physician designees providing on-line medical direction.

f. Rescinded IAB 2/6/02, effective 3/13/02.

g. The department may verify a hospital's communications system to ensure compliance with the on-line medical direction agreement.

h. A supervising physician or physician designee who gives orders (directly or via communications equipment from some other point) to an emergency medical care provider is not subject to criminal liability by reason of having issued the orders and is not liable for civil damages for acts or omissions relating to the issuance of the orders unless the acts or omissions constitute recklessness.

i. Nothing in these rules requires or obligates a hospital, supervising physician or physician designee to approve requests for orders received from emergency medical care personnel.

NOTE: Hospitals in other states may participate provided the applicable requirements of this subrule are met.

641—132.10(147A) Complaints and investigations—denial, citation and warning, probation, suspension or revocation of service program authorization or renewal.

132.10(1) All complaints regarding the operation of authorized emergency medical care service programs, or those purporting to be or operating as the same, shall be reported to the department. The

address is: Iowa Department of Public Health, Bureau of Emergency Medical Services, Lucas State Office Building, Des Moines, Iowa 50319-0075.

132.10(2) Complaints and the investigative process will be treated as confidential in accordance with Iowa Code section 22.7.

132.10(3) Service program authorization may be denied, issued a civil penalty not to exceed $1000, issued a citation and warning, placed on probation, suspended, revoked, or otherwise disciplined by the department in accordance with Iowa Code subsection 147A.5(3) for any of the following reasons:

a. Knowingly allowing the falsifying of a patient care report (PCR).

b. Failure to submit required reports and documents.

c. Delegating professional responsibility to a person when the service program knows that the person is not qualified by training, education, experience or certification to perform the required duties.

d. Practicing, condoning, or facilitating discrimination against a patient, student or employee based on race, ethnicity, national origin, color, sex, sexual orientation, age, marital status, political belief, religion, mental or physical disability diagnosis, or social or economic status.

e. Knowingly allowing sexual harassment of a patient, student or employee. Sexual harassment includes sexual advances, sexual solicitations, requests for sexual favors, and other verbal or physical conduct of a sexual nature.

f. Failure or repeated failure of the applicant or alleged violator to meet the requirements or standards established pursuant to Iowa Code chapter 147A or the rules adopted pursuant to that chapter.

g. Obtaining or attempting to obtain or renew or retain service program authorization by fraudulent means or misrepresentation or by submitting false information.

h. Engaging in conduct detrimental to the well-being or safety of the patients receiving or who may be receiving emergency medical care.

i. Failure to correct a deficiency within the time frame required by the department.

132.10(4) The department shall notify the applicant of the granting or denial of authorization or renewal, or shall notify the alleged violator of action to issue a citation and warning, place on probation or suspend or revoke authorization or renewal pursuant to Iowa Code sections 17A.12 and 17A.18. Notice of issuance of a denial, citation and warning, probation, suspension or revocation shall be served by restricted certified mail, return receipt requested, or by personal service.

132.10(5) Any requests for appeal concerning the denial, citation and warning, probation, suspension or revocation of service program authorization or renewal shall be submitted by the aggrieved party in writing to the department by certified mail, return receipt requested, within 20 days of the receipt of the department's notice. The address is: Iowa Department of Public Health, Bureau of Emergency Medical Services, Lucas State Office Building, Des Moines, Iowa 50319-0075. If such a request is made within the 20-day time period, the notice shall be deemed to be suspended. Prior to or at the hearing, the department may rescind the notice upon satisfaction that the reason for the denial, citation and warning, probation, suspension or revocation has been or will be removed. After the hearing, or upon default of the applicant or alleged violator, the administrative law judge shall affirm, modify or set aside the denial, citation and warning, probation, suspension or revocation. If no request for appeal is received within the 20-day time period, the department's notice of denial, probation, suspension or revocation shall become the department's final agency action.

132.10(6) Upon receipt of an appeal that meets contested case status, the appeal shall be forwarded within five working days to the department of inspections and appeals pursuant to the rules adopted by that agency regarding the transmission of contested cases. The information upon which the adverse action is based and any additional information which may be provided by the aggrieved party shall also be provided to the department of inspections and appeals.

132.10(7) The hearing shall be conducted according to the procedural rules of the department of inspections and appeals found in 481—Chapter 10.

132.10(8) When the administrative law judge makes a proposed decision and order, it shall be served by restricted certified mail, return receipt requested, or delivered by personal service. That proposed decision and order then becomes the department's final agency action without further proceedings ten

days after it is received by the aggrieved party unless an appeal to the director is taken as provided in subrule 132.10(9).

132.10(9) Any appeal to the director for review of the proposed decision and order of the administrative law judge shall be filed in writing and mailed to the director by certified mail, return receipt requested, or delivered by personal service within ten days after the receipt of the administrative law judge's proposed decision and order by the aggrieved party. A copy of the appeal shall also be mailed to the administrative law judge. Any request for an appeal shall state the reason for appeal.

132.10(10) Upon receipt of an appeal request, the administrative law judge shall prepare the record of the hearing for submission to the director. The record shall include the following:

a. All pleadings, motions, and rules.

b. All evidence received or considered and all other submissions by recording or transcript.

c. A statement of all matters officially noticed.

d. All questions and offers of proof, objections, and rulings thereon.

e. All proposed findings and exceptions.

f. The proposed decision and order of the administrative law judge.

132.10(11) The decision and order of the director becomes the department's final agency action upon receipt by the aggrieved party and shall be delivered by restricted certified mail, return receipt requested, or by personal service.

132.10(12) It is not necessary to file an application for a rehearing to exhaust administrative remedies when appealing to the director or the district court as provided in Iowa Code section 17A.19. The aggrieved party to the final agency action of the department who has exhausted all administrative remedies may petition for judicial review of that action pursuant to Iowa Code chapter 17A.

132.10(13) Any petition for judicial review of a decision and order shall be filed in the district court within 30 days after the decision and order becomes final. A copy of the notice of appeal shall be sent to the department by certified mail, return receipt requested, or by personal service. The address is: Bureau of Emergency Medical Services, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075.

132.10(14) The party who appeals a final agency action to the district court shall pay the cost of the preparation of a transcript of the contested case hearing for the district court.

132.10(15) Final decisions of the department relating to disciplinary proceedings may be transmitted to the appropriate professional associations, the news media or employer.

132.10(16) This rule is not subject to waiver or variance pursuant to 641—Chapter 178 or any other provision of law.

132.10(17) Emergency adjudicative proceedings.

a. Necessary emergency action. To the extent necessary to prevent or avoid immediate danger to the public health, safety, or welfare, and consistent with the Constitution and other provisions of law, the department may issue a written order in compliance with Iowa Code section 17A.18 to suspend a certificate in whole or in part, order the cessation of any continuing activity, order affirmative action, or take other action within the jurisdiction of the department by emergency adjudicative order.

b. Before issuing an emergency adjudicative order, the department shall consider factors including, but not limited to, the following:

(1) Whether there has been a sufficient factual investigation to ensure that the department is proceeding on the basis of reliable information;

(2) Whether the specific circumstances which pose immediate danger to the public health, safety or welfare have been identified and determined to be continuing;

(3) Whether the program required to comply with the emergency adjudicative order may continue to engage in other activities without posing immediate danger to the public health, safety or welfare;

(4) Whether imposition of monitoring requirements or other interim safeguards would be sufficient to protect the public health, safety or welfare; and

(5) Whether the specific action contemplated by the department is necessary to avoid the immediate danger.

c. Issuance of order.

(1) An emergency adjudicative order shall contain findings of fact, conclusions of law, and policy reasons to justify the determination of an immediate danger in the department's decision to take immediate action. The order is a public record.

(2) The written emergency adjudicative order shall be immediately delivered to the service program that is required to comply with the order by utilizing one or more of the following procedures:

1. Personal delivery.
2. Certified mail, return receipt requested, to the last address on file with the department.
3. Fax. Fax may be used as the sole method of delivery if the service program required to comply with the order has filed a written request that agency orders be sent by fax and has provided a fax number for that purpose.

(3) To the degree practicable, the department shall select the procedure for providing written notice that best ensures prompt, reliable delivery.

(4) Unless the written emergency adjudicative order is provided by personal delivery on the same day that the order issues, the department shall make reasonable immediate efforts to contact by telephone the service program that is required to comply with the order.

(5) After the issuance of an emergency adjudicative order, the department shall proceed as quickly as feasible to complete any proceedings that would be required if the matter did not involve an immediate danger.

(6) Issuance of a written emergency adjudicative order shall include notification of the date on which department proceedings are scheduled for completion. After issuance of an emergency adjudicative order, continuance of further department proceedings to a later date will be granted only in compelling circumstances upon application in writing unless the service program that is required to comply with the order is the party requesting the continuance.

[**ARC 8661B**, IAB 4/7/10, effective 5/12/10]

641—132.11(147A) Complaints and investigations—denial, citation and warning, probation, suspension, or revocation of emergency medical care personnel certificates or renewal. Rescinded IAB 2/9/00, effective 3/15/00.

641—132.12(147A) Complaints and investigations—denial, citation and warning, probation, suspension, or revocation of training program or continuing education provider approval or renewal. Rescinded IAB 2/9/00, effective 3/15/00.

641—132.13(147A) Complaints, investigations and appeals. Rescinded IAB 2/9/00, effective 3/15/00.

641—132.14(147A) Temporary variances.

132.14(1) If during a period of authorization there is some occurrence that temporarily causes a service program to be in noncompliance with these rules, the department may grant a temporary variance. Temporary variances to these rules (not to exceed six months in length per any approved request) may be granted by the department to a currently authorized service program. Requests for temporary variances shall apply only to the service program requesting the variance and shall apply only to those requirements and standards for which the department is responsible.

132.14(2) To request a variance, the service program shall:

a. Notify the department verbally (as soon as possible) of the need to request a temporary variance. Submit to the department, within ten days after having given verbal notification to the department, a written explanation for the temporary variance request. The address and telephone number are Iowa Department of Public Health, Bureau of Emergency Medical Services, Lucas State Office Building, Des Moines, Iowa 50319-0075; (515)725-0326.

b. Cite the rule from which the variance is requested.

c. State why compliance with the rule cannot be maintained.

d. Explain the alternative arrangements that have been or will be made regarding the variance request.

e. Estimate the period of time for which the variance will be needed.

f. Rescinded IAB 2/2/05, effective 3/9/05.

132.14(3) Upon notification of a request for variance, the department shall take into consideration, but shall not be limited to:

a. Examining the rule from which the temporary variance is requested to determine if the request is appropriate and reasonable.

b. Evaluating the alternative arrangements that have been or will be made regarding the variance request.

c. Examining the effect of the requested variance upon the level of care provided to the general populace served.

d. Requesting additional information if necessary.

132.14(4) Preliminary approval or denial shall be provided verbally within 24 hours. Final approval or denial shall be issued in writing within ten days after having received the written explanation for the temporary variance request and shall include the reason for approval or denial. If approval is granted, the effective date and the duration of the temporary variance shall be clearly stated.

132.14(5) Rescinded, effective July 10, 1987.

132.14(6) Any request for appeal concerning the denial of a request for temporary variance shall be in accordance with the procedures outlined in rule 641—132.10(147A).

132.14(7) Rescinded IAB 2/3/93, effective 3/10/93.

641—132.15(147A) Transport options for fully authorized paramedic service programs.

132.15(1) Upon responding to an emergency call, ambulance or nontransport paramedic level services may make a determination at the scene as to whether emergency medical transportation or nonemergency transportation is needed. The determination shall be made by a paramedic or paramedic specialist and shall be based upon the nonemergency transportation protocol approved by the service program's medical director. When applying this protocol, the following criteria, as a minimum, shall be used to determine the appropriate transport option:

a. Primary assessment,

b. Focused history and physical examination,

c. Chief complaint,

d. Name, address and age, and

e. Nature of the call for assistance.

Emergency medical transportation shall be provided whenever any of the above criteria indicate that treatment should be initiated.

132.15(2) If treatment is not indicated, the service program may make arrangements for nonemergency transportation. If arrangements are made, the service program shall remain at the scene until nonemergency transportation arrives. During the wait for nonemergency transportation, however, the ambulance or nontransport service may respond to an emergency.

641—132.16(147A) Public access defibrillation. Rescinded IAB 2/2/05, effective 3/9/05.

These rules are intended to implement Iowa Code chapter 147A.

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[1] See IAB, Inspections and Appeals Department.

[2] Rescission of paragraph 132.14(2)*"f"* inadvertently omitted from 2/2/05 Supplement.

CHAPTER 144
EMERGENCY MEDICAL SERVICES—AIR MEDICAL SERVICE PROGRAM AUTHORIZATION

641—144.1(147A) Definitions. For the purposes of this chapter, the following definitions shall apply:

"Air ambulance" means any privately or publicly owned rotorcraft or fixed-wing aircraft which may be specifically designed, modified, constructed, equipped, staffed and used regularly to transport the sick, injured or otherwise incapacitated who are in need of out-of-hospital emergency medical care or whose condition requires treatment or continuous observation while being transported.

"Air ambulance crew member" means an individual who has been trained to provide emergency and nonemergency medical care at the certification or licensure levels recognized by the department and who has been issued a certificate or license by the department.

"Air ambulance service" means any privately or publicly owned service program which utilizes rotorcraft or fixed-wing aircraft in order to provide patient transportation and emergency medical services.

"Continuous quality improvement" or *"CQI"* means a program that is an ongoing process to monitor standards at all EMS operational levels including the structure, process, and outcomes of the patient care event.

"Critical care paramedic" or *"CCP"* means a currently certified paramedic specialist who has successfully completed a critical care course of instruction approved by the department and has received endorsement from the department as a critical care paramedic.

"Critical care transport" or *"CCT"* means specialty care patient transportation when medically necessary, for a critically ill or injured patient needing CCP skills, between medical care facilities, and provided by an authorized ambulance service that is approved by the department to provide critical care transportation and staffed by one or more critical care paramedics or other health care professional in an appropriate specialty area.

"Deficiency" means noncompliance with Iowa Code chapter 147A or these rules.

"Department" means the Iowa department of public health.

"Director" means the director of the Iowa department of public health.

"Direct supervision" means services provided by an EMS provider in a hospital setting or other health care entity in which health care is ordinarily performed when in the personal presence of a physician or under the direction of a physician who is immediately available or under the direction of a physician assistant or registered nurse who is immediately available and is acting consistent with adopted policies and protocols of a hospital or other health care entity.

"Emergency medical care" means such medical procedures as:

1. Administration of intravenous solutions.
2. Intubation.
3. Performance of cardiac defibrillation and synchronized cardioversion.
4. Administration of emergency drugs as provided by protocol.
5. Any medical procedure authorized by 641—subrule 131.3(3).

"Emergency medical care provider" means an individual who has been trained to provide emergency and nonemergency medical care at the first responder, EMT-basic, EMT-intermediate, EMT-paramedic, paramedic specialist or other certification levels recognized by the department before 1984 and who has been issued a certificate by the department.

"Emergency medical services" or *"EMS"* means an integrated medical care delivery system to provide emergency and nonemergency medical care at the scene or during out-of-hospital patient transportation in an ambulance.

"Emergency medical technician-basic" or *"EMT-B"* means an individual who has successfully completed the current United States Department of Transportation's Emergency Medical Technician-Basic curriculum and department enhancements, has passed the department's approved written and practical examinations, and is currently certified by the department as an EMT-B.

"Emergency medical technician-paramedic" or *"EMT-P"* means an individual who has successfully completed the current United States Department of Transportation's (DOT) EMT-intermediate curriculum or the 1985 or earlier DOT EMT-P curriculum, has passed the department's approved written and practical examinations, and is currently certified by the department as an EMT-P.

"Emergency medical transportation" means the transportation by ambulance of sick, injured or otherwise incapacitated persons who require emergency medical care.

"EMS advisory council" means a council appointed by the director to advise the director and develop policy recommendations concerning regulation, administration, and coordination of emergency medical services in the state.

"EMS system" means any specific arrangement of emergency medical personnel, equipment, and supplies designed to function in a coordinated fashion.

"Endorsement" means providing approval in an area related to emergency medical care including, but not limited to, CCP and emergency medical services.

"FAA" means Federal Aviation Administration.

"FAR" means Federal Aviation Regulation.

"Fixed-wing ambulance" means any privately or publicly owned fixed-wing aircraft specifically designed, modified, constructed, equipped, staffed and used regularly to transport the sick, injured or otherwise incapacitated who are in need of out-of-hospital emergency medical care or whose condition requires treatment or continuous observation while being transported.

"Hospital" means any hospital licensed under the provisions of Iowa Code chapter 135B.

"Inclusion criteria" means criteria determined by the department and adopted by reference to determine which patients are to be included in the Iowa EMS service program registry or the trauma registry.

"Iowa EMS Patient Registry Data Dictionary" means reportable data elements for all ambulance service responses and definitions determined by the department and adopted by reference.

"Medical direction" means direction, advice, or orders provided by a medical director, supervising physician, or physician designee (in accordance with written parameters and protocols) to emergency medical care personnel.

"Medical director" means any physician licensed under Iowa Code chapter 148, who shall be responsible for overall medical direction of the service program and who has completed a medical director workshop, sponsored by the department, within one year of assuming duties.

"Nonemergency transportation" means transportation that may be provided for those persons determined to need transportation only.

"NTSB" means National Transportation Safety Board.

"Off-line medical direction" means the monitoring of EMS providers through retrospective field assessments and treatment documentation review, critiques of selected cases with the EMS personnel, and statistical review of the system.

"On-line medical direction" means immediate medical direction provided directly to service program EMS providers, in accordance with written parameters and protocols, by the medical director, supervising physician or physician designee either on-scene or by any telecommunications system.

"Paramedic" or *"EMT-P"* means an emergency medical technician-paramedic.

"Paramedic specalist" or *"PS"* means an individual who has successfully completed the current United States Department of Transportation's EMT-Paramedic curriculum or equivalent, has passed the department's approved written and practical examinations, and is currently certified by the department as a paramedic specialist.

"Patient" means any individual who is sick, injured, or otherwise incapacitated.

"Patient care report" or *"PCR"* means a computerized or written report that documents the assessment and management of the patient by the emergency care provider in the out-of-hospital setting.

"Physician" means any individual licensed under Iowa Code chapter 148.

"Physician assistant" or *"PA"* means an individual licensed pursuant to Iowa Code chapter 148C.

"Physician designee" means any registered nurse licensed under Iowa Code chapter 152, or any physician assistant licensed under Iowa Code chapter 148C and approved by the board of physician

assistants. The physician designee acts as an intermediary for a supervising physician in accordance with written policies and protocols in directing the care provided by emergency medical care providers.

"Preceptor" means an individual who has been assigned by the training program, clinical facility or service program to supervise students while the students are completing their clinical or field experience. A preceptor must be an emergency medical care provider certified at the level being supervised or higher, or must be licensed as a registered nurse, physician assistant or physician.

"Protocols" means written directions and orders, consistent with the department's standard of care, that are to be followed by an emergency medical care provider in emergency and nonemergency situations. Protocols must be approved by the service program's medical director and must address the care of both adult and pediatric patients.

"Registered nurse" or *"RN"* means an individual licensed pursuant to Iowa Code chapter 152.

"Reportable patient data" means data elements and definitions determined by the department and adopted by reference to be reported to the Iowa EMS service program registry or the trauma registry or a trauma care facility on patients meeting the inclusion criteria.

"Rotorcraft ambulance" means any privately or publicly owned rotorcraft specifically designed, modified, constructed, equipped, staffed and used regularly to transport the sick, injured or otherwise incapacitated who are in need of out-of-hospital emergency medical care or whose condition requires treatment or continuous observation while being transported.

"Service director" means an individual who is responsible for the operation and administration of a service program.

"Service program" or *"service"* means any medical care air ambulance service that has received authorization by the department.

"Service program area" means the geographic area of responsibility served by any given ambulance or nontransport service program.

"Student" means any individual enrolled in a training program and participating in the didactic, clinical, or field experience portions.

"Supervising physician" means any physician licensed under Iowa Code chapter 148. The supervising physician is responsible for medical direction of emergency medical care personnel when such personnel are providing emergency medical care.

"Training program" means an NCA-approved Iowa college, the Iowa law enforcement academy or an Iowa hospital approved by the department to conduct emergency medical care training.

"Transport agreement" means a written agreement between two or more service programs that specifies the duties and responsibilities of the agreeing parties to ensure appropriate transportation of patients in a given service area.

[**ARC 8662B**, IAB 4/7/10, effective 5/12/10]

641—144.2(147A) Authority of emergency medical care provider.

144.2(1) An emergency medical care provider who holds an active certification issued by the department may:

a. Render via on-line medical direction emergency and nonemergency medical care in those areas for which the emergency medical care provider is certified, as part of an authorized service program:

(1) At the scene of an emergency;

(2) During transportation to a hospital;

(3) While in the hospital emergency department;

(4) Until patient care is directly assumed by a physician or by authorized hospital personnel; and

(5) During transfer from one entity where health care is normally provided to another.

b. Function in any hospital or any other entity in which health care is ordinarily provided only when under the direct supervision of a physician when:

(1) Enrolled as a student in and approved by a training program;

(2) Fulfilling continuing education requirements;

(3) Employed by or assigned to a hospital or other entity in which health care is ordinarily provided only when under the direct supervision of a physician as a member of an authorized service

program, or in an individual capacity, by rendering lifesaving services in the facility in which employed or assigned pursuant to the emergency medical care provider's certification and under direct supervision of a physician, physician assistant, or registered nurse. An emergency medical care provider shall not routinely function without the direct supervision of a physician, physician assistant, or registered nurse. However, when the physician, physician assistant, or registered nurse cannot directly assume emergency care of the patient, the emergency medical care personnel may perform, without direct supervision, emergency medical care procedures for which certified, if the life of the patient is in immediate danger and such care is required to preserve the patient's life;

(4) Employed by or assigned to a hospital or other entity in which health care is ordinarily provided only when under the direct supervision of a physician, as a member of an authorized service program, or in an individual capacity, to perform nonlifesaving procedures for which certified and designated in a written job description. Such procedures may be performed after the patient is observed by and when the emergency medical care provider is under the supervision of the physician, physician assistant, or registered nurse, including when the registered nurse is not acting in the capacity of a physician designee, and where the procedure may be immediately abandoned without risk to the patient.

144.2(2) When emergency medical care personnel are functioning in a capacity identified in paragraph 144.2(1)*"a,"* they may perform emergency and nonemergency medical care without contacting a supervising physician or physician designee if written protocols have been approved by the service program medical director which clearly identify when the protocols may be used in lieu of voice contact.

144.2(3) An emergency medical care provider who has knowledge of an emergency medical care provider, service program or training program that has violated Iowa Code chapter 147A or these rules shall report such information to the department within 30 days.

[**ARC 8662B**, IAB 4/7/10, effective 5/12/10]

641—144.3(147A) Air ambulance service program—authorization and renewal procedures, inspections and transfer or assignment of certificates of authorization.

144.3(1) *General requirements for air ambulance authorization and renewal of authorization.*

a. An air ambulance service in this state that desires to provide emergency medical care in an out-of-hospital setting shall apply to the department for authorization to establish a program utilizing certified emergency medical care providers for delivery of care at the scene of an emergency or a nonemergency, during transportation to a hospital, during transfer from one medical care facility to another, or while in the hospital emergency department and until care is directly assumed by a physician or by authorized hospital personnel. Application for authorization shall be made on forms provided by the department. Applicants shall complete and submit the forms to the department at least 30 days prior to the anticipated date of authorization.

b. To renew service program authorization, the service program shall continue to meet the requirements of Iowa Code chapter 147A and these rules. The renewal application shall be completed and submitted to the department at least 30 days before the current authorization expires.

c. Applications for authorization and renewal of authorization may be obtained upon request to: Iowa Department of Public Health, Bureau of Emergency Medical Services, Lucas State Office Building, Des Moines, Iowa 50319-0075, or the bureau of EMS Web site (www.idph.state.ia.us/ems).

d. The department shall approve an application when the department is satisfied that the program proposed by the application will be operated in compliance with Iowa Code chapter 147A and these rules.

e. Service program authorization is valid for a period of three years from its effective date unless otherwise specified on the certificate of authorization or unless sooner suspended or revoked.

f. Service programs shall be fully operational upon the effective date and at the level specified on the certificate of authorization and shall meet all applicable requirements of Iowa Code chapter 147A and these rules. Deficiencies that are identified shall be corrected within a time frame determined by the department.

g. Any service program owner in possession of a certificate of authorization as a result of transfer or assignment shall continue to meet all applicable requirements of Iowa Code chapter 147A and these rules. In addition, the new owner shall apply to the department for a new certificate of authorization within 30 days following the effective date of the transfer or assignment.

h. Service programs that acquire and maintain current status with a nationally recognized EMS service program accreditation entity that meets or exceeds Iowa requirements may be exempted from the service application/inspection process. A copy of the state service application and accreditation inspection must be filed with the department for approval.

144.3(2) *Out-of-state air ambulance service programs.*

a. Service programs located in other states which wish to provide emergency medical care in Iowa must meet all requirements of Iowa Code chapter 147A and these rules and must be authorized by the department except when:

(1) Transporting patients from locations within Iowa to destinations outside of Iowa;

(2) Transporting patients from locations outside of Iowa to destinations within Iowa;

(3) Transporting patients to and from locations outside of Iowa when doing so requires travel through Iowa;

(4) Responding to a request for mutual aid in this state; or

(5) Making less than 30 EMS responses per year to locations within Iowa and then transporting the patients to destinations within Iowa.

b. An out-of-state service program that meets any of the exception criteria established in this subrule shall be authorized to provide emergency medical care by the state in which the program resides and shall provide the department with verification of current state authorization upon request.

144.3(3) *Air ambulance service program inspections.*

a. The department shall inspect each service program at least once every three years. The department without prior notification may make additional inspections at times, places and under such circumstances as it deems necessary to ensure compliance with Iowa Code chapter 147A and these rules.

b. The department may request additional information from or may inspect the records of any service program which is currently authorized or which is seeking authorization to ensure continued compliance or to verify the validity of any information presented on the application for service program authorization.

c. The department may inspect the patient care records of a service program to verify compliance with Iowa Code chapter 147A and these rules.

d. No person shall interfere with the inspection activities of the department or its agents pursuant to Iowa Code section 135.36.

e. Interference with or failure to allow an inspection by the department or its agents may be cause for disciplinary action in reference to service program authorization.

144.3(4) *Temporary service program authorization.*

a. A temporary service program authorization may be issued to services that wish to operate during special events that may need emergency medical care coverage at a level other than basic care. Temporary authorization is valid for a period of 30 days unless otherwise specified on the certificate of authorization or unless sooner suspended or revoked. Temporary authorization shall apply to those requirements and standards for which the department is responsible. Applicants shall complete and submit the necessary forms to the department at least 30 days prior to the anticipated date of need.

b. The service shall meet applicable requirements of these rules but may apply for a variance using the criteria outlined in rule 641—144.7(147A).

c. The service shall submit a justification which demonstrates the need for the temporary service program authorization.

d. The service shall submit a report to the department within 30 days after the expiration of the temporary authorization which includes as a minimum:

(1) Number of patients treated;

(2) Types of treatment rendered;

(3) Any operational or medical problems.

[**ARC 8662B**, IAB 4/7/10, effective 5/12/10]

641—144.4(147A) Service program levels of care and staffing standards.

144.4(1) An air ambulance service program seeking authorization shall:

a. Apply for authorization at the following levels:

(1) EMT-Basic.

(2) Paramedic specialist.

(3) Critical care transport.

b. Conduct all air ambulance service flights under a minimum of FAR rules, Part 135.

c. Maintain an adequate number of aircraft and personnel to provide 24-hour-per-day, 7-day-per-week coverage. The number of aircraft and personnel to be maintained shall be determined by the service and shall be based upon, but not limited to, the following:

(1) Number of calls;

(2) Service area and population; and

(3) Availability of other services in the area.

d. Staff fixed-wing ambulances, at a minimum on each flight request, with the following staff while a patient is being transported:

(1) One health care provider who is certified or licensed in the state from which the aircraft launches and is certified as an EMT-Basic or higher level; and

(2) One FAA-certified commercial pilot who is appropriately rated in the aircraft being used for the transport.

e. Staff rotorcraft ambulances, at a minimum on each flight request, with the following staff while a patient is being transported:

(1) Two health care providers who are certified or licensed in the state from which the aircraft launches, one of whom must at a minimum be certified as a paramedic specialist; and

(2) One FAA-certified commercial pilot who is appropriately rated in the aircraft being used for the transport.

f. Train medical crew members in the following areas:

(1) Patient care limitations in flight.

(2) Altitude physiology.

(3) Appropriate utilization of air medical services.

(4) Communication system.

(5) Aircraft operations and safety.

(6) Emergency safety and survival.

(7) Prehospital scene response and safety.

(8) Crew resource management.

(9) Program flight risk assessment procedures.

g. Apply to the department to receive approval to provide critical care transportation based upon appropriately trained staff and approved equipment.

h. Ensure that the health care provider with the highest level of certification (on the transporting service) attends the patient, unless otherwise established by protocol approved by the medical director.

144.4(2) Air ambulance service program operational requirements. Air ambulance service programs shall:

a. Complete and maintain a patient care report concerning the care provided to each patient. Services shall provide, at a minimum, a verbal report upon delivery of a patient to a receiving facility and shall provide a complete PCR within 24 hours to the receiving facility.

b. Ensure that personnel duties are consistent with the level of certification and the service program's level of authorization.

c. Maintain current personnel rosters and personnel files. The files shall include the names and addresses of all personnel and documentation that verifies EMS provider credentials including, but not limited to:

(1) Current provider level certification.

(2) Current course completions/certifications/endorsements as may be required by the medical director.

d. If requested by the department, notify the department in writing of any changes in personnel rosters.

e. Have a medical director and 24-hour-per-day, 7-day-per-week on-line medical direction available.

f. Ensure that the appropriate service program personnel respond as required in this rule and that personnel respond in a reasonable amount of time.

g. Notify the department in writing within seven days of any change in service director or ownership or control or of any reduction or discontinuance of operations.

h. Select a new or temporary medical director if for any reason the current medical director cannot or no longer wishes to serve in that capacity. Selection shall be made before the current medical director relinquishes the duties and responsibilities of that position.

i. Within seven days of any change of medical director, notify the department in writing of the selection of the new or temporary medical director who must have indicated in writing a willingness to serve in that capacity.

j. Implement a continuous quality improvement program for patient transport missions to include as a minimum:

(1) Medical audits.

(2) Skills competency.

(3) Flight safety procedures.

(4) Appropriateness of air medical response.

(5) Review of flight risk assessment.

(6) Loop closure requiring physician review of patient transport missions.

k. Document an equipment maintenance program to ensure proper working condition and appropriate quantities.

144.4(3) Air ambulance equipment and vehicle standards.

a. All air ambulance service programs shall carry equipment and supplies in quantities as determined by the medical director and appropriate to the service program's level of care and available medical crew member personnel, and as established in the service program's approved protocols.

b. Pharmaceutical drugs may be carried and administered by appropriate staff upon completion of training and pursuant to the service program's established protocols approved by the medical director.

c. All pharmaceuticals shall be maintained in accordance with the rules of the state board of pharmacy.

d. Accountability for drug exchange, distribution, storage, ownership, and security shall be subject to applicable state and federal requirements. The method of accountability shall be described in the written pharmacy agreement. A copy of the written pharmacy agreement shall be submitted to the department.

e. Each aircraft shall be equipped and maintained in accordance with FAA operating requirements.

f. Each aircraft shall be equipped with a survival kit.

144.4(4) Communications and flight dispatch program.

a. Each service program shall maintain a telecommunications system between the medical crew member and the source of the service program's medical direction and other appropriate entities.

b. All telecommunications shall be conducted in an appropriate manner and on a frequency approved by the Federal Communications Commission and the department.

c. A flight-following policy shall be adopted. This policy shall at a minimum contain the following:

(1) Minimum time between communications with aircraft and its monitoring center;

(2) Documentation of communications with flight;

(3) Lost communications procedures; and

(4) Overdue aircraft procedures.

d. Flight programs shall provide staff or contract with a flight dispatch system for receiving flight requests. Communication specialists shall be trained in the following:

(1) Flight operations;

(2) Aviation weather;

(3) Aviation maintenance;

(4) Flight following;

(5) Flight risk assessment;

(6) Flight service minimum safety standards; and

(7) Overdue aircraft procedures.

144.4(5) Flight risk assessment policy.

a. Each service shall have a flight risk assessment policy in accordance with current FAA guidelines.

b. Flight risk assessment policies shall mandate adherence to policy for all flights.

c. Flight risk assessment policies shall address other flight services being requested, en route, or having been denied request to same incident.

144.4(6) Air ambulance service program—incident and accident response and reports.

a. Air medical services shall have a policy in place outlining missing/overdue/accident issues. This policy will contain at a minimum the following:

(1) Overdue aircraft procedures; and

(2) Postincident action plans.

b. Incidents of fire or other destructive or damaging occurrences or theft of a service program aircraft, vehicle, equipment, or drugs shall be reported to the department within 48 hours following the occurrence of the incident.

c. A report relating to an accident resulting in personal injury, death or property damage shall be submitted to the department within seven days following an accident involving a service program aircraft or vehicle. A complete FAA/NTSB accident report shall be submitted to the bureau of EMS upon completion of the report.

144.4(7) Reportable patient data—adoption by reference.

a. The department shall prepare compilations for release or dissemination on all reportable patient data entered into the EMS service program registry during the reporting period. The compilations shall include, but not be limited to, trends and patient care outcomes for local, regional, and statewide evaluations. The compilations shall be made available to all service programs submitting reportable patient data to the registry.

b. Access and release of reportable patient data and information.

(1) The data collected by and furnished to the department pursuant to this subrule are confidential records of the condition, diagnosis, care, or treatment of patients or former patients, including outpatients, pursuant to Iowa Code section 22.7. The compilations prepared for release or dissemination from the data collected are not confidential under Iowa Code subsection 22.7(2). However, information which individually identifies patients shall not be disclosed, and state and federal law regarding patient confidentiality shall apply.

(2) The department may approve requests for reportable patient data for special studies and analysis provided that the request has been reviewed and approved by the deputy director of the department with respect to the scientific merit and confidentiality safeguards and the department has given administrative approval for the proposal. The confidentiality of patients and the EMS service program shall be protected.

(3) The department may require entities requesting the data to pay any or all of the reasonable costs associated with furnishing the reportable patient data.

c. To the extent possible, activities under this subrule shall be coordinated with other health data collection methods.

d. Quality assurance.

(1) For the purpose of ensuring the completeness and quality of reportable patient data, the department or an authorized representative may examine all or part of the patient care report as necessary to verify or clarify all reportable patient data submitted by a service program.

(2) Review of a patient care report by the department shall be scheduled in advance with the service program and completed in a timely manner.

e. "Iowa Trauma Patient Data Dictionary" is available through the Iowa Department of Public Health, Bureau of Emergency Medical Services, Lucas State Office Building, Des Moines, Iowa 50319-0075, or the bureau of EMS Web site (www.idph.state.ia.us/ems).

f. "Iowa EMS Patient Registry Data Dictionary" identified in 641—paragraph 136.2(1)*"c"* is incorporated by reference for inclusion criteria and reportable patient data to be reported to the department. For any differences which may occur between the adopted reference and this chapter, the administrative rules shall prevail.

g. "Iowa EMS Patient Registry Data Dictionary" identified in 641—paragraph 136.2(1)*"c"* is available through the Iowa Department of Public Health, Bureau of Emergency Medical Services, Lucas State Office Building, Des Moines, Iowa 50319-0075, or the bureau of EMS Web site (www.idph.state.ia.us/ems).

144.4(8) An air ambulance service program shall:

a. Submit reportable patient data identified in subrule 144.4(7) via electronic transfer. Data shall be submitted in a format approved by the department.

b. Submit reportable patient data identified in subrule 144.4(7) to the department for each calendar quarter. Reportable patient data shall be submitted no later than 90 days after the end of the quarter.

144.4(9) The patient care report is a confidential document and shall be exempt from disclosure pursuant to Iowa Code subsection 22.7(2) and shall not be accessible to the general public. Information contained in these reports, however, may be utilized by any of the indicated distribution recipients and may appear in any document or public health record in a manner which prevents the identification of any patient or person named in these reports.

144.4(10) Implementation. The director may grant exceptions and variances from the requirements of this chapter for any air medical service. Exceptions or variations shall be reasonably related to undue hardships which existing services experience in complying with this chapter. Services requesting exceptions and variances shall be subject to other applicable rules adopted pursuant to Iowa Code chapter 147A. Nothing in this chapter shall be construed to require any service to provide a level of care beyond minimum basic care standards.

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641—144.5(147A) Air ambulance service program—off-line medical direction.

144.5(1) The medical director shall be responsible for providing appropriate medical direction and overall supervision of the medical aspects of the service program and shall ensure that those duties and responsibilities are not relinquished before a new or temporary replacement is functioning in that capacity.

144.5(2) The medical director's duties include, but need not be limited to:

a. Developing, approving and updating protocols to be used by service program personnel that meet or exceed the minimum standard protocols developed by the department.

b. Developing and maintaining liaisons between the service, other physicians, physician designees, hospitals, and the medical community served by the service program.

c. Monitoring and evaluating the activities of the service program and individual personnel performance, including establishment of measurable outcomes that reflect the goals and standards of the EMS system.

d. Assessing the continuing education needs of the service and individual service program personnel and assisting them in the planning of appropriate continuing education programs.

e. Being available for individual evaluation and consultation to service program personnel.

f. Performing or appointing a designee to complete the medical audits required in subrule 144.5(4).

g. Developing and approving an applicable continuous quality improvement policy to be used for all patient care encounters, including an action plan and follow-up.

h. Informing the medical community of the emergency medical care being provided according to approved protocols in the service program area.

i. Helping to resolve service operational problems.

j. Approving or removing an individual from service program participation.

144.5(3) Supervising physicians, physician designees, or other appointees as defined in the continuous quality improvement policy referenced in paragraph 144.5(2)*"g"* may assist the medical director by:

a. Providing medical direction.

b. Reviewing the emergency medical care provided.

c. Reviewing and updating protocols.

d. Providing and assessing continuing education needs for service program personnel.

e. Helping to resolve operational problems.

144.5(4) The medical director or other qualified designees shall randomly audit (at least quarterly) documentation of calls where emergency medical care was provided. The medical director shall randomly review audits performed by the qualified appointee. The audit shall be in writing and shall include, but need not be limited to:

a. Reviewing the patient care provided by service program personnel and remedying any deficiencies or potential deficiencies that may be identified regarding medical knowledge or skill performance.

b. Response time and time spent at the scene.

c. Overall EMS system response to ensure that the patient's needs were matched to available resources including, but not limited to, mutual aid and tiered response.

d. Completeness of documentation.

144.5(5) On-line medical direction when provided through a hospital.

a. The medical director shall designate in writing at least one hospital which has established a written on-line medical direction agreement with the department. It shall be the medical director's responsibility to notify the department in writing of changes regarding this designation.

b. Hospitals signing an on-line medical direction agreement shall:

(1) Ensure that the supervising physicians or physician designees will be available to provide on-line medical direction via telecommunications on a 24-hour-per-day basis.

(2) Identify the service programs for which on-line medical direction will be provided.

(3) Establish written protocols for use by supervising physicians and physician designees who provide on-line medical direction.

(4) Administer a quality assurance program to review orders given. The program shall include a mechanism for the hospital and service program medical directors to discuss and resolve any identified problems.

c. A hospital which has a written medical direction agreement with the department may provide medical direction for any or all service program authorization levels and may also agree to provide backup on-line medical direction for any other service program when that service program is unable to contact its primary source of on-line medical direction.

d. Only supervising physicians or physician designees shall provide on-line medical direction. However, a physician assistant, registered nurse or EMT (of equal or higher level) may relay orders to emergency medical care personnel, without modification, from a supervising physician. A physician designee may not deviate from approved protocols.

e. The hospital shall provide, upon request to the department, a list of supervising physicians and physician designees providing on-line medical direction.

f. The department may verify a hospital's communications system to ensure compliance with the on-line medical direction agreement.

g. A supervising physician or physician designee who gives orders (directly or via communications equipment from some other point) to an emergency medical care provider is not subject to criminal liability by reason of having issued the orders and is not liable for civil damages for acts or omissions relating to the issuance of the orders unless the acts or omissions constitute recklessness.

h. Nothing in these rules requires or obligates a hospital, supervising physician or physician designee to approve requests for orders received from emergency medical care personnel.

NOTE: Hospitals in other states may participate provided that the applicable requirements of this subrule are met.

[**ARC 8662B**, IAB 4/7/10, effective 5/12/10]

641—144.6(147A) Complaints and investigations—denial, citation and warning, probation, suspension or revocation of service program authorization or renewal.

144.6(1) All complaints regarding the operation of authorized air medical service programs, or those purporting to be or operating as the same, shall be reported to the department. The address is: Iowa Department of Public Health, Bureau of Emergency Medical Services, Lucas State Office Building, Des Moines, Iowa 50319-0075.

144.6(2) Complaints and the investigative process will be treated as confidential in accordance with Iowa Code section 22.7 and chapter 272C.

144.6(3) Air ambulance service program authorization may be denied or a program may be disciplined as provided in subrule 144.6(4) by the department in accordance with Iowa Code subsections 147A.5(3) and 272C.3(2) for any of the following reasons:

a. Knowingly allowing the falsifying of a patient care report (PCR).

b. Failure to submit required reports and documents.

c. Delegating professional responsibility to a person when the service program knows that the person is not qualified by training, education, experience or certification to perform the required duties.

d. Practicing, condoning, or facilitating discrimination against a patient, student or employee based on race, ethnicity, national origin, color, sex, sexual orientation, age, marital status, political belief, religion, mental or physical disability diagnosis, or social or economic status.

e. Knowingly allowing sexual harassment of a patient, student or employee. Sexual harassment includes sexual advances, sexual solicitations, requests for sexual favors, and other verbal or physical conduct of a sexual nature.

f. Failure or repeated failure of the applicant or alleged violator to meet the requirements or standards established pursuant to Iowa Code chapter 147A or the rules adopted pursuant to that chapter.

g. Obtaining or attempting to obtain or renew or retain service program authorization by fraudulent means or misrepresentation or by submitting false information.

h. Engaging in conduct detrimental to the well-being or safety of the patients receiving or who may be receiving emergency medical care.

i. Failure to correct a deficiency within the time frame required by the department.

144.6(4) Method of discipline. The department has the authority to impose the following disciplinary sanctions against an authorized service program:

a. Issue a citation and warning.

b. Impose a civil penalty not to exceed $1,000.

c. Require additional education or training.

d. Impose a period of probation under specified conditions.

e. Prohibit permanently, until further order of the department, or for a specific period a service program's ability to engage in specific procedures, methods, acts, or activities incident to the practice of the profession.

f. Suspend an authorization until further order of the department or for a specific period.

g. Revoke an authorization.

h. Impose such other sanctions as allowed by law and as may be appropriate.

144.6(5) The department shall notify the applicant of the granting or denial of authorization or renewal, or shall notify the alleged violator of action to issue a citation and warning, place on probation, suspend or revoke authorization or renewal pursuant to Iowa Code sections 17A.12 and 17A.18. Notice of issuance of a denial, citation and warning, probation, suspension or revocation shall be served by restricted certified mail, return receipt requested, or by personal service.

144.6(6) Any requests for appeal concerning the denial, citation and warning, probation, suspension or revocation of service program authorization or renewal shall be submitted by the aggrieved party in writing to the department by certified mail, return receipt requested, within 20 days of the receipt of the department's notice. The address is: Iowa Department of Public Health, Bureau of Emergency Medical Services, Lucas State Office Building, Des Moines, Iowa 50319-0075. If such a request is made within the 20-day time period, the notice shall be deemed to be suspended. Prior to or at the hearing, the department may rescind the notice upon satisfaction that the reason for the denial, citation and warning, probation, suspension or revocation has been or will be removed. After the hearing, or upon default of the applicant or alleged violator, the administrative law judge shall affirm, modify or set aside the denial, citation and warning, probation, suspension or revocation. If no request for appeal is received within the 20-day time period, the department's notice of denial, probation, citation and warning, suspension or revocation shall become the department's final agency action.

144.6(7) Upon receipt of an appeal that meets contested case status, the appeal shall be forwarded within five working days to the department of inspections and appeals pursuant to the rules adopted by that agency regarding the transmission of contested cases. The information upon which the adverse action is based and any additional information which may be provided by the aggrieved party shall also be provided to the department of inspections and appeals.

144.6(8) The hearing shall be conducted according to the procedural rules of the department of inspections and appeals found in 481—Chapter 10.

144.6(9) When the administrative law judge makes a proposed decision and order, it shall be served by restricted certified mail, return receipt requested, or delivered by personal service. That proposed decision and order then becomes the department's final agency action without further proceedings ten days after it is received by the aggrieved party unless an appeal to the director is taken as provided in subrule 144.6(10).

144.6(10) Any appeal to the director for review of the proposed decision and order of the administrative law judge shall be filed in writing and mailed to the director by certified mail, return receipt requested, or delivered by personal service within ten days after the receipt of the administrative law judge's proposed decision and order by the aggrieved party. A copy of the appeal shall also be mailed to the administrative law judge. Any request for an appeal shall state the reason for appeal.

144.6(11) Upon receipt of an appeal request, the administrative law judge shall prepare the record of the hearing for submission to the director. The record shall include the following:

a. All pleadings, motions, and rules.

b. All evidence received or considered and all other submissions by recording or transcript.

c. A statement of all matters officially noticed.

d. All questions and offers of proof, objections, and rulings thereon.

e. All proposed findings and exceptions.

f. The proposed decision and order of the administrative law judge.

144.6(12) The decision and order of the director becomes the department's final agency action upon receipt by the aggrieved party and shall be delivered by restricted certified mail, return receipt requested, or by personal service.

144.6(13) It is not necessary to file an application for a rehearing to exhaust administrative remedies when appealing to the director or the district court as provided in Iowa Code section 17A.19. The aggrieved party to the final agency action of the department who has exhausted all administrative remedies may petition for judicial review of that action pursuant to Iowa Code chapter 17A.

144.6(14) Any petition for judicial review of a decision and order shall be filed in the district court within 30 days after the decision and order becomes final. A copy of the notice of appeal shall be sent to the department by certified mail, return receipt requested, or by personal service. The address is: Bureau of Emergency Medical Services, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075.

144.6(15) The party who appeals a final agency action to the district court shall pay the cost of the preparation of a transcript of the contested case hearing for the district court.

144.6(16) Final decisions of the department relating to disciplinary proceedings may be transmitted to the appropriate professional associations, the news media or an employer.

144.6(17) This rule is not subject to waiver or variance pursuant to 641—Chapter 178 or any other provision of law.

144.6(18) Emergency adjudicative proceedings.

a. Necessary emergency action. To the extent necessary to prevent or avoid immediate danger to the public health, safety, or welfare, and consistent with the Constitution and other provisions of law, the department may issue a written order in compliance with Iowa Code section 17A.18 to suspend authorization in whole or in part, order the cessation of any continuing activity, order affirmative action, or take other action within the jurisdiction of the department by emergency adjudicative order.

b. Before issuing an emergency adjudicative order, the department shall consider factors including, but not limited to, the following:

(1) Whether there has been a sufficient factual investigation to ensure that the department is proceeding on the basis of reliable information;

(2) Whether the specific circumstances which pose immediate danger to the public health, safety, or welfare have been identified and determined to be continuing;

(3) Whether the program required to comply with the emergency adjudicative order may continue to engage in other activities without posing immediate danger to the public health, safety, or welfare;

(4) Whether imposition of monitoring requirements or other interim safeguards would be sufficient to protect the public health, safety, or welfare; and

(5) Whether the specific action contemplated by the department is necessary to avoid the immediate danger.

c. Issuance of order.

(1) An emergency adjudicative order shall contain findings of fact, conclusions of law, and policy reasons to justify the determination of an immediate danger in the department's decision to take immediate action. The order is a public record.

(2) The written emergency adjudicative order shall be immediately delivered to the service program that is required to comply with the order by utilizing one or more of the following procedures:

1. Personal delivery.

2. Certified mail, return receipt requested, to the last address on file with the department.

3. Facsimile. Fax may be used as the sole method of delivery if the service program required to comply with the order has filed a written request that agency orders be sent by fax and has provided a fax number for that purpose.

(3) To the degree practicable, the department shall select the procedure for providing written notice that best ensures prompt, reliable delivery.

(4) Unless the written emergency adjudicative order is provided by personal delivery on the same day that the order issues, the department shall make reasonable immediate efforts to contact by telephone the service program that is required to comply with the order.

(5) After the issuance of an emergency adjudicative order, the department shall proceed as quickly as feasible to complete any proceedings that would be required if the matter did not involve an immediate danger.

(6) Issuance of a written emergency adjudicative order shall include notification of the date on which department proceedings are scheduled for completion. After issuance of an emergency adjudicative order, continuance of further department proceedings to a later date will be granted only in compelling circumstances upon application in writing unless the service program that is required to comply with the order is the party requesting the continuance.

[**ARC 8662B**, IAB 4/7/10, effective 5/12/10]

641—144.7(147A) Temporary variances.

144.7(1) If during a period of authorization there is some occurrence that temporarily causes a service program to be in noncompliance with these rules, the department may grant a temporary variance. Temporary variances from these rules (not to exceed six months in length per any approved

request) may be granted by the department to a currently authorized service program. Requests for temporary variances shall apply only to the service program requesting the variance and shall apply only to those requirements and standards for which the department is responsible.

144.7(2) To request a variance, the service program shall:

a. Notify the department verbally (as soon as possible) of the need to request a temporary variance. Submit to the department, within ten days after having given verbal notification to the department, a written explanation for the temporary variance request. The address and telephone number are Iowa Department of Public Health, Bureau of Emergency Medical Services, Lucas State Office Building, Des Moines, Iowa 50319-0075; (515)725-0326.

b. Cite the rule from which the variance is requested.

c. State why compliance with the rule cannot be maintained.

d. Explain the alternative arrangements that have been or will be made regarding the variance request.

e. Estimate the period of time for which the variance will be needed.

144.7(3) Upon notification of a request for variance, the department shall consider, but shall not be limited to the following:

a. Examining the rule from which the temporary variance is requested to determine if the request is appropriate and reasonable.

b. Evaluating the alternative arrangements that have been or will be made regarding the variance request.

c. Examining the effect of the requested variance upon the level of care provided to the general populace served.

d. Requesting additional information if necessary.

144.7(4) Preliminary approval or denial shall be provided verbally within 24 hours. Final approval or denial shall be issued in writing within ten days after department receipt of the written explanation for the temporary variance request and shall include the reason for approval or denial. If approval is granted, the effective date and the duration of the temporary variance shall be clearly stated.

144.7(5) Any request for appeal concerning the denial of a request for temporary variance shall be in accordance with the procedures outlined in rule 641—144.6(147A).

[**ARC 8662B**, IAB 4/7/10, effective 5/12/10]

641—144.8(147A) Transport options for air medical services.

144.8(1) Upon responding to an emergency call, air medical services may make a determination at the scene as to whether air medical transportation is needed. The determination shall be made by a medical crew member and shall be based upon protocol and concurrence of medical control approved by the service program's medical director. When the medical crew member applies this protocol to determine the appropriate transport option, the following criteria, as a minimum, shall be used:

a. Primary assessment;

b. Focused history and physical examination;

c. Chief complaint;

d. Name, address and age of the individual in need of emergency assistance; and

e. Nature of the call for assistance.

144.8(2) Air medical transportation shall be provided whenever any of the above criteria indicate that treatment should be initiated. If treatment is not indicated, the air medical service program shall make arrangements for alternate transportation, if indicated.

[**ARC 8662B**, IAB 4/7/10, effective 5/12/10]

These rules are intended to implement Iowa Code chapter 147A.

[Filed ARC 8662B (Notice ARC 8499B, IAB 1/27/10), IAB 4/7/10, effective 5/12/10]

CHAPTERS 145 to 149
Reserved

CHAPTER 170
ORGANIZATION OF THE DEPARTMENT
[Prior to 7/29/87, Health Department[470]Ch 170]

641—170.1(17A,135) Definitions.

"Department" means the Iowa department of public health.

"Deputy director" means the deputy director of the department of public health.

"Director" means the director of the department of public health.

[**ARC 8663B**, IAB 4/7/10, effective 5/12/10]

641—170.2(17A,135) Mission. The mission of the department of public health is to promote and protect the health of Iowans. The department strives to improve the quality of life for all Iowans by:

1. Preventing epidemics and the spread of disease;
2. Protecting against environmental hazards;
3. Preventing injuries;
4. Promoting healthy behaviors;
5. Preparing for, responding to, and recovering from public health emergencies;
6. Improving access to quality health services; and
7. Strengthening the public health infrastructure.

[**ARC 8663B**, IAB 4/7/10, effective 5/12/10]

641—170.3(17A,136) State board of health. The state board of health is the policymaking body for the Iowa department of public health and has the power and duty to adopt, promulgate, amend and repeal rules; consider legislation; and advise or make recommendations to the governor, general assembly, and director relative to public health, hygiene, and sanitation.

170.3(1) The state board of health consists of 11 members appointed by the governor.

170.3(2) The state board of health meets on the second Wednesday of July and on the second Wednesday of each second month thereafter and at such other times as may be deemed necessary by the president of the board.

[**ARC 8663B**, IAB 4/7/10, effective 5/12/10]

641—170.4(17A,135) Director of the department of public health. The director is the chief administrative officer of the department, and in that capacity is responsible for the programs and services of the department. The director provides the department with national exposure and works with policymakers in both Iowa and Washington, D.C.

170.4(1) The following are the duties and responsibilities of the director. The director:

a. Oversees the establishment of the administrative organization;

b. Makes recommendations to the state board of health;

c. Oversees the adoption of rules for the implementation of statutes;

d. Serves as secretary to the state board of health;

e. Serves as spokesperson and advocate for public health across the state of Iowa, regionally and nationally;

f. Acts as a liaison to local boards of health, local public health administrators, health care providers, and consumers;

g. Represents the department in a variety of state and national organizations; and

h. Serves as the incident commander during public health emergencies and disasters.

170.4(2) Acting director.

a. The director may appoint an employee of the department to serve as acting director, who shall have all the powers and duties of the director.

b. The director may appoint more than one acting director, but only one acting director shall exercise the powers and perform the duties of the director at any time.

[**ARC 8663B**, IAB 4/7/10, effective 5/12/10]

641—170.5(17A,135) Deputy director.

170.5(1) Under the direction of the director, the deputy director has the following duties and responsibilities. The deputy director:

a. Is responsible for the operations of the department, including but not limited to fiscal and personnel management.

b. Supervises and evaluates the work of the department's division directors.

c. Working with the director, is responsible for developing policy, legislation and administrative rules.

d. Assists the director in the development of policies related to marketing and communications, both internally and externally with other agencies, partners, and the public.

e. Provides advice to the director on matters relating to department strategic planning, goals, mission and programs.

f. Represents the director at private, state, and national meetings.

g. Reports on department accomplishments and performance to the director.

h. Is responsible for departmentwide strategic and performance plans, including preparation of the annual report.

i. Serves as the deputy incident commander during public health emergencies and disasters.

j. Represents the director during the director's absence.

170.5(2) The deputy director also serves as the director of one of the divisions in the department.

[**ARC 8663B**, IAB 4/7/10, effective 5/12/10]

641—170.6(17A,135) Executive team. The executive team serves as the leadership team for the department. The director appoints the members of the executive team.

170.6(1) The executive team assists the department director with strategic planning, policy development, and programmatic decision making.

170.6(2) The executive team members communicate division-level information that contributes to intradepartmental and interdepartmental planning and utilization of resources.

[**ARC 8663B**, IAB 4/7/10, effective 5/12/10]

641—170.7(17A,135) Administrative divisions of the department. The department is divided into seven organizational units. In addition to the director's office, there are six divisions in the department, each directed by a division director who reports either to the deputy director or the director.

170.7(1) *Office of the director.* The following are included in the office of the director.

a. *Medical director.* The medical director of the department is a doctor of medicine (M.D.) or osteopathy (D.O.), specializing in public health, who serves as a medical advisor to the department, medical professionals, and the public. The medical director may also serve as the state epidemiologist.

b. *Office of state medical examiner.* The mission of the office of state medical examiner is to establish credibility in death investigation in a system that will operate efficiently and serve the needs of the citizens of Iowa. This is done by providing assistance, direction, and training to county medical examiner personnel and law enforcement officials. Staff is responsible for conducting death investigations and performing autopsies.

c. *Dental board.* The dental board consists of nine members and has the overall responsibility for regulating the professions of dentistry, dental hygiene, and dental assisting in Iowa.

d. *Board of medicine.* The board of medicine, consisting of ten members, regulates the practice of medicine and surgery, osteopathic medicine and surgery, osteopathy and acupuncture.

e. *Board of nursing.* The six-member board of nursing enforces regulations for nursing education, nursing practice and continuing education for nurses.

f. *Board of pharmacy.* The seven-member board of pharmacy is responsible for regulating the practice of pharmacy and the legal distribution and dispensing of prescription drugs and precursor substances throughout Iowa.

170.7(2) *Division of acute disease prevention and emergency response.* This division provides support, technical assistance, education and consultation regarding departmentwide strategic and project planning, personnel resources, public information, infectious disease prevention and control,

injury prevention and control, emergency medical services, and public health and health care emergency preparedness and response. Division programs within these areas also provide regulatory functions. The deputy state epidemiologist and state public health veterinarian are in this division and report to the division director. Included in the division are the following bureaus and centers.

a. The bureau of communication and planning (CAP) provides communication services to the public, public health partners, media, governor's office, and legislators concerning public health programs, services, statutory requirements, administrative rules, and health-related issues. The bureau leads planning work to develop the department's strategic plan and measure and evaluate performance; improve the dissemination of public health data; and improve and evaluate the public health system in Iowa. The bureau provides administrative services to the state health facilities council and manages the certificate of need program. The bureau ensures a competent workforce through human resources and workforce development services.

b. The center for acute disease epidemiology (CADE) works to protect and preserve the health and safety of Iowans from infectious diseases through disease surveillance; investigation of acute outbreaks; education and consultation to county, local, and private health agencies on infectious diseases; immunization and vaccine guidelines; treatment after animal bites; and vaccines for international travel. The center also provides consultation to county and local health agencies on diseases requiring public health intervention; collaborates with the Centers for Disease Control and Prevention by weekly reporting of nationally reportable diseases; and offers health education opportunities through lectures and organizational seminars.

c. The bureau of emergency medical services (EMS) is responsible for EMS provider certification and renewal, service program authorization, and trauma care facility certification and renewal. The bureau provides leadership and resource support for planning, medical direction, EMS education, public education and injury prevention. Through oversight and coordination, the bureau's objective is the development, implementation and evaluation of a comprehensive statewide EMS system.

d. The center for disaster operations and response (CDOR) is responsible for the development and implementation of emergency plans and operating procedures for the department while ensuring integration into Iowa's Homeland Security and Emergency Management Plan. CDOR works with local public health agencies, hospitals, and other health care entities to ensure communications, capacity, capability, emergency planning, drills and exercises, and education to detect, respond to, and recover from bioterrorism, public health emergencies, and other disasters that may affect the health of Iowans. Additionally, CDOR is responsible for the department's emergency coordination center (ECC), continuity of operations plan, Iowa public health response teams, and the Strategic National Stockpile (SNS).

e. The bureau of immunization and tuberculosis works to protect the health of Iowans from vaccine-preventable diseases and tuberculosis, with the goal of reducing and ultimately eliminating the incidence of these diseases. The bureau conducts surveillance and prevention activities in conjunction with public and private health care providers. Surveillance activities include disease monitoring and reporting, laboratory testing, disease investigation, and rapid institution of disease control measures, including isolation and quarantine. Bureau prevention and treatment activities include targeted disease testing, vaccination programs, dispensing medications, health care provider consultation, and education.

f. The office of health information technology works to ensure a healthier Iowa through the use and exchange of electronic health information to improve patient-centered health care and population health. The office leads planning work to implement statewide electronic exchange of health information to improve the quality of health care, ensure patient safety, and increase efficiency in health care delivery.

170.7(3) *Division of administration and professional licensure.* This division provides services for birth, marriage and death certificates; monitors and reports progress on health objectives and identifies emerging health issues; coordinates 19 licensing boards regulating the activities of 39 health professions; provides fiscal management of department funding and contract administration; and provides software, network and computer support. The following bureaus are included in this division.

a. The bureau of finance provides support to department staff in functions of fiscal and office services, including fiscal management of revenues and expenditures, coordination of office supply purchases, contract administration, use of state vehicles, mail, printing, and inventory control.

b. The bureau of information management provides information technology support for the department, including maintaining the local area network, core software applications, mainframe access, program-specific software application development, hardware installation and help-desk activities.

c. The bureau of professional licensure provides staff support in licensing and certification to the following boards:

(1) Athletic training.
(2) Barbering.
(3) Behavioral science.
(4) Chiropractic.
(5) Cosmetology arts and sciences.
(6) Dietetics.
(7) Hearing aid dispensers.
(8) Sign language interpreters and transliterators.
(9) Massage therapy.
(10) Mortuary science.
(11) Nursing home administrators.
(12) Optometry.
(13) Physical and occupational therapy.
(14) Physician assistants.
(15) Podiatry.
(16) Psychology.
(17) Respiratory care.
(18) Social work.
(19) Speech pathology and audiology.

d. The bureau of health statistics provides certified copies of birth, death, and marriage records to Iowans and other entitled persons.

170.7(4) *Division of behavioral health.* This division promotes the prevention of substance abuse and problem gambling, secondary conditions among people with disabilities, and violent behavior. The division also regulates substance abuse and gambling treatment programs. The division is responsible for approving laboratories that desire to perform drug-testing services for businesses located or doing business in Iowa. Included in the division are the following bureaus and offices.

a. The bureau of administration, regulation, and licensure licenses and monitors substance abuse treatment programs, including community-based and hospital-based programs, assessment and evaluation services, and operating while intoxicated (OWI) correctional and correctional institution programs. The bureau also licenses and monitors problem gambling treatment programs in Iowa.

b. The bureau of substance abuse prevention and treatment provides leadership and resources pertaining to substance abuse in the state. The bureau focuses on both substance abuse prevention and treatment and oversees resources provided by the state and federal governments.

c. The office of gambling treatment and prevention provides funding on a sliding fee scale for outpatient counseling for families, concerned persons, and gamblers affected by problem gambling. The program serves as a resource for all Iowans by providing information, referral, and educational services.

d. The office of injury prevention strives to address the burden of injury on the public health by disseminating information about injury, deaths and hospitalizations and promoting programs directed at preventing both intentional and unintentional injuries.

e. The bureau of HIV, STD, and hepatitis administers programs for the prevention, detection, and treatment of HIV, chlamydia, gonorrhea, syphilis, and viral hepatitis. Program staff provides information, training, and funding to local public health agencies and community-based organizations for prevention and control of these diseases; offers counseling, testing, and referral services; notifies sexual and needle-sharing partners of potential exposures; provides medications, case management,

and supportive services for diagnosed persons; and collects data on disease diagnoses to be used for program planning and evaluation related to prevention and care.

170.7(5) *Division of environmental health.* This division provides both educational and regulatory services to ensure a safe and healthy environment for Iowans. The state toxicologist is in this division and reports to the division director. Included in the division are the following bureaus and offices.

a. The bureau of radiological health regulates facilities that use radioactive materials or utilize ionizing radiation-producing machines; credentials persons who use radioactive material or operate ionizing radiation-producing machines; and provides emergency response related to radioactive materials and nuclear power plant incidents.

b. The bureau of lead poisoning prevention ensures that children are tested for lead poisoning and provides medical and environmental case management for cases of childhood lead poisoning through direct services and grant support to local public health partners. The bureau also regulates professionals who work with lead-based paint through required notification, certification, and work practice standards for those individuals. In addition, the bureau conducts surveillance and education on lead exposure, pesticide exposure, and occupational health and safety issues.

c. The bureau of environmental health services provides assessment, education, consultation, technical assistance and resource referral related to the delivery of environmental health services, emergency response, and regulatory functions to local public health agencies and local boards of health. In addition, the bureau provides consultation and assistance to the public on environmental health matters. The bureau also has regulatory oversight for public swimming pools and spas, water treatment devices, backflow prevention assembly testers, tattoo artists and establishments, and migrant labor camps. In addition, the bureau conducts Grade A milk rating inspections.

d. The office of plumbing and mechanical systems supports the plumbing and mechanical systems board and administers licensing and continuing education requirements for professionals in the plumbing, mechanical, hydronics and refrigeration trades.

170.7(6) *Division of health promotion and chronic disease prevention.* This division promotes and supports healthy behaviors and communities, the prevention and management of chronic diseases, and the development of public health infrastructure and access to health care services at local and state levels. Included in the division are the following bureaus and offices.

a. The bureau of nutrition and health promotion provides nutrition education, supplemental foods, breast-feeding promotion and support, and referrals for health services for low-income women and their children through the Women, Infants and Children (WIC) program. Health promotion programs bring state and local partners together to build a network of health partners dedicated to healthy nutrition and physical activity and provide funding and technical support/coaching to Iowa communities for community wellness initiatives.

b. The oral health bureau, overseen by the public health dental director, promotes and advances health behaviors to reduce the risk of oral diseases and improve the oral health status of all Iowans. Programs are in place targeting pregnant women, children, and youth for the prevention, early identification, referral, and treatment of oral disease.

c. The bureau of local public health provides education, ongoing technical assistance, monitoring, and support to local boards of health and local public health agencies for the development and delivery of services that contribute to compliance with the Iowa Public Health Standards. The bureau acts as a direct liaison between the department and the local public health system to achieve a common goal of promoting and protecting the health of Iowans and contributing to the state of Iowa's goal of becoming a "healthy community."

d. The office of multicultural health assists in fostering partnerships between state government programs, local governments, community groups, and ethnic/racial communities, assists in policy analysis to improve health care access and services for minority populations, and advocates for policies and practices that will reduce health disparities among Iowa's minority, immigrant, and refugee populations.

e. The office for healthy communities works to build healthy communities, thus supporting the department's vision of healthy people in healthy communities. Communities benefit from technical

assistance and support services that improve the capacity of communities to plan and implement health improvement programs.

f. The bureau of family health promotes the health of Iowa families by developing family-centered, community-based, coordinated, and culturally sensitive systems of care for women, infants, children, and adolescents and their families.

g. The bureau of health care access advocates for quality health care delivery systems for all Iowans and provides information, referrals, education, grant opportunities, technical assistance, and planning for Iowa communities. The bureau is the designated state entity for addressing rural health, primary care and health care workforce issues in Iowa and works to improve access to health care for vulnerable populations.

h. The bureau of chronic disease prevention and management supports the development and implementation of services that help prevent chronic disease or assist in the detection and management of chronic disease, including cancer, cardiovascular disease and diabetes.

170.7(7) *Division of tobacco use prevention and control.* This division promotes partnerships among state government, local communities, and the people of Iowa to reduce tobacco use. The division works to reduce tobacco use and the toll of tobacco-caused disease and death by preventing youth from starting to smoke, helping adults to quit smoking, and preventing exposure to secondhand smoke.
[**ARC 8663B**, IAB 4/7/10, effective 5/12/10]

641—170.8(17A) Central office. The address of the central office is: Iowa Department of Public Health, Sixth Floor, Lucas State Office Building, Des Moines, Iowa 50319-0075. Locations of specific offices and regional offices may be obtained by writing to the department at the above address.
[**ARC 8663B**, IAB 4/7/10, effective 5/12/10]

641—170.9(17A) Business hours. The normal business hours of the department are 8 a.m. to 4:30 p.m., Monday through Friday, except legal holidays. One notable exception is the vital records section, which staffs a customer service window just inside the north entrance of the Lucas State Office Building from 7 a.m. to 4:45 p.m., Monday through Friday, except legal holidays.
[**ARC 8663B**, IAB 4/7/10, effective 5/12/10]

641—170.10(17A) Submission of materials. Requests for applications and submission of applications and other materials shall be made directly to the division of the department administering the relevant program. Any person who submits materials should enclose a cover letter which states the use for which the materials are intended. Where the administrative rules give a specific procedure, such procedure should be followed.
[**ARC 8663B**, IAB 4/7/10, effective 5/12/10]

641—170.11(17A) Requests for information. Requests for information concerning programs within the department should be addressed to the specific division of the department. General requests for information may be made to: Public Information Officer, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075. The department's home page on the Internet, www.idph.state.ia.us, also features a "contact us" option.
[**ARC 8663B**, IAB 4/7/10, effective 5/12/10]

These rules are intended to implement Iowa Code section 17A.3 and chapter 135.

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CHAPTER 171
PETITIONS FOR RULE MAKING
[Prior to 7/29/87, Department of Health[470] Ch 171]

641—171.1(17A) Petition for rule making.

171.1(1) Any person or agency may file a petition for rule making with the Director, Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075. A petition is deemed filed when it is received by that office. The department must provide the petitioner with a file-stamped copy of the petition if the petitioner provides the agency an extra copy for this purpose. The petition must be typewritten, or legibly handwritten in ink and must substantially conform to the following form:

BEFORE THE DEPARTMENT OF PUBLIC HEALTH

Petition by (Name of Petitioner) for the (adoption, amendment, or repeal) of rules relating to (state subject matter).	PETITION FOR RULE MAKING

The petition must provide the following information:

1. A statement of the specific rule-making action sought by the petitioner including the text or a summary of the contents of the proposed rule or amendment to a rule and, if it is a petition to amend or repeal a rule, a citation and the relevant language to the particular portion or portions of the rule proposed to be amended or repealed.
2. A citation to any law deemed relevant to the department's authority to take the action urged or to the desirability of that action.
3. A brief summary of petitioner's arguments in support of the action urged in the petition.
4. A brief summary of any data supporting the action urged in the petition.
5. The names and addresses of other persons, or a description of any class of persons, known by petitioner to be affected by or interested in, the proposed action which is the subject of the petition.
6. Any request by petitioner for a meeting provided for by rule 641—171.4(17A).

171.1(2) The petition must be dated and signed by the petitioner or the petitioner's representative. It must also include the name, mailing address, and telephone number of the petitioner and petitioner's representative, and a statement indicating the person to whom communications concerning the petition should be directed.

171.1(3) The department may deny a petition because it does not substantially conform to the required form.

641—171.2(17A) Briefs. The petitioner may attach a brief to the petition in support of the action urged in the petition. The department may request a brief from the petitioner or from any other person concerning the substance of the petition.

641—171.3(17A) Inquiries. Inquiries concerning the status of a petition for rule making may be made to the Director, Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075.

641—171.4(17A) Department consideration.

171.4(1) Within 14 days after the filing of a petition, the department must submit a copy of the petition and any accompanying brief to the administrative rules coordinator and to the administrative rules review committee. Upon request by petitioner in the petition, the department must schedule a brief and informal meeting between the petitioner and a member of the staff of the department, to discuss the petition. The department may request the petitioner to submit additional information or argument concerning the petition. The department may also solicit comments from any person on the substance of the petition. Also, comments on the substance of the petition may be submitted to the department by any person.

171.4(2) Within 60 days after the filing of the petition, or within any longer period agreed to by the petitioner, the department must, in writing, deny the petition, and notify petitioner of its action and the specific grounds for the denial, or grant the petition and notify petitioner that it has instituted rule-making proceedings on the subject of the petition. Petitioner shall be deemed notified of the denial or grant of the petition on the date when the department mails or delivers the required notification to petitioner.

171.4(3) Denial of a petition because it does not substantially conform to the required form does not preclude the filing of a new petition on the same subject that seeks to eliminate the grounds for the agency's rejection of the petition.

These rules are intended to implement Iowa Code chapter 17A.

[Filed 3/18/76, Notice 2/9/76—published 4/5/76, effective 5/10/76]
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[Filed ARC 8664B (Notice ARC 8494B, IAB 1/27/10), IAB 4/7/10, effective 5/12/10]

CHAPTER 172
DECLARATORY ORDERS

[Prior to 7/29/87, Health Department[470] Ch 172]

641—172.1(17A) Petition for declaratory order. Any person may file a petition with the department of public health for a declaratory order as to the applicability to specified circumstances of a statute, rule, or order within the primary jurisdiction of the Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075. A petition is deemed filed when it is received by that office. The department shall provide the petitioner with a file-stamped copy of the petition if the petitioner provides the department an extra copy for this purpose. The petition must be typewritten or legibly handwritten in ink and must substantially conform to the following form:

BEFORE THE DEPARTMENT OF PUBLIC HEALTH

Petition by (Name of Petitioner) for a Declaratory Order on (Cite provisions of law involved).	}	PETITION FOR DECLARATORY ORDER

The petition must provide the following information:

1. A clear and concise statement of all relevant facts on which the order is requested.
2. A citation and the relevant language of the specific statutes, rules, policies, decisions, or orders, whose applicability is questioned, and any other relevant law.
3. The questions petitioner wants answered, stated clearly and concisely.
4. The answers to the questions desired by the petitioner and a summary of the reasons urged by the petitioner in support of those answers.
5. The reasons for requesting the declaratory order and disclosure of the petitioner's interest in the outcome.
6. A statement indicating whether the petitioner is currently a party to another proceeding involving the questions at issue and whether, to the petitioner's knowledge, those questions have been decided by, are pending determination by, or are under investigation by, any governmental entity.
7. The names and addresses of other persons, or a description of any class of persons, known by petitioner to be affected by, or interested in, the questions presented in the petition.
8. Any request by petitioner for a meeting provided for by 172.7(17A).

The petition must be dated and signed by the petitioner or the petitioner's representative. It must also include the name, mailing address, and telephone number of the petitioner and petitioner's representative and a statement indicating the person to whom communications concerning the petition should be directed.

641—172.2(17A) Notice of petition. Within 15 days after receipt of a petition for a declaratory order, the department shall give notice of the petition to all persons not served by the petitioner pursuant to 172.6(17A) to whom notice is required by any provision of law. The department may also give notice to any other persons.

641—172.3(17A) Intervention.

172.3(1) Persons who qualify under any applicable provision of law as an intervenor and who file a petition for intervention within 20 days of the filing of a petition for declaratory order shall be allowed to intervene in a proceeding for a declaratory order.

172.3(2) Any person who files a petition for intervention at any time prior to the issuance of an order may be allowed to intervene in a proceeding for a declaratory order at the discretion of the department.

172.3(3) A petition for intervention shall be filed at the Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075. Such a petition is deemed filed when it is received by that office. The department will provide the petitioner with a file-stamped copy of the petition for

intervention if the petitioner provides an extra copy for this purpose. A petition for intervention must be typewritten or legibly handwritten in ink and must substantially conform to the following form:

BEFORE THE DEPARTMENT OF PUBLIC HEALTH

Petition by (Name of Original Petitioner) for a Declaratory Order on (Cite provisions of law cited in original petition).	PETITION FOR INTERVENTION

The petition for intervention must provide the following information:

1. Facts supporting the intervenor's standing and qualifications for intervention.
2. The answers urged by the intervenor to the question or questions presented and a summary of the reasons urged in support of those answers.
3. Reasons for requesting intervention and disclosure of the intervenor's interest in the outcome.
4. A statement indicating whether the intervenor is currently a party to any proceeding involving the questions at issue and whether, to the intervenor's knowledge, those questions have been decided by, are pending determination by, or are under investigation by, any governmental entity.
5. The names and addresses of any additional persons, or a description of any additional class of persons, known by the intervenor to be affected by, or interested in, the questions presented.
6. Whether the intervenor consents to be bound by the determination of the matters presented in the declaratory order proceeding.

The petition must be dated and signed by the intervenor or the intervenor's representative. It must also include the name, mailing address, and telephone number of the intervenor and intervenor's representative, and a statement indicating the person to whom communications should be directed.

641—172.4(17A) Briefs. The petitioner or any intervenor may file a brief in support of the position urged. The department may request a brief from the petitioner, any intervenor, or any other person concerning the questions raised.

641—172.5(17A) Inquiries. Inquiries concerning the status of a declaratory order proceeding may be made to the Director, Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075.

641—172.6(17A) Service and filing of petitions and other papers.

172.6(1) *Service—when required.* Except where otherwise provided by law, every petition for declaratory order, petition for intervention, brief, or other paper filed in a proceeding for a declaratory order shall be served upon each of the parties of record to the proceeding, and on all other persons identified in the petition for declaratory order or petition for intervention as affected by or interested in the questions presented, simultaneously with their filing. The party filing a document is responsible for service on all parties and other affected or interested persons.

172.6(2) *Filing—when required.* All petitions for declaratory orders, petitions for intervention, briefs, or other papers in a proceeding for a declaratory order shall be filed with the Director, Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075. All petitions, briefs, or other papers that are required to be served upon a party shall be filed simultaneously with the department.

172.6(3) *Method of service, time of filing, and proof of mailing.* Method of service, time of filing, and proof of mailing shall be as provided by 641—173.12(17A).

641—172.7(17A) Consideration. Upon request by petitioner, the department must schedule a brief and informal meeting between the original petitioner, all intervenors, and a member of the staff of the department, to discuss the questions raised. The department may solicit comments from any person on the questions raised. Also, comments on the questions raised may be submitted to the department by any person.

641—172.8(17A) Action on petition.

172.8(1) Within the time allowed by Iowa Code section 17A.9, after receipt of a petition for a declaratory order, the department or designee shall take action on the petition as required by Iowa Code section 17A.9.

172.8(2) The date of issuance of an order or of a refusal to issue an order is as defined in 641—173.2(17A).

[**ARC 8665B**, IAB 4/7/10, effective 5/12/10]

641—172.9(17A) Refusal to issue order.

172.9(1) The department shall not issue a declaratory order where prohibited by Iowa Code section 17A.9 and may refuse to issue a declaratory order on some or all questions raised for the following reasons:

1. The petition does not substantially comply with the required form.
2. The petition does not contain facts sufficient to demonstrate that the petitioner will be aggrieved or adversely affected by the failure of the department to issue an order.
3. The department does not have jurisdiction over the questions presented in the petition.
4. The questions presented by the petition are also presented in a current rule making, contested case, or other agency or judicial proceeding, that may definitively resolve them.
5. The questions presented by the petition would more properly be resolved in a different type of proceeding or by another body with jurisdiction over the matter.
6. The facts or questions presented in the petition are unclear, overbroad, insufficient, or otherwise inappropriate as a basis upon which to issue an order.
7. There is no need to issue an order because the questions raised in the petition have been settled due to a change in circumstances.
8. The petition is not based upon facts calculated to aid in the planning of future conduct but is, instead, based solely upon prior conduct in an effort to establish the effect of that conduct or to challenge an agency decision already made.
9. The petition requests a declaratory order that would necessarily determine the legal rights, duties, or responsibilities of other persons who have not joined in the petition, intervened separately, or filed a similar petition and whose position on the questions presented may fairly be presumed to be adverse to that of petitioner.
10. The petitioner requests the department to determine whether a statute is unconstitutional on its face.

172.9(2) A refusal to issue a declaratory order must indicate the specific grounds for the refusal and constitutes final agency action on the petition.

172.9(3) Refusal to issue a declaratory order pursuant to this provision does not preclude the filing of a new petition that seeks to eliminate the grounds for the refusal to issue an order.

[**ARC 8665B**, IAB 4/7/10, effective 5/12/10]

641—172.10(17A) Contents of declaratory order—effective date. In addition to the order itself, a declaratory order must contain the date of its issuance, the name of petitioner and all intervenors, the specific statutes, rules, policies, decisions, or orders involved, the particular facts upon which it is based, and the reasons for its conclusion. A declaratory order is effective on the date of issuance.

641—172.11(17A) Copies of orders. A copy of all orders issued in response to a petition for a declaratory order shall be mailed promptly to the original petitioner and all intervenors.

641—172.12(17A) Effect of a declaratory order. A declaratory order has the same status and binding effect as a final order issued in a contested case proceeding. It is binding on the department, the petitioner, and any intervenors and is applicable only in circumstances where the relevant facts and the law involved are indistinguishable from those on which the order was based. As to all other persons, a declaratory

order serves only as precedent and is not binding on the department. The issuance of a declaratory order constitutes final agency action on the petition.

These rules are intended to implement Iowa Code chapter 17A.

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NOTE: Editorial correction IAC 5/11/05

PHARMACY BOARD[657]

[Prior to 2/10/88, see Pharmacy Examiners, Board of [620], renamed Pharmacy Examiners Board[657] under the "umbrella" of Public Health Department by 1986 Iowa Acts, ch 1245; renamed by 2007 Iowa Acts, Senate File 74]

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CHAPTER 1
PURPOSE AND ORGANIZATION
[Prior to 2/10/88, see Pharmacy Examiners[620] Ch 9]

657—1.1(17A) Board mission. The board of pharmacy promotes, preserves, and protects the public health, safety, and welfare by fostering the provision of pharmaceutical care to all Iowans through the effective regulation of the practice of pharmacy, the operation of pharmacies, the appropriate utilization of pharmacy technicians and pharmacy support persons, the distribution of prescription drugs and devices, and the education and training of pharmacists.
[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—1.2(17A,147,272C) Description and organization of board. The board is comprised of five pharmacist members and two representatives of the general public, all appointed by the governor. An administrative staff headed by a board-appointed executive director assists board members.

The board's authority for regulating the practice of pharmacy and the legal distribution and dispensing of prescription drugs and devices and of precursor substances in the state of Iowa is found in Iowa Code chapters 124, 124A, 124B, 126, 147, 155A, 205, and 272C.

657—1.3(17A,272C) Responsibilities. The responsibilities of the board include but are not limited to:

1. Licensing of qualified applicants for the practice of pharmacy, by examination, renewal, and reciprocity under the provisions of Iowa Code chapters 147 and 155A.
2. Administering a continuing education program to ensure continued competency of individuals licensed by the board to practice pharmacy. Authority for this function comes from Iowa Code chapter 272C.
3. Regulating the legal distribution of prescription drugs through the licensing of pharmacies and wholesalers under the authority of Iowa Code chapter 155A.
4. Regulating the legal distribution of controlled substances through the registration of authorized persons and entities engaged in the manufacture and distribution of controlled substances throughout the state under the authority of Iowa Code chapter 124.
5. Registering pharmacist-interns and administering an internship program to prepare individuals for the practice of pharmacy pursuant to the authority of Iowa Code chapter 155A.
6. Registering pharmacy technicians assisting in the technical functions of the practice of pharmacy pursuant to the authority of Iowa Code chapter 155A.
7. Performing compliance investigations and audits of all persons or entities registered pursuant to Iowa Code chapter 124 and compliance inspections and investigations of any persons or entities licensed or registered pursuant to Iowa Code chapter 155A. These investigations and audits are conducted to ensure accountability for all controlled substances and to ensure compliance with laws regulating the practice of pharmacy and the distribution of prescription drugs and devices in Iowa.
8. Regulating the legal distribution of precursor substances through the issuance of permits to vendors and recipients of precursor substances throughout the state under the authority of Iowa Code chapter 124B.
9. Instituting disciplinary actions, hearing contested cases, issuing decisions and orders, and enforcing the terms of disciplinary orders filed against licensees, registrants, or permit holders for grounds provided in Iowa Code sections 124.303, 124.304, 124B.12, 147.55, 155A.6, 155A.12, 155A.13A, 155A.15, and 155A.17, as appropriate.
10. Registering pharmacy support persons assisting in the nontechnical functions of the practice of pharmacy pursuant to the authority of Iowa Code chapter 155A.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—1.4(17A,272C) Submission of complaints and requests. Members of the general public may obtain information or submit requests or complaints relative to the practice of pharmacy, continuing education for pharmacists, the legal distribution and dispensing of prescription drugs, or any other matters relating to the function and authority of the board. Correspondence should be submitted

to the Executive Director, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. Communication may also be submitted via the board's Web site at www.state.ia.us/ibpe.

657—1.5(17A,21) Meetings. All meetings of the board shall be open and public, and all members of the public shall be permitted to attend any meeting unless Iowa Code section 21.5 or another provision of law authorizes a closed session. Closed session shall only be by affirmative public vote of either two-thirds of the members of the board or all of the members present at the meeting.

1.5(1) *Where held.* Meetings of the board shall be held in Des Moines, Iowa, except as designated otherwise by the chairperson.

1.5(2) *Meeting schedule and public notice.* The board shall set the dates of its meetings at the first meeting following May 1 of each fiscal year. Notices of meetings shall be routinely posted in the space set aside for that purpose in the office of the board and on the board's Web site at www.state.ia.us/ibpe. Members of the general public may obtain the dates, times, and locations of board meetings by submitting a request to the Executive Director, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688, or by accessing the board's Web site.

1.5(3) *Special meetings.* Special meetings of the board may be called by the chairperson or upon written request of four of its members.

a. The reason for calling a special meeting shall be recorded in the minutes.

b. Special meetings shall be open to the public except as otherwise provided by statute.

1.5(4) *Minutes of meetings.* The executive secretary shall keep a record of all minutes of the board, and these minutes, except as otherwise provided by statute, shall be open to the public for inspection.

1.5(5) *Quorum.* A majority of the members of the board shall constitute a quorum.

Rules 657—1.1(17A) through 657—1.5(17A,21) are intended to implement Iowa Code sections 17A.3, 21.3 through 21.5, 124.301, 147.14, 147.76, 155A.2, 272C.3, and 272C.4.

657—1.6(124,147,155A) Fee for returned check. A fee of $20 may be charged for a check returned for any reason. If a license, registration, or permit has been issued by the board office based on a check for the payment of fees and the check is later returned by the bank, the board shall request payment by certified check, cashier's check, or money order. If the fees, including the fee for a returned check, are not paid within 15 calendar days of notification of the returned check, the license, registration, or permit is no longer in effect and the status reverts to what it would have been had the license, registration, or permit not been issued. Late payment penalties will be assessed, as provided in board rules, for subsequent requests to renew or reissue the license, registration, or permit.

657—1.7(124,124B,147,155A) Overpayment of fees. "Overpayment" refers to the payment of any license, registration, permit, or service fee in excess of the required amount of the fee. Overpayment of $10 or less received by the board shall not be refunded.

These rules are intended to implement Iowa Code sections 124.301, 124B.11, 147.96, 155A.6, 155A.11, 155A.13, 155A.13A, 155A.14, and 155A.17.

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◊ Two or more ARCs

CHAPTER 2
PHARMACIST LICENSES

[Prior to 2/10/88, see Pharmacy Examiners[620] Chs 1, 5]

657—2.1(147,155A) Licensure by examination. The board of pharmacy, in conjunction with the National Association of Boards of Pharmacy (NABP), shall provide for the administration of pharmacist licensure examinations.

2.1(1) *Components.* Applicants shall take and pass the following components: the North American Pharmacist Licensure Examination (NAPLEX); the Multistate Pharmacy Jurisprudence Examination (MPJE), Iowa Edition. A total scaled score of no less than 75 is required to pass each examination.

2.1(2) *Timeliness.* To be eligible for a license by examination, the candidate shall pass all components in Iowa within a period of one year beginning with the date the candidate passed an initial component. A candidate may request waiver or variance from this deadline pursuant to the procedures and requirements of 657—Chapter 34.

657—2.2(155A) Application for examination—requirements. Application for examination shall be on forms provided by the board, and all requested information shall be provided on or with such application. An applicant shall complete the NABP Computerized Examination Registration Form to apply for registration to take the NAPLEX. An applicant shall complete an additional registration form to apply for registration to take the MPJE, Iowa Edition.

2.2(1) *Required information.* The application for examination shall require that the applicant provide, at a minimum, the following: name; address; telephone number; date of birth; social security number; name and location of college of pharmacy and date of graduation; one current photograph of a quality at least similar to a passport photograph; and internship experience. Each applicant shall also declare the following: history of prior pharmacist licensure examinations and record of offenses including but not limited to charges, convictions, and fines which relate to the profession or that may affect the licensee's ability to practice pharmacy.

2.2(2) *Sworn statement.* The application for examination shall be made as a sworn statement before a notary public, and the notary public shall witness the signature of the applicant.

657—2.3(147,155A) Examination fee. The fee for examination shall consist of the biennial license fee, a processing fee, administration fees, and examination registration fees.

2.3(1) *Fees to the board.* The biennial license fee shall be the fee established by rule 2.11(147,155A), including surcharge. The processing fee shall be $80. No refunds of the processing fee shall be made for cancellation or withdrawal of applications. The license fee and processing fee shall be payable to the Iowa Board of Pharmacy and may be remitted in the form of personal check, money order, or certified check. No refund of fees shall be made for failure to complete all licensure requirements within the period specified in subrule 2.1(2).

2.3(2) *Fees to NABP.* The examination registration and administration fees shall be amounts determined by NABP, shall be payable to the National Association of Boards of Pharmacy, and shall be in the form of a certified check or money order. Refunds of fees paid to NABP shall be at the discretion of NABP.

2.3(3) *Submission of forms and fees.* The biennial license fee including surcharge, the processing fee, the administration fees, and the examination registration fees shall accompany the applications and registration forms and shall be submitted to the Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688, or as otherwise directed by the board.

657—2.4(155A) Internship requirements. Each applicant shall furnish to the board evidence certifying completion of satisfactory internship experience. The board will not certify an applicant eligible to take any of the examination components prior to receipt of evidence of satisfactory completion of internship experience. Internship experience shall comply with the requirements in 657—Chapter 4. Internship experience completed in compliance with the requirements in 657—Chapter 4 shall be valid for application for licensure in Iowa by examination or score transfer for a period of three years

following graduation from an approved college of pharmacy or as otherwise approved by the board on a case-by-case basis.

657—2.5(155A) College graduate certification. Each applicant shall furnish a certificate from a recognized college of pharmacy stating that the applicant has successfully graduated from a school or college of pharmacy with either a bachelor of science degree in pharmacy or a doctor of pharmacy (Pharm.D.) degree. Certification shall be completed by an individual authorized by the college on a form provided by the board. A recognized college of pharmacy is a United States institution that meets the minimum standards of the American Council on Pharmaceutical Education and appears on its list of accredited colleges of pharmacy published by the council as of July 1 of each year.

657—2.6(147) Reexamination applications and fees. A candidate who fails to pass the NAPLEX once shall be allowed to schedule a time to retake the examination no less than 91 days following administration of the failed examination. A candidate who fails to pass the MPJE, Iowa Edition, once shall be allowed to schedule a time to retake the examination no less than 30 days following administration of the failed examination. A candidate who fails to pass either examination following a second or subsequent examination may petition the board for permission to take the examination again. Determination of a candidate's eligibility to take an examination more than two times shall be at the discretion of the board.

Each applicant for reexamination shall file an application on forms provided by the board. Processing fees of $40 each will be charged to take NAPLEX or MPJE, Iowa Edition, and shall be paid to the board as provided in subrule 2.3(1). In addition, candidates will be required to complete the appropriate examination registration application as provided in rule 2.2(155A) and to pay to NABP the registration and administration fees for each examination as provided in subrule 2.3(2). All applications, registration forms, and fees shall be submitted as provided in subrules 2.3(2) and 2.3(3).

657—2.7(147) Examination results. Examination scores and original license certificates shall be provided to each new licensee as soon after the examinations as possible.

657—2.8(155A) Transfer of examination scores. The board of pharmacy participates in the NAPLEX score transfer program offered by NABP. This program allows candidates for pharmacist licensure to take the standardized NAPLEX in one state and have the score from that examination transferred to other participant states in which the candidate is seeking licensure. MPJE scores cannot be transferred.

2.8(1) *Score transfer application.* The NAPLEX Score Transfer Form must be completed and submitted with the proper fee to NABP prior to, or postmarked no later than, the date on which the candidate takes the NAPLEX. The fee to NABP for score transfer is determined by NABP. Payment shall be made in the form of a money order or certified check payable to the National Association of Boards of Pharmacy. NABP makes no refunds of score transfer fees.

2.8(2) *Requirements and deadline.* Score transfer candidates shall meet the requirements established in rules 2.1(147,155A) through 2.5(155A) within 12 months of the date of transfer. No refund of fees paid to the board will be made for failure to complete all licensure requirements within this one-year period.

2.8(3) *Fees.* In addition to the score transfer fee identified in subrule 2.8(1), fees for licensure pursuant to the NABP score transfer program shall consist of the fees identified in rule 2.3(147,155A) excluding the NAPLEX examination registration and administration fees.

657—2.9(147,155A) Licensure by license transfer/reciprocity. An applicant for license transfer/reciprocity must be a pharmacist licensed by examination in a state or territory of the United States with which Iowa has a reciprocal agreement, and the license by examination must be in good standing at the time of the application. All candidates shall take and pass the MPJE, Iowa Edition, as provided in subrule 2.1(1). Any candidate who fails to pass the examination shall be eligible for reexamination as provided in rule 2.6(147).

2.9(1) *Eligibility.* Each applicant for license transfer to this state who obtains the applicant's original license after January 1, 1980, must have passed the NABP Licensure Examination (NABPLEX), the NAPLEX, or an equivalent examination as determined by NABP.

a. Preliminary application. Each applicant for license transfer/reciprocity to Iowa shall complete and submit to NABP, with the appropriate fee as indicated on the application, the NABP Preliminary Application for Transfer of Pharmaceutic Licensure. Refunds of fees paid to NABP shall be at the discretion of NABP.

b. Foreign pharmacy graduates. If the applicant is a graduate of a school or college of pharmacy located outside the United States that has not been recognized and approved by the board, proof of qualifications shall include certification from the FPGEC pursuant to subrule 2.10(1).

2.9(2) *Application requirements.* Application to the board shall consist of the final application for license transfer prepared by NABP pursuant to the NABP license transfer program. A foreign pharmacy graduate shall submit certification from the FPGEC as provided in subrule 2.10(1). Applications, together with other required information and fees, shall be submitted as provided in subrule 2.3(3).

2.9(3) *MPJE required.* An applicant shall also be required to submit the registration application for MPJE, Iowa Edition, as provided in rule 2.2(155A). The form and fees shall be submitted as provided in subrules 2.3(2) and 2.3(3).

2.9(4) *Fees.* The fee for license transfer shall consist of the biennial license fee established by rule 2.11(147,155A) including surcharge and a processing fee of $100. No refunds of the processing fee shall be made for cancellation or withdrawal of an application. The license fee and processing fee shall be payable to the Iowa Board of Pharmacy and may be remitted in the form of personal check, money order, or certified check.

2.9(5) *Timeliness.* A final application for license transfer is valid for 12 months following the date of issuance by NABP. A candidate for license transfer shall complete, within that one-year period, all licensure requirements established by this rule. No refund of fees will be made for failure to complete all licensure requirements within this one-year period.

657—2.10(155A) Foreign pharmacy graduates.

2.10(1) *Education equivalency.* Any applicant who is a graduate of a school or college of pharmacy located outside the United States that has not been recognized and approved by the board shall be deemed to have satisfied the requirements of Iowa Code section 155A.8, subsection 1, by certification by the Foreign Pharmacy Graduate Examination Committee (FPGEC). Each applicant shall have successfully passed the Foreign Pharmacy Graduate Equivalency Examination (FPGEE) given by the FPGEC established by the NABP. The FPGEE is hereby recognized and approved by the board. Each applicant shall also demonstrate proficiency in written English by passing the Test of English as a Foreign Language (TOEFL) and proficiency in spoken English by passing the Test of Spoken English (TSE) or proficiency in basic English language skills by passing the Internet Based TOEFL (TOEFL iBT). The TOEFL, TOEFL iBT, and TSE are hereby recognized and approved by the board. Certification by the FPGEC shall be evidence of the applicant's successfully passing the FPGEE, TSE, and TOEFL, or the FPGEE and TOEFL iBT, and certification is a prerequisite to taking the licensure examinations required in subrule 2.1(1).

2.10(2) *Internship.* A foreign pharmacy graduate applicant shall also be required to obtain internship experience in one or more board-licensed community or hospital pharmacies as provided in rule 657—4.7(155A). Internship requirements shall, in all other aspects, meet the requirements established in 657—Chapter 4.

657—2.11(147,155A) License expiration and renewal. A license to practice pharmacy shall expire on the second thirtieth day of June following the date of issuance of the license, with the exception that a new pharmacist license issued between April 1 and June 29 shall expire on the third thirtieth day of June following the date of issuance. The license renewal certificate shall be issued upon completion of the renewal application and timely payment of a $200 fee plus applicable surcharge pursuant to 657—30.8(155A).

2.11(1) *Late payment penalty.* Failure to renew the license before July 1 following expiration shall require payment of the renewal fee, a penalty fee of $200, and applicable surcharge pursuant to 657—30.8(155A). Failure to renew the license before August 1 following expiration shall require payment of the renewal fee, a penalty fee of $300, and applicable surcharge pursuant to 657—30.8(155A). Failure to renew the license before September 1 following expiration shall require payment of the renewal fee, a penalty fee of $400, and applicable surcharge pursuant to 657—30.8(155A). Failure to renew the license before October 1 following expiration may require an appearance before the board and shall require payment of the renewal fee, a penalty fee of $500, and applicable surcharge pursuant to 657—30.8(155A). In no event shall the combined fee and penalty fee for late renewal of the license exceed $700 plus applicable surcharge pursuant to 657—30.8(155A). The provisions of Iowa Code section 147.11 shall apply to a license that is not renewed within five months of the expiration date.

2.11(2) *Delinquent license.* If a license is not renewed before its expiration date, the license is delinquent and the licensee may not practice pharmacy in the state of Iowa until the licensee reactivates the delinquent license. Reactivation of a delinquent license shall include submission of a completed application and appropriate fees and may include requirements relating to the reactivation of an inactive license pursuant to subrule 2.13(2). A pharmacist who continues to practice pharmacy in Iowa without a current license may be subject to disciplinary sanctions pursuant to the provisions of 657—subrule 36.1(4).

657—2.12(272C) Continuing education requirements. Pharmacists shall complete continuing education for license renewal pursuant to the requirements of this rule. For purposes of this rule, "continuing education" means a structured educational activity that is applicable to the practice of pharmacy, that promotes problem solving and critical thinking, and that is designed or intended to support the continuing development of pharmacists to maintain and enhance their competence.

2.12(1) *Continuing education activity attendance.* Continuing education activities that carry the seal of an Accreditation Council for Pharmacy Education (ACPE)-accredited provider will automatically qualify for continuing education credit. Attendance is mandated in order for a pharmacist to receive credit unless the activity is an ACPE-accredited correspondence course.

a. Non-ACPE provider activity. A maximum of 50 percent of the total continuing education credits required pursuant to subrule 2.12(4) may be obtained through completion of non-ACPE provider activities if such activities are provided by an accredited health-professional continuing education provider, such as a continuing medical education (CME) provider, and if the activity content directly relates to the pharmacist's professional practice.

b. Exemption for health-related graduate studies. A pharmacist who is continuing formal education in health-related graduate programs may be exempted from meeting the continuing education requirements during the period of such enrollment. An applicant for this exemption shall petition the board, as soon as possible following enrollment in the qualifying graduate program, on forms provided by the board office. At the discretion of the board, exemption during part-time or short-term enrollment in a health-related graduate program may be prorated for the actual period of such enrollment.

2.12(2) *Continuing education unit required.* The nationally accepted measurement of continuing education is referred to as CEU (continuing education unit), and the board of pharmacy employs that measurement. Ten contact hours of approved continuing education are equivalent to one CEU. The board of pharmacy will require 3.0 CEUs each renewal period. For purposes of this rule, "renewal period" means the 27-month period commencing April 1 prior to the previous license expiration and ending June 30, the date of current license expiration. A pharmacist who fails to complete the required CEUs within the renewal period shall be required to complete one and one-half times the number of delinquent CEUs prior to reactivation of the license. CEUs that are used to satisfy the continuing education requirement for one renewal period shall not be used to satisfy the requirement for a subsequent renewal period.

2.12(3) *Continuing education activity statement of credit.*

a. An accredited provider will be required to make available to an individual pharmacist a statement of credit that indicates successful completion of and participation in a continuing education activity. The statement of credit will carry the following information:

(1) Pharmacist's full name.

(2) Number of contact hours or CEUs awarded for activity completion.

(3) Date of live activity or date of completion of home study activity.

(4) Name of accredited provider.

(5) Activity title and universal activity number.

b. A pharmacist must retain statements of credit in the pharmacist's personal files for four years.

2.12(4) *Continuing education activity topics.* Each pharmacist is required to obtain a minimum of 50 percent of the pharmacist's required 3.0 CEUs in ACPE-accredited courses dealing with drug therapy. Activities qualifying for the drug therapy requirement will include the ACPE topic designator "01" or "02" in the last two digits of the universal activity number.

2.12(5) *New license holders licensed by examination.* After the initial license is issued by examination, the new license holder is exempt from meeting continuing education requirements for the first license renewal. However, if the licensee qualifies as a mandatory abuse reporter, the licensee shall not be exempt from mandatory training for identifying and reporting abuse pursuant to rule 2.16(235B,272C). Regardless of when the license is first issued, the new license holder will be required to obtain, prior to the second renewal, 30 contact hours (3.0 CEUs) of continuing education pursuant to subrules 2.12(1) through 2.12(4).

2.12(6) *New license holders licensed by license transfer/reciprocity.* After the initial license is issued by license transfer, the new license holder will be required to obtain, prior to the first license renewal, 30 contact hours (3.0 CEUs) of continuing education credits pursuant to subrules 2.12(1) through 2.12(4).

2.12(7) *Reporting continuing education credits.*

a. A pharmacist shall submit on or with the renewal application form documentation that the continuing education requirements have been met. Documentation shall be in a format that includes the following:

(1) The total number of credits accumulated for the renewal period;

(2) The individual activities completed, including activity title and universal activity number;

(3) The dates of completion;

(4) The credits awarded for each activity;

(5) The name of the provider of each activity; and

(6) Identification of the activities completed to comply with the drug therapy requirements in subrule 2.12(4).

b. The board may require a pharmacist to submit the activity statements of credit that document successful completion of the activities included with or on the renewal application.

c. Failure to receive the renewal application shall not relieve the pharmacist of the responsibility of meeting continuing education requirements.

2.12(8) *Relicensure examination.* Nothing in these rules precludes the board from requiring an applicant for renewal to submit to a relicensure examination.

2.12(9) *Physical disability or illness.* The board may, in individual cases involving physical disability or illness, grant waivers of the minimum continuing education requirements or extensions of time within which to fulfill the same or make the required reports. No waiver or extension of time shall be granted unless written application is made and signed by the licensee and the licensee's physician. The board may grant waivers of the minimum continuing education requirements for physical disability or illness for any period of time not to exceed one renewal period. In the event that the physical disability or illness upon which a waiver has been granted continues beyond the period of the waiver, the licensee must reapply for an extension of the waiver. The board may, as a condition of any waiver granted, require the licensee to make up all or any portion of the waived continuing education requirements by any method prescribed by the board.

[**ARC 8672B**, IAB 4/7/10, effective 5/12/10]

657—2.13(272C) Active and inactive license status.

2.13(1) *Active license.* Active license status applies to a pharmacist who has submitted the renewal application and fee and has met Iowa requirements for continuing education. Active license status also applies to a pharmacist who has submitted the renewal application and fee and who is a resident of another state, is licensed to practice pharmacy in that state, and has met the continuing education requirements of that state. A pharmacist who meets the continuing education requirements of another state shall provide documentation on the renewal application of the pharmacist's license status in that state. An Iowa licensee actively practicing in a state that does not require continuing education for license renewal shall be required to meet Iowa continuing education requirements.

2.13(2) *Inactive license.* Failure of a pharmacist to comply with the continuing education requirements during the renewal period will result in the issuance of a renewal card marked "inactive" upon submission of the renewal application and fee. Reactivation of an inactive pharmacist license shall be accomplished by the appropriate method described below. Internship, in each instance where internship is mentioned below, shall be in a pharmacy approved by the board. The pharmacist will be issued an intern registration certificate.

a. An inactive pharmacist who wishes to become active and who has been actively practicing pharmacy during the last five years in any state or states which required continuing education during that five-year period shall submit proof of continued licensure in good standing in the state or states of such practice.

b. An inactive pharmacist who wishes to become active and who has been actively practicing pharmacy during the last five years in a state which does not require continuing education shall submit proof of continued licensure in good standing in the state or states of such practice. The pharmacist shall also complete one of the following options:

(1) Take and successfully pass the MPJE, Iowa Edition, as provided in subrule 2.1(1);

(2) Complete 160 hours of internship for each year the pharmacist was on inactive status (not to exceed 1,000 hours); or

(3) Obtain one and one-half times the number of continuing education credits required under 2.12(2) for each renewal period the pharmacist was inactive.

c. An inactive pharmacist who wishes to become active and who has not been actively practicing pharmacy during the past five years, and whose license has been inactive for not more than five years, shall complete one of the following options:

(1) Successfully pass all components of the licensure examination as required in rule 2.1(147,155A);

(2) Complete 160 hours of internship for each year the pharmacist was on inactive status; or

(3) Obtain one and one-half times the number of continuing education credits required under 2.12(2) for each renewal period the pharmacist was inactive.

d. An inactive pharmacist who wishes to become active and who has not been actively practicing pharmacy for more than five years shall petition the board for reactivation of the license to practice pharmacy under one or more of the following options:

(1) Successfully pass all components of the licensure examination as required in rule 2.1(147,155A);

(2) Complete 160 hours internship for each year the pharmacist was on inactive status (not to exceed 1,000 hours); or

(3) Obtain one and one-half times the number of continuing education credits required under 2.12(2) for each renewal period the pharmacist was inactive.

657—2.14(155A) Fees for additional license certificates. Only original license certificates issued by the board of pharmacy for licensed pharmacists are valid. Additional original license certificates for licensed pharmacists may be obtained from the board of pharmacy for a prepaid fee of $20 each. The fee shall be considered a repayment receipt as defined in Iowa Code section 8.2.

657—2.15(155A) Notifications to the board. A pharmacist shall report to the board within ten days a change of the pharmacist's name, address, or pharmacy employment.

657—2.16(235B,272C) Mandatory training for identifying and reporting abuse. "Mandatory training for identifying and reporting abuse" means training on identifying and reporting child abuse or dependent adult abuse required of a pharmacist who qualifies as a mandatory abuse reporter under Iowa Code section 232.69 or 235B.16. A licensed pharmacist shall be responsible for determining whether or not, by virtue of the pharmacist's practice or employment, the pharmacist qualifies as a mandatory abuse reporter under either or both of these sections.

2.16(1) *Training required.* A licensed pharmacist who qualifies as a mandatory abuse reporter shall have completed approved abuse education training as follows.

a. Mandatory reporter of child abuse. A pharmacist who qualifies as a mandatory reporter of child abuse shall have completed two hours of training in child abuse identification and reporting within the previous five years.

b. Mandatory reporter of dependent adult abuse. A pharmacist who qualifies as a mandatory reporter of dependent adult abuse shall have completed two hours of training in dependent adult abuse identification and reporting within the previous five years.

c. Mandatory reporter of child abuse and dependent adult abuse. A pharmacist who qualifies as a mandatory reporter of child abuse and dependent adult abuse may complete separate courses pursuant to paragraphs *"a"* and *"b"* or may complete, within the previous five years, one combined two-hour course that includes curricula for identifying and reporting child abuse and dependent adult abuse.

2.16(2) *Persons exempt from training requirements.* The requirements of this rule shall not apply to a pharmacist during periods that the pharmacist serves honorably on active duty in the military or during periods that the pharmacist resides outside Iowa and does not practice pharmacy in Iowa.

2.16(3) *Mandatory training records.* A pharmacist subject to the requirements of this rule shall maintain documentation of completion of the mandatory training for identifying and reporting abuse, including dates, subjects, duration of programs, and proof of participation, for five years following the date of the training. The board may audit this information at any time within the five-year period.

2.16(4) *Approved programs.* "Approved abuse education training" means a training program using a curriculum approved by the abuse education review panel of the Iowa department of public health.

These rules are intended to implement Iowa Code sections 147.10, 147.36, 147.94, 147.96, 155A.8, 155A.9, 155A.11, 155A.39, and 272C.2.

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CHAPTER 3
PHARMACY TECHNICIANS
[Prior to 9/4/02, see 657—Ch 22]

657—3.1(155A) Definitions. For the purposes of this chapter, the following definitions shall apply:

"Board" means the Iowa board of pharmacy.

"Cashier" means a person whose duties within the pharmacy are limited to accessing finished, packaged prescription orders and processing payments for and delivering such orders to the patient or the patient's representative.

"Certified pharmacy technician" or *"certified technician"* means an individual who holds a valid current national certification and who has registered with the board as a certified pharmacy technician. The term includes an individual registered with the board who voluntarily acquired certification as provided in subrule 3.5(2).

"Delivery" means the transport and conveyance of a finished, securely packaged prescription order to the patient or the patient's caregiver.

"Nationally accredited program" means a program and examination for the certification of pharmacy technicians that is accredited by the NCCA.

"NCCA" means the National Commission for Certifying Agencies.

"Pharmacy support person" means a person, other than a licensed pharmacist, a registered pharmacist-intern, or a registered pharmacy technician, who may perform nontechnical duties assigned by the pharmacist under the pharmacist's responsibility and supervision pursuant to 657—Chapter 5.

"Pharmacy technician" or *"technician"* means a person who is employed in Iowa by a licensed pharmacy under the responsibility of an Iowa-licensed pharmacist to assist in the technical functions of the practice of pharmacy, as provided in rules 657—3.22(155A) through 657—3.24(155A).

"Pharmacy technician certification" or *"national certification"* means a certificate issued by a national pharmacy technician certification authority accredited by the NCCA attesting that the technician has successfully completed the requirements of the certification program. The term includes evidence of renewal of the national certification.

"Pharmacy technician trainee" or *"technician trainee"* means an individual who is in training to become a pharmacy technician and who is in the process of acquiring national certification as a pharmacy technician as provided in rule 657—3.5(155A).

"Pharmacy technician training" or *"technician training"* means education or experience acquired for the purpose of qualifying for and preparing for national certification.

"Supervising pharmacist" means an Iowa-licensed pharmacist who is on duty in an Iowa-licensed pharmacy and who is responsible for the actions of a pharmacy technician or other supportive personnel.
[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—3.2(155A) Purpose of registration. A registration program for pharmacy technicians is established for the purposes of determining the competency of a pharmacy technician or of an applicant for registration as a pharmacy technician, a certified technician, or a pharmacy technician trainee and for the purposes of identification, tracking, and disciplinary action for violations of federal or state pharmacy or drug laws or regulations.

657—3.3(155A) Registration required. Any person employed in Iowa as a pharmacy technician, except a pharmacist-intern whose pharmacist-intern registration is in good standing with the board, shall obtain and maintain during such employment a current registration as a pharmacy technician, certified pharmacy technician, or pharmacy technician trainee pursuant to these rules. An individual accepting employment as a pharmacy technician or technician trainee in Iowa who fails to register as a pharmacy technician, certified technician, or technician trainee as provided by these rules may be subject to disciplinary sanctions.

3.3(1) *Licensed health care provider.* Except as provided in this rule, a licensed health care provider whose registration or license is in good standing with and not subject to current disciplinary sanctions

or practice restrictions imposed by the licensee's professional licensing board and who assists in the technical functions of the practice of pharmacy shall be required to register as a pharmacy technician, certified technician, or technician trainee pursuant to these rules.

3.3(2) *Original application required.* Any person not currently registered with the board as a pharmacy technician or certified technician shall complete an application for registration within 30 days of accepting employment in an Iowa pharmacy as a pharmacy technician. Such application shall be received in the board office before the expiration of this 30-day period.

3.3(3) *Technician training.* A person who is enrolled in a college-based or American Society of Health-System Pharmacists (ASHP)-accredited technician training program shall obtain a pharmacy technician trainee registration prior to beginning on-site practical experience. A person who is employed in a pharmacy and who is receiving pharmacy technician training through work experience shall obtain a pharmacy technician trainee registration within 30 days of the commencement of pharmacy technician training.

3.3(4) *Registration number.* Each pharmacy technician, certified technician, and technician trainee registered with the board will be assigned a unique registration number.

657—3.4 Reserved.

657—3.5(155A) Certification of pharmacy technicians. Prior to July 1, 2010, the certification and recertification of pharmacy technicians shall be voluntary and not mandatory. Beginning July 1, 2010, the certification of pharmacy technicians shall be required as provided by this rule. National certification does not supplant the need for licensed pharmacist control over the performance of delegated functions, nor does national certification exempt the pharmacy technician from registration pursuant to these rules.

3.5(1) *Voluntary certification prior to July 1, 2010.* An individual who holds a valid current national certification from the Institute for the Certification of Pharmacy Technicians (ICPT) or the Pharmacy Technician Certification Board (PTCB) and who acquired such certification prior to July 1, 2010, shall be deemed to have met the requirement for national certification beginning July 1, 2010, provided the certification is maintained in current standing.

3.5(2) *Required certification effective July 1, 2010.* Beginning July 1, 2010, a pharmacy technician shall acquire national certification through any NCCA-accredited pharmacy technician certification program and examination, the successful completion of which fulfills the requirement for national certification.

3.5(3) *Pharmacy technician trainee.* Beginning July 1, 2009, a person who is in the process of acquiring national certification as a pharmacy technician shall register with the board as a pharmacy technician trainee. The registration shall be issued for a period of one year and shall not be renewed.

3.5(4) *Certified pharmacy technician.* Beginning July 1, 2010, all applicants for a new pharmacy technician registration, except as provided by subrule 3.5(3), and all applicants for renewal of a pharmacy technician registration shall provide proof of current national pharmacy technician certification and shall complete the application for certified pharmacy technician registration.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—3.6 and **3.7** Reserved.

657—3.8(155A) Application form.

3.8(1) *Required information.* The application for a pharmacy technician registration, certified technician registration, or pharmacy technician trainee registration shall include the following:

a. Information sufficient to identify the applicant including, but not limited to, name, address, date of birth, gender, and social security number;

b. Educational background;

c. Work experience;

d. Current place or places of employment;

e. Any other information deemed necessary by the board and as provided by this rule.

3.8(2) *Declaration of current impairment or limitations.* The applicant shall declare any current use of drugs, alcohol, or other chemical substances that in any way impairs or limits the applicant's ability to perform the duties of a pharmacy technician with reasonable skill and safety.

3.8(3) *History of felony or misdemeanor crimes.* The applicant shall declare any history of being charged, convicted, found guilty of, or entering a plea of guilty or no contest to a felony or misdemeanor crime (other than minor traffic violations with fines under $100).

3.8(4) *History of disciplinary actions.* The applicant shall declare any history of disciplinary actions or practice restrictions imposed by a state health care professional or technician licensure or registration authority.

3.8(5) *Additional information.* The following additional information shall be required from an applicant for the specified registration.

a. *Technician trainee.* The applicant for technician trainee registration shall identify the source of technician training, the anticipated date of completion of training, and the anticipated date of national certification.

b. *Certified pharmacy technician.* The applicant for certified technician registration shall provide proof of current pharmacy technician certification. The applicant shall also identify all current pharmacy employers including pharmacy name, license number, address, and average hours worked per week.

c. *Licensed health care provider.* In addition to the additional information required by paragraph *"a"* or *"b"* as applicable, a licensed health care provider shall provide evidence that the licensee's professional license or registration is current and in good standing and is not subject to current disciplinary sanctions or practice restrictions imposed by the licensee's professional licensing authority.

3.8(6) *Sworn signature.* The applicant shall sign the application under penalty of perjury and shall submit the application to the board with the appropriate fees pursuant to rule 657—3.10(155A).

657—3.9(155A) Registration term and renewal. Prior to July 1, 2008, a pharmacy technician registration shall expire on the second last day of the birth month following initial registration, with the exception that a new pharmacy technician registration issued within the two months immediately preceding the applicant's birth month shall expire on the third last day of the birth month following initial registration. A pharmacy technician registration issued between July 1, 2008, and July 1, 2009, except as provided in subrule 3.9(1), shall expire no later than June 30, 2010. Registration shall not require continuing education for renewal.

3.9(1) *Certified pharmacy technician registration.* A certified pharmacy technician registration shall expire on the second last day of the birth month following initial registration, with the exception that a new certified pharmacy technician registration issued within the two months immediately preceding the applicant's birth month shall expire on the third last day of the birth month following initial registration.

3.9(2) *Pharmacy technician trainee registration.* Beginning July 1, 2009, a registration for a pharmacy technician who is in the process of acquiring national certification (technician trainee) shall expire on the last day of the registration month 12 months following the date of registration or 12 months following the date registration was required pursuant to subrule 3.3(3).

a. *National certification completed.* When the registered technician trainee completes national certification, and no later than the date of expiration of the technician trainee registration, the pharmacy technician trainee shall complete and submit an application for certified pharmacy technician registration. A successful application shall result in issuance of a new certified pharmacy technician registration as provided in subrule 3.9(1).

b. *Voluntary cancellation of registration.* A registered technician trainee who fails to complete national certification prior to expiration of the technician trainee registration shall notify the board that the pharmacy technician trainee registration should be canceled and that the individual has ceased practice as a pharmacy technician.

c. *Failure to notify the board.* If a pharmacy technician trainee fails to notify the board prior to the expiration date of the technician trainee registration regarding the individual's intentions as provided in paragraph *"a"* or *"b,"* the technician trainee registration shall be canceled and the individual shall cease practice as a pharmacy technician.

657—3.10(155A) Registration fee. The following fees for initial registration and registration renewal shall apply to the specified registration applications filed within the following time frames. The appropriate fee shall be submitted with the registration application in the form of a personal check, certified check or cashier's check, or a money order payable to the Iowa Board of Pharmacy.

3.10(1) *Registration prior to July 1, 2009.* The fee for obtaining an initial technician registration, for obtaining an initial certified pharmacy technician registration, or for renewal of a technician or certified technician registration prior to July 1, 2009, shall be $40 plus applicable surcharge pursuant to rule 657—30.8(155A).

3.10(2) *Registration beginning July 1, 2009.* The fee for obtaining an initial certified pharmacy technician registration or for biennial renewal of a certified pharmacy technician registration beginning July 1, 2009, shall be $50 plus applicable surcharge pursuant to rule 657—30.8(155A).

3.10(3) *Technician trainee registration beginning July 1, 2009.* The fee for a one-year pharmacy technician trainee registration shall be $20 plus applicable surcharge pursuant to rule 657—30.8(155A).

657—3.11(155A) Late applications and fees.

3.11(1) *Initial registration.* An application for initial registration that is not received within the applicable period specified in subrule 3.3(2) or 3.3(3) shall be delinquent, and the applicant shall be assessed a late payment fee. The late payment fee shall be equal to the amount of the fee for initial registration. A delinquent initial registration shall include payment of the initial registration fee, applicable surcharge pursuant to rule 657—30.8(155A), and late payment fee.

3.11(2) *Registration renewal.* A technician registration that is not renewed before its expiration date shall be delinquent, and the registrant shall not continue employment as a pharmacy technician until the registration is reactivated. An individual who continues employment as a pharmacy technician without a current registration, in addition to the pharmacy and the pharmacist in charge that allow the individual to continue practice as a pharmacy technician, may be subject to disciplinary sanctions.

a. A person who is required to renew a registration pursuant to these rules and who fails to renew the registration before the first day of the month following expiration shall pay the renewal fee, a penalty fee equal to the amount of the renewal fee, plus the applicable surcharge pursuant to rule 657—30.8(155A).

b. A person who is required to renew a registration pursuant to these rules and who fails to renew the registration before the first day of the second month following expiration shall pay the renewal fee, a penalty fee equal to the amount of the renewal fee, the applicable surcharge pursuant to rule 657—30.8(155A), plus an additional penalty fee of $10 for each additional month, not to exceed three additional months, that the registration is delinquent. The maximum combined fee payment for reactivation of a delinquent registration shall not exceed an amount equal to twice the renewal fee plus $30 plus the applicable surcharge pursuant to rule 657—30.8(155A).

657—3.12(155A) Registration certificates. The certificate of technician registration issued by the board to a pharmacy technician, certified pharmacy technician, or pharmacy technician trainee is the property of and shall be maintained by the registered technician. The certificate or a copy of the certificate shall be maintained in each pharmacy where the pharmacy technician, certified pharmacy technician, or pharmacy technician trainee works. Each pharmacy utilizing pharmacy technicians shall be responsible for verifying that all technicians, certified technicians, and technician trainees working in the pharmacy are registered, and that technician registrations remain current and active.

657—3.13(155A) Notifications to the board. A pharmacy technician, certified pharmacy technician, or technician trainee shall report to the board within ten days a change of the technician's name, address, or pharmacy employment status.

657—3.14 to **3.16** Reserved.

657—3.17(155A) Training and utilization of pharmacy technicians. All Iowa-licensed pharmacies utilizing pharmacy technicians shall develop, implement, and periodically review written policies

and procedures for the training and utilization of pharmacy technicians appropriate to the practice of pharmacy. Pharmacy policies shall specify the frequency of review. Technician training shall be documented and maintained by the pharmacy for the duration of employment. Policies and procedures and documentation of technician training shall be available for inspection and copying by the board or an agent of the board.

657—3.18(147,155A) Identification of pharmacy technician.

3.18(1) *Identification badge.* A pharmacy technician shall wear a visible identification badge while on duty that clearly identifies the person as a pharmacy technician and that includes at least the technician's first name.

3.18(2) *Misrepresentation prohibited.* A pharmacy technician shall not represent himself or herself in any manner as a pharmacist or pharmacist-intern. A pharmacy technician shall not represent himself or herself in any manner as a certified pharmacy technician unless the technician has attained national pharmacy technician certification. A technician trainee shall not represent himself or herself in any manner as a certified pharmacy technician, as a pharmacist-intern, or as a pharmacist.

657—3.19 Reserved.

657—3.20(155A) Responsibility of supervising pharmacist. The ultimate responsibility for the actions of a pharmacy technician, a certified pharmacy technician, or a pharmacy technician trainee shall remain with the supervising pharmacist.

657—3.21(155A) Delegation of functions.

3.21(1) *Technical dispensing functions.* A pharmacist may delegate technical dispensing functions to an appropriately trained and registered pharmacy technician, but only if the pharmacist is on site and available to supervise the pharmacy technician when delegated functions are performed, except as provided in 657—subrule 6.7(2) or 657—subrule 7.6(2), as appropriate, or as provided for telepharmacy in 657—Chapter 9. The pharmacist shall provide and document the final verification for the accuracy, validity, completeness, and appropriateness of the patient's prescription or medication order prior to the delivery of the medication to the patient or the patient's representative. A pharmacy technician shall not delegate technical functions to a pharmacy support person.

3.21(2) *Nontechnical functions.* A pharmacist may delegate nontechnical functions to a pharmacy technician or a pharmacy support person only if the pharmacist is present to supervise the pharmacy technician or pharmacy support person when delegated nontechnical functions are performed, except as provided in 657—subrule 6.7(2) or 657—subrule 7.6(2), as appropriate, or as provided for telepharmacy in 657—Chapter 9.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—3.22(155A) Technical functions. At the discretion of the supervising pharmacist, technical functions which may be delegated to a pharmacy technician, a certified pharmacy technician, or a pharmacy technician trainee include, but are not limited to, the following:

1. Performing packaging, manipulative, or repetitive tasks relating to the processing of a prescription or medication order in a licensed pharmacy.
2. Accepting prescription refill authorizations communicated to a pharmacy by a prescriber or by the prescriber's office.
3. Contacting prescribers to obtain prescription refill authorizations.
4. Processing pertinent patient information, including information regarding allergies and disease state.
5. Entering prescription and patient information into the pharmacy computer system.
6. Inspecting drug supplies provided and controlled by an Iowa-licensed pharmacy but located or maintained outside the pharmacy department, including but not limited to drug supplies maintained in an ambulance or other emergency medical service vehicle, a long-term care facility, a hospital patient care unit, or a hospice facility.

7. Affixing required prescription labels upon any container of drugs sold or dispensed pursuant to the prescription of an authorized prescriber.

8. Prepackaging or labeling multidose and single-dose packages of drugs, including dose picks for unit dose cart or AMDS fills for hospital or long-term care facility patients.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—3.23(155A) Tasks a pharmacy technician shall not perform. A pharmacy technician, a certified pharmacy technician, or a pharmacy technician trainee shall not:

1. Provide the final verification for the accuracy, validity, completeness, or appropriateness of a filled prescription or medication order;

2. Conduct prospective drug use review or evaluate a patient's medication record for purposes identified in rule 657—8.21(155A);

3. Provide patient counseling, consultation, or patient-specific drug information, tender an offer of patient counseling on behalf of a pharmacist, or accept a refusal of patient counseling from a patient or patient's agent;

4. Make decisions that require a pharmacist's professional judgment, such as interpreting prescription drug orders or applying information;

5. Transfer a prescription drug order to another pharmacy or receive the transfer of a prescription drug order from another pharmacy;

6. Delegate technical functions to a pharmacy support person.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—3.24(155A) New prescription drug orders or medication orders. At the discretion of the supervising pharmacist, a pharmacy technician or a certified pharmacy technician may be allowed to accept new prescription drug orders or medication orders communicated to the pharmacy by a prescriber or by the prescriber's agent if the pharmacy technician or certified pharmacy technician has received appropriate training pursuant to the pharmacy's policies and procedures. The supervising pharmacist shall remain responsible for ensuring the accuracy, validity, and completeness of the information received by the pharmacy technician or certified technician. The pharmacist shall contact the prescriber to resolve any questions, inconsistencies, or other issues relating to the information received by the pharmacy technician or certified technician that involve a pharmacist's professional judgment.

657—3.25(155A) Delegation of nontechnical functions. Rescinded IAB 4/7/10, effective 6/1/10.

657—3.26 and **3.27** Reserved.

657—3.28(147,155A) Unethical conduct or practice. Violation by a pharmacy technician, certified pharmacy technician, or pharmacy technician trainee of any of the provisions of this rule shall constitute unethical conduct or practice and may be grounds for disciplinary action as provided in rule 657—3.30(155A).

3.28(1) *Misrepresentative deeds.* A pharmacy technician, certified technician, or technician trainee shall not make any statement tending to deceive, misrepresent, or mislead anyone, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in pharmacy or in the operation or conduct of a pharmacy.

3.28(2) *Confidentiality.* In the absence of express written authorization from the patient or written order or direction of a court, except where the best interests of the patient require, a pharmacy technician, certified technician, or technician trainee shall not divulge or reveal to any person other than the patient or the patient's authorized representative, the prescriber or other licensed practitioner then caring for the patient, a licensed pharmacist, a person duly authorized by law to receive such information, or as otherwise provided in rule 657—8.16(124,155A), any of the following:

a. A patient's name, address, social security number, or any information that could be used to identify a patient;

b. The contents of any prescription drug order or medication order or the therapeutic effect thereof, or the nature of professional pharmaceutical services rendered to a patient;

c. The nature, extent, or degree of illness suffered by any patient; or

d. Any medical information furnished by the prescriber or the patient.

3.28(3) *Discrimination.* It is unethical to unlawfully discriminate between patients or groups of patients for reasons of religion, race, creed, color, gender, gender identity, sexual orientation, marital status, age, national origin, physical or mental disability, or disease state when providing pharmaceutical services.

3.28(4) *Unethical conduct or behavior.* A pharmacy technician, certified technician, or technician trainee shall not exhibit unethical behavior in connection with the technician's pharmacy employment. Unethical behavior shall include, but is not limited to, the following acts: verbal or physical abuse, coercion, intimidation, harassment, sexual advances, threats, degradation of character, indecent or obscene conduct, and theft.

657—3.29(155A) Denial of registration. The executive director or designee may deny an application for registration as a pharmacy technician, certified pharmacy technician, or pharmacy technician trainee for any violation of the laws of this state, another state, or the United States relating to prescription drugs, controlled substances, or nonprescription drugs or for any violation of Iowa Code chapter 124, 124A, 124B, 126, 147, 155A, or 205 or any rule of the board.

An individual whose application for registration as a pharmacy technician, certified pharmacy technician, or pharmacy technician trainee is denied pursuant to this rule may, within 30 days after issuance of the notice of denial, appeal to the board for reconsideration of the application.

657—3.30(155A) Discipline of pharmacy technicians.

3.30(1) *Violations.* The board may impose discipline for any violation of the laws of this state, another state, or the United States relating to prescription drugs, controlled substances, or nonprescription drugs, or for any violation of Iowa Code chapter 124, 124A, 124B, 126, 147, 155A, or 205 or any rule of the board.

3.30(2) *Sanctions.* The board may impose the following disciplinary sanctions:

a. Revocation of a pharmacy technician, certified pharmacy technician, or pharmacy technician trainee registration.

b. Suspension of a pharmacy technician, certified pharmacy technician, or pharmacy technician trainee registration until further order of the board or for a specified period.

c. Nonrenewal of a pharmacy technician or certified pharmacy technician registration.

d. Prohibition, permanently, until further order of the board, or for a specified period, from engaging in specified procedures, methods, or acts.

e. Probation.

f. The ordering of a physical or mental examination.

g. The imposition of civil penalties not to exceed $25,000.

h. Issuance of a citation and warning.

i. Such other sanctions allowed by law as may be appropriate.

These rules are intended to implement Iowa Code sections 147.72, 155A.23, 155A.33, and 155A.39 and Iowa Code Supplement sections 155A.6 and 155A.6A.

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[1] April 30, 2008, effective date delayed 70 days by the Administrative Rules Review Committee at its meeting held April 4, 2008.

CHAPTER 5
PHARMACY SUPPORT PERSONS

657—5 .1(155A) Definitions. For purposes of this chapter, the following definitions shall apply:

"Board" means the Iowa board of pharmacy.

"Delivery" means the transport and conveyance of a finished, securely packaged prescription order to the patient or the patient's agent.

"Direct access" means physical access, without direct supervision by a pharmacist, to opened, unpackaged, or unsecured stock containers or prescription vials containing prescription drugs.

"Pharmacy clerk" means a person whose duties within the pharmacy department include accessing filled prescription orders and processing payments for and delivering such orders to the patient or the patient's agent under the supervision of a pharmacist.

"Pharmacy support person" means a person, other than a licensed pharmacist, a registered pharmacist-intern, or a registered pharmacy technician, who may perform nontechnical duties assigned by a supervising pharmacist under the pharmacist's responsibility and supervision.

"Pharmacy technician" or *"technician"* means a person who is employed in Iowa by a licensed pharmacy under the responsibility of an Iowa-licensed pharmacist to assist in the technical functions of the practice of pharmacy and who is registered pursuant to 657—Chapter 3.

"Secure package" means the prescription order is enclosed in tamper-evident packaging. An IV bag is considered tamper-evident packaging.

"Supervising pharmacist" means an Iowa-licensed pharmacist who is on duty in an Iowa-licensed pharmacy and who is responsible for assigning and supervising the duties performed by a pharmacy support person.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—5.2(155A) Purpose of registration. A registration program for pharmacy support persons is established for the purposes of identification, tracking, and disciplinary action. The registration shall not include any determination of the competency of the registered individual. The use of pharmacy support persons to assist the pharmacist with nontechnical duties associated with the practice of pharmacy enables the pharmacist to provide pharmaceutical care to the patient.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—5.3 Reserved.

657—5.4(155A) Registration required.

5.4(1) *Effective date.* Beginning June 1, 2010, a pharmacy support person shall register with the board pursuant to the requirements of this chapter.

5.4(2) *Registration number.* Each pharmacy support person registered with the board will be assigned a unique registration number.

5.4(3) *Original application required.* Any person required to register and not previously registered with the board as a pharmacy support person shall complete an application for registration within 30 days of accepting employment in an Iowa pharmacy as a pharmacy support person. Such application shall be received in the board office before the expiration of this 30-day period.

5.4(4) *Employment terminated.* A registered pharmacy support person who discontinues employment as a pharmacy support person shall not be required to maintain a registration and shall request cancellation of the registration as provided in rule 657—5.14(155A).

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—5.5(155A) Exempt from registration. Unless a person has direct access to prescription drugs, the following shall be exempt from registration as a pharmacy support person:

1. Delivery person.
2. Billing clerk, including a person who processes claims for third-party payments.
3. Data processing support, maintenance, or programming personnel.

4. Facility maintenance personnel including but not necessarily limited to cleaning, sanitation, structural, and mechanical maintenance personnel. Facility maintenance personnel deemed exempt from registration shall be directly supervised by a pharmacist or a certified pharmacy technician who is responsible for the maintenance person's activities within the pharmacy department to ensure medication security and patient privacy.

5. Any person not directly employed by or under contract to the pharmacy, and not under the direct supervision of a pharmacist, who provides data processing, billing, maintenance, or administrative support functions outside the pharmacy department.

6. A registered pharmacist-intern or a registered pharmacy technician.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—5.6 Reserved.

657—5.7(155A) Registration application form.

5.7(1) *Required information.* The application form for a pharmacy support person registration shall require the following:

a. Information sufficient to identify the applicant including, but not limited to, name, address, date of birth, gender, and social security number;

b. Educational background;

c. Work experience;

d. Current place or places of employment;

e. Any other information deemed necessary by the board.

5.7(2) *Declaration of current impairment or limitations.* The applicant shall declare any current use of drugs, alcohol, or other chemical substances that in any way impairs or limits the applicant's ability to perform the duties of a pharmacy support person with reasonable skill and safety.

5.7(3) *History of felony or misdemeanor crimes.* The applicant shall declare any history of being charged, convicted, found guilty of, or entering a plea of guilty or no contest to a felony or misdemeanor crime (other than minor traffic violations with fines under $100).

5.7(4) *History of disciplinary actions.* The applicant shall declare any history of disciplinary actions or practice restrictions imposed by a state health care professional, licensure, or registration authority.

5.7(5) *Sworn signature.* The applicant shall sign the application under penalty of perjury and shall submit the application to the board with the appropriate fees pursuant to rules 657—5.9(155A) and 657—5.11(155A).

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—5.8 Reserved.

657—5.9(155A) Registration fee.

5.9(1) *Initial fee.* The fee for obtaining an initial registration shall be $30.

5.9(2) *Renewal fee.* The renewal fee for obtaining a biennial registration shall be $30.

5.9(3) *Timeliness.* Fees shall be paid at the time the new application or the renewal application is submitted for filing.

5.9(4) *Form of payment.* Fee payment shall be in the form of a personal check, certified or cashier's check, or money order payable to Iowa Board of Pharmacy.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—5.10(155A) Registration renewal. A pharmacy support person registration shall expire on the second last day of the birth month following initial registration. Registration shall not require continuing education for renewal.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—5.11(155A) Late application.

5.11(1) *Fee.* A person required to register or to renew the person's registration who files a late application shall pay an additional $30 late payment fee.

5.11(2) *Timeliness of initial application.* An application for initial registration shall be assessed a late payment fee if not received within the applicable period specified in rule 657—5.4(155A).

5.11(3) *Timeliness of renewal application.* An application for registration renewal shall be assessed a late payment fee if not received by the expiration date of the registration. A late payment fee shall not be assessed on an expired registration if the person was not employed as a pharmacy support person during the period following expiration of the registration.
[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—5.12 Reserved.

657—5.13(155A) Registration certificates. The original registration certificate issued by the board to a pharmacy support person shall be maintained by the pharmacy support person. Verification of current registration shall be maintained in each pharmacy where the pharmacy support person is employed in that capacity and shall be available for inspection by the board.
[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—5.14(155A) Notifications to the board. A pharmacy support person shall report to the board within ten days a change of name, address, place of employment, or employment status.
[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—5.15(155A) Identification of pharmacy support person.

5.15(1) *Name badge.* A pharmacy support person shall wear a name badge or other form of identification while on duty which clearly identifies the person as a pharmacy support person.

5.15(2) *Misrepresentation prohibited.* A pharmacy support person shall not, in any manner, represent himself or herself as a pharmacist, a pharmacist-intern, or a pharmacy technician.
[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—5.16 Reserved.

657—5.17(155A) Tasks a pharmacy support person shall not perform. A pharmacy support person shall not perform any of the following judgmental or technical functions. Performance of any of these tasks by a pharmacy support person shall constitute the practice of pharmacy without a license in violation of Iowa Code section 155A.7. A pharmacy support person shall not:

1. Provide the final verification for the accuracy, validity, completeness, or appropriateness of a filled prescription or medication order.
2. Conduct prospective drug use review or evaluate a patient's medication record for purposes identified in rule 657—8.21(155A).
3. Provide patient counseling, consultation, or patient-specific drug information; make an offer of patient counseling on behalf of the pharmacist; or accept a refusal of patient counseling from a patient or patient's agent.
4. Make decisions that require a pharmacist's professional judgment, such as interpreting or applying information.
5. Accept by oral communication any new or refill prescription authorizations communicated to a pharmacy by a prescriber or by the prescriber's office or contact a prescriber to obtain prescription refill authorizations.
6. Provide a prescription or drug to a patient without a pharmacist's verification as to the accuracy of the dispensed medication and without the physical presence of a pharmacist.
7. Package, pour, or place in a container for dispensing, sale, distribution, transfer, vending, or barter any drug which, under federal or state laws, may be sold or dispensed only pursuant to the prescription of a practitioner authorized to prescribe drugs. This prohibited task includes the addition of water or other liquid for reconstitution of oral antibiotic liquids.
8. Affix required prescription labels upon any container of drugs sold or dispensed pursuant to the prescription of an authorized prescriber.

9. Process or enter pertinent patient or prescription information, including entry of that information into the pharmacy computer system, except as provided in rule 657—5.18(155A).

10. Prepackage or label multidose and single-dose packages of drugs, including dose picks for unit dose cart fills for hospital or long-term care facility patients.

11. Check or inspect drug supplies provided and controlled by an Iowa-licensed pharmacy but located or maintained outside the pharmacy department, including but not limited to drug supplies maintained in an ambulance or other emergency medical service vehicle, a long-term care facility, a hospital nursing unit, or a hospice facility.

12. Reconstitute prefabricated noninjectable medication, prepare parenteral products, or compound sterile or nonsterile drug products.

13. Communicate, transmit, or receive patient or prescription information to or from the pharmacy for the purpose of transferring a patient's prescription between pharmacies.

14. Assist with or witness the destruction or wastage of controlled substances pursuant to 657—subrule 10.18(2).

15. Perform any of the duties identified in 657—Chapter 3 as technical functions that may be delegated to a pharmacy technician.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—5.18(155A) Nontechnical pharmacy support tasks. An appropriately trained and registered pharmacy support person may perform any of the following nontechnical functions that have been delegated to the pharmacy support person by the supervising pharmacist:

1. Perform the duties of a pharmacy clerk.

2. Process wholesale drug orders, including the submission of orders, the receipt and processing of drug deliveries from drug wholesalers, reconciling products received with packing slips or invoices, and affixing appropriate inventory or price stickers to drug stock bottles or containers.

3. Perform routine clerical duties, such as filing processed, hard-copy prescriptions and other pharmacy records.

4. Update or change patient demographic information, excluding allergies and disease state information, in the pharmacy computer system or patient profile.

5. Receive from a patient the patient's request for a prescription refill, excluding the processing of the refill request.

6. Perform pharmacy drug inventory control duties, including checking pharmacy stock shelves for outdated drugs and assisting with annual inventory counts.

7. Deliver drugs to patient care areas, long-term care facilities, patient residences, or patient employment locations, excluding the restocking of automated medication distribution system components.

8. Perform any routine clerical or pharmacy support function not prohibited in rule 657—5.17(155A).

9. In nuclear pharmacy practice, perform nonjudgmental tasks under the direct supervision of a nuclear pharmacist pursuant to 657—Chapter 16.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—5.19 Reserved.

657—5.20(155A) Training and utilization of pharmacy support persons. All Iowa-licensed pharmacies utilizing pharmacy support persons shall develop, implement, and periodically review written policies and procedures for the training and utilization of pharmacy support persons. Pharmacy policies shall specify the frequency of review. Pharmacy support person training shall be documented and maintained by the pharmacy for the duration of employment. Such policies and procedures and documentation of pharmacy support person training shall be available for inspection by the board or an agent of the board.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—5.21(155A) Responsibility of supervising pharmacist. The ultimate responsibility for the actions of a pharmacy support person working under a supervising pharmacist shall remain with the supervising pharmacist.
[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—5.22(155A) Delegation of nontechnical functions. A pharmacist may delegate nontechnical functions to an appropriately trained and registered pharmacy support person, but only if the pharmacist is present to supervise the pharmacy support person when delegated functions are performed, except as provided in 657—subrule 6.7(2) or 657—subrule 7.6(2), as appropriate.
[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—5.23 Reserved.

657—5.24(155A) Denial of registration. The board may deny an application for registration as a pharmacy support person for any violation of the laws of this state, another state, or the United States relating to prescription drugs, controlled substances, or nonprescription drugs or for any violation of Iowa Code chapter 124, 124A, 124B, 126, 147, 155A, or 205 or any rule of the board.
[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—5.25(147,155A) Unethical conduct or practice. Violation by a pharmacy support person of any of the provisions of this rule shall constitute unethical conduct or practice and may be grounds for disciplinary action as provided in rule 657—5.26(155A).

5.25(1) *Misrepresentative deeds.* A pharmacy support person shall not make any statement tending to deceive, misrepresent or mislead anyone, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in pharmacy or in the operation or conduct of a pharmacy.

5.25(2) *Confidentiality.* In the absence of express consent from the patient or order or direction of a court, except where the best interests of the patient require, a pharmacy support person shall not divulge or reveal to any person other than the patient or the patient's authorized representative, the prescriber or other licensed practitioner then caring for the patient, a licensed pharmacist, or a person duly authorized by law to receive such information the contents of any prescription or the therapeutic effect thereof or the nature of professional pharmaceutical services rendered to a patient; the nature, extent, or degree of illness suffered by any patient; or any medical information furnished by the prescriber.

5.25(3) *Discrimination.* It is unethical for a pharmacy support person to unlawfully discriminate between patients or groups of patients for reasons of religion, race, creed, color, sex, sexual orientation, gender identity, age, national origin, or disease state when providing pharmaceutical services.

5.25(4) *Unethical conduct or behavior.* A pharmacy support person shall not exhibit unethical behavior in connection with the pharmacy support person's pharmacy employment. Unethical behavior shall include, but is not limited to, the following acts: verbal abuse, coercion, intimidation, harassment, sexual advances, threats, degradation of character, indecent or obscene conduct, and theft.
[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—5.26(155A) Discipline of pharmacy support persons.

5.26(1) *Violations.* The board may impose discipline for any violation of the laws of this state, another state, or the United States relating to prescription drugs, controlled substances, or nonprescription drugs or for any violation of Iowa Code chapter 124, 124A, 124B, 126, 147, 155A, or 205 or any rule of the board.

5.26(2) *Sanctions.* The board may impose the following disciplinary sanctions:

a. Revocation of a pharmacy support person registration.

b. Suspension of a pharmacy support person registration until further order of the board or for a specified period.

c. Nonrenewal of a pharmacy support person registration.

d. Prohibition, permanently, until further order of the board, or for a specified period, from engaging in specified procedures, methods, or acts.

e. Probation.

f. Imposition of civil penalties not to exceed $25,000.

g. Issuance of citation and warning.

h. Such other sanctions allowed by law as may be appropriate.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

These rules are intended to implement Iowa Code sections 147.55, 155A.3, 155A.18 and 155A.23 and 2009 Iowa Code Supplement section 155A.6B.

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CHAPTER 6
GENERAL PHARMACY PRACTICE

[Prior to 2/10/88, see Pharmacy Examiners[620] Ch 2]

657—6.1(155A) Purpose and scope. A general pharmacy is a location where a pharmacist provides pharmaceutical services or dispenses pharmaceutical products to patients in accordance with pharmacy laws. This chapter does not apply to a hospital pharmacy as defined in 657—Chapter 7. The requirements of these rules for general pharmacy practice are in addition to the requirements of 657—Chapter 8 and other rules of the board relating to services provided by the pharmacy.

657—6.2(155A) Pharmacist in charge. One professionally competent, legally qualified pharmacist in charge in each pharmacy shall be responsible for, at a minimum, the following:

1. Ensuring that the pharmacy utilizes an ongoing, systematic program for achieving performance improvement and ensuring the quality of pharmaceutical services.
2. Ensuring that the pharmacy employs an adequate number of qualified personnel commensurate with the size and scope of services provided by the pharmacy.
3. Ensuring the availability of any equipment and references necessary for the particular practice of pharmacy.
4. Ensuring that a pharmacist performs prospective drug use review as specified in rule 657—8.21(155A).
5. Ensuring that a pharmacist provides patient counseling as specified in rule 6.14(155A).
6. Dispensing drugs to patients, including the packaging, preparation, compounding, and labeling functions performed by pharmacy personnel.
7. Delivering drugs to the patient or the patient's agent.
8. Ensuring that patient medication records are maintained as specified in rule 6.13(155A).
9. Training pharmacy technicians and pharmacy support persons.
10. Procuring and storing prescription drugs and devices and other products dispensed from the pharmacy.
11. Distributing and disposing of drugs from the pharmacy.
12. Maintaining records of all transactions of the pharmacy necessary to maintain accurate control over and accountability for all drugs as required by applicable state and federal laws, rules, and regulations.
13. Establishing and maintaining effective controls against the theft or diversion of prescription drugs and records for such drugs.
14. Establishing and implementing policies and procedures for all operations of the pharmacy.
15. Ensuring the legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, and regulations governing the practice of pharmacy.
16. Ensuring that there is adequate space within the prescription department or a locked room not accessible to the public for the storage of prescription drugs, devices, and controlled substances and to support the operations of the pharmacy.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—6.3(155A) Reference library. References may be printed or computer-accessed. A reference library shall be maintained which includes, as a minimum, one current reference from each of the following categories, including access to current periodic updates.

1. The Iowa Pharmacy Law and Information Manual.
2. A patient information reference that includes or provides patient information in compliance with rule 657—6.14(155A).
3. A reference on drug interactions.
4. A general information reference.
5. A drug equivalency reference.
6. A reference on natural or herbal medicines.
7. The readily accessible telephone number of a poison control center that serves the area.

8. Additional references as may be necessary for the pharmacist to adequately meet the needs of the patients served.

657—6.4(155A) Exemption from duplicate requirements. A pharmacy established in the same location as another licensed pharmacy and with direct and immediate access to required references, patient counseling area, refrigerator, or sink with hot and cold running water may utilize the references, counseling area, refrigerator, or sink of the other pharmacy to satisfy the requirements of rule 657—6.3(155A), subrule 6.14(3), or rule 657—8.5(155A), paragraphs "1" and "2."

657—6.5 and **6.6** Reserved.

657—6.7(124,155A) Security. While on duty, each pharmacist shall be responsible for the security of the prescription department, including provisions for effective control against theft of, diversion of, or unauthorized access to prescription drugs, records for such drugs, and patient records as provided in 657—Chapter 21.

6.7(1) *Department locked.* The prescription department shall be locked by key or combination so as to prevent access when a pharmacist is not on site except as provided in subrule 6.7(2).

6.7(2) *Temporary absence of pharmacist.* In the temporary absence of the pharmacist, only the pharmacist in charge may designate pharmacy technicians or pharmacy support persons who may be present in the prescription department to perform technical or nontechnical functions, respectively, designated by the pharmacist in charge. Activities identified in subrule 6.7(3) may not be performed during such temporary absence of the pharmacist. A temporary absence is an absence of short duration not to exceed two hours. In the absence of the pharmacist, the pharmacy shall notify the public that the pharmacist is temporarily absent and that no prescriptions will be dispensed until the pharmacist returns.

6.7(3) *Activities prohibited in absence of pharmacist.* Activities which shall not be designated and shall not be performed during the temporary absence of the pharmacist include:

a. Dispensing or distributing any prescription drugs or devices to patients or others.

b. Providing the final verification for the accuracy, validity, completeness, or appropriateness of a filled prescription or medication order.

c. Conducting prospective drug use review or evaluating a patient's medication record for purposes identified in rule 657—8.21(155A).

d. Providing patient counseling, consultation, or drug information.

e. Making decisions that require a pharmacist's professional judgment such as interpreting or applying information.

f. Transferring prescriptions to or from other pharmacies.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—6.8(124,155A) Prescription processing documentation. All prescriptions shall be dated and assigned a unique identification number that shall be recorded on the original prescription. The original prescription, whether transmitted orally, electronically, or in writing, shall be retained by the pharmacy filling the prescription. Refill documentation shall include date of refill and the initials or other unique identification of the pharmacist. The name, strength, and either the manufacturer's name or the National Drug Code (NDC) of the actual drug product dispensed shall be maintained and be readily retrievable.

657—6.9(124,155A) Transfer of prescription. The transmission of a prescription drug order from a pharmacy to a pharmacy engaged in centralized prescription filling or processing on behalf of the originating pharmacy pursuant to the requirements of 657—Chapter 18 shall not constitute the transfer of a prescription. Upon the request of a patient or the patient's caregiver, a pharmacy shall transfer original prescription drug order information and prescription refill information to a pharmacy designated by the patient or the patient's caregiver, central fill or processing pharmacies excepted, subject to the following requirements:

6.9(1) *Schedule III, IV, or V prescriptions.* The transfer of original prescription drug order information for controlled substances listed in Schedule III, IV, or V is permissible between pharmacies on a one-time basis except as provided in subrule 6.9(9).

6.9(2) *Noncontrolled substances prescriptions.* The transfer of original prescription drug order information for noncontrolled prescription drugs between pharmacies is permissible as long as the number of transfers does not exceed the number of originally authorized refills and the original prescription is still valid.

6.9(3) *Communication.* The transfer is communicated directly between pharmacists, directly between pharmacist-interns under the direct supervision of pharmacists at the respective pharmacies, directly between a pharmacist and a pharmacist-intern under the direct supervision of a pharmacist, or as authorized in subrule 6.9(9).

6.9(4) *Prescriptions maintained.* Both the original and the transferred prescription drug orders are maintained for a period of two years from the date of last refill.

6.9(5) *Record of transfer out.* The pharmacist or pharmacist-intern transferring the prescription drug order information shall:

a. Invalidate the prescription drug order;

b. Record on or with the invalidated prescription drug order the following information:

(1) The name, address, and, for a controlled substance, the DEA registration number of the pharmacy to which such prescription is transferred;

(2) The name of the pharmacist or pharmacist-intern receiving the prescription drug order information;

(3) The name of the pharmacist or pharmacist-intern transferring the prescription drug order information; and

(4) The date of the transfer.

6.9(6) *Original prescription status.* The original prescription drug order shall be invalidated in the data processing system for purposes of filling or refilling, but shall be maintained in the data processing system for refill history purposes.

6.9(7) *Controlled substance prescription status.* The data processing system shall have a mechanism to prohibit the transfer or refilling of controlled substance prescription drug orders that have been previously transferred.

6.9(8) *Record of transfer received.* The pharmacist or pharmacist-intern receiving the transferred prescription drug order information shall:

a. Indicate that the prescription drug order has been transferred;

b. Record on or with the transferred prescription drug order the following information:

(1) Original date of issuance and date of dispensing, if different from date of issuance;

(2) Original prescription number;

(3) Number of valid refills remaining, the date of last refill, and, for a controlled substance, the dates and locations of all previous refills;

(4) Name, address, and, for a controlled substance, the DEA registration number of the pharmacy from which such prescription drug order information is transferred;

(5) The date of the transfer;

(6) Name of the pharmacist or pharmacist-intern receiving the prescription drug order information;

(7) Name of the pharmacist or pharmacist-intern transferring the prescription drug order information; and

(8) If transferring a controlled substance prescription from a pharmacy utilizing a shared electronic database system as described in subrule 6.9(9) to a pharmacy outside that shared system, the pharmacy name, location, DEA registration number, and prescription number from which the prescription was originally filled.

6.9(9) *Electronic transfer between pharmacies.* Pharmacies electronically accessing the same prescription drug order records via a real-time, on-line database may electronically transfer prescription information, including controlled substance prescription information, up to the maximum refills permitted by law and the prescriber's authorization, if the following requirements are met.

a. The data processing system shall have a mechanism to send the transferring pharmacy a message containing the following information:

(1) The fact that the prescription drug order was transferred;

(2) The unique identification number of the prescription drug order transferred;

(3) The name, address, and DEA registration number of the pharmacy to which the prescription drug order was transferred and the name of the pharmacist or pharmacist-intern receiving the prescription information; and

(4) The date and time of transfer.

b. A pharmacist or pharmacist-intern under the direct supervision of a pharmacist in the transferring pharmacy shall review the message and document the review by signing and dating a hard copy of the message or logbook containing the information required on the message, or by a notation in the electronic message that includes the unique identification of the pharmacist or pharmacist-intern and the date of review, as soon as practical, but in no event more than 72 hours from the time of such transfer.

c. For transfers of controlled substance prescriptions, all information requirements included in subrules 6.9(1) and 6.9(3) through 6.9(8) shall be satisfied in the electronic system. Transfers of controlled substance prescriptions shall also identify the pharmacy name, address, DEA registration number, and prescription number from which the prescription was originally filled.

[**ARC 7634B**, IAB 3/11/09, effective 4/15/09; **ARC 8169B**, IAB 9/23/09, effective 10/28/09]

657—6.10(126,155A) Prescription label requirements.

6.10(1) *Required information.* The label affixed to or on the dispensing container of any prescription drug or device dispensed by a pharmacy pursuant to a prescription drug order shall bear the following:

a. Serial number (a unique identification number of the prescription);

b. The name, telephone number, and address of the pharmacy;

c. The name of the patient or, if such drug is prescribed for an animal, the species of the animal and the name of its owner;

d. The name of the prescribing practitioner;

e. The date the prescription is dispensed;

f. The directions or instructions for use, including precautions to be observed;

g. Unless otherwise directed by the prescriber, the label shall bear the name, strength, and quantity of the drug dispensed.

(1) If a pharmacist selects an equivalent drug product for a brand name drug product prescribed by a practitioner, the prescription container label shall identify the generic drug and may identify the brand name drug for which the selection is made, such as "(generic name) Generic for (brand name product)."

(2) If a pharmacist selects a brand name drug product for a generic drug product prescribed by a practitioner, the prescription container label shall identify the brand name drug product dispensed and may identify the generic drug product ordered by the prescriber, such as "(brand name product) for (generic name)";

h. The initials or other unique identification of the dispensing pharmacist.

6.10(2) *Exceptions.* The requirements of subrule 6.10(1) do not apply to unit dose dispensing systems, 657—22.1(155A); sterile products, 657—Chapter 13; and patient med paks, 657—22.5(126,155A).

657—6.11 and **6.12** Reserved.

657—6.13(155A) Patient record system.

6.13(1) *Information required.* A patient record system shall be maintained by all pharmacies for patients for whom prescription drug orders are dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing. The pharmacist shall be responsible for obtaining, recording, and maintaining the following information:

a. Full name of the patient for whom the drug is intended;

b. Address and telephone number of the patient;

c. Patient's age or date of birth;

d. Patient's gender;

e. Known allergies;

f. Significant patient information including a list of all prescription drug orders dispensed by the pharmacy during the two years immediately preceding the most recent entry showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber; and

g. Pharmacist comments relevant to the individual's drug therapy, including:

(1) Known drug reactions,

(2) Identified idiosyncrasies,

(3) Known chronic conditions or disease states of the patient,

(4) The identity of any other drugs, over-the-counter drugs, herbals, other alternative medications, or devices currently being used by the patient that may relate to prospective drug review.

6.13(2) *Record retained.* A patient record shall be maintained for a period of not less than two years from the date of the last entry in the patient record. This record may be a hard copy or a computerized form.

6.13(3) *Confidential.* Information in the patient record shall be deemed to be confidential and may be released only as provided in rule 657—8.16(124,155A).

657—6.14(155A) Patient counseling and instruction. Every general pharmacy located in Iowa shall post in the prescription pickup area in a manner clearly visible to patients a notice that Iowa law requires the pharmacist to discuss with the patient any new prescriptions dispensed to the patient. The board shall provide a general pharmacy with the required signage. A pharmacy that provides no direct patient access to the pharmacy department, commonly referred to as a "closed-door pharmacy," shall not be required to post the counseling notice.

6.14(1) *Counseling required.* Upon receipt of a new prescription drug order and following a prospective drug use review pursuant to 657—8.21(155A), a pharmacist shall counsel each patient or patient's caregiver. An offer to counsel shall not fulfill the requirements of this rule. Patient counseling shall be on matters which, in the pharmacist's professional judgment, will enhance or optimize drug therapy. Appropriate elements of patient counseling may include:

a. The name and description of the drug;

b. The dosage form, dose, route of administration, and duration of drug therapy;

c. Intended use of the drug, if known, and expected action;

d. Special directions and precautions for preparation, administration, and use by the patient;

e. Common severe side effects or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

f. Techniques for self-monitoring drug therapy;

g. Proper storage;

h. Prescription refill information;

i. Action to be taken in the event of a missed dose;

j. Pharmacist comments relevant to the individual's drug therapy including any other information peculiar to the specific patient or drug.

6.14(2) *Instruction.* A pharmacist may instruct patients and demonstrate procedures for self-monitoring of medical conditions and for self-administration of drugs.

6.14(3) *Counseling area.* A pharmacy shall contain an area which is suitable for confidential patient counseling. Such area shall:

a. Be easily accessible to both patient and pharmacists and not allow patient access to prescription drugs;

b. Be designed to maintain the confidentiality and privacy of the pharmacist/patient communication.

6.14(4) *Oral counseling not practicable.* If in the pharmacist's professional judgment oral counseling is not practicable, the pharmacist may use alternative forms of patient information. "Not practicable" refers to patient variables including, but not limited to, the absence of the patient or patient's caregiver, the patient's or caregiver's hearing impairment, or a language barrier. "Not practicable" does not include pharmacy variables such as inadequate staffing, technology failure, or high prescription volume. Alternative forms of patient information may include written information leaflets, pictogram labels, video programs, or information generated by electronic data processing equipment. When used in place of oral counseling, alternative forms of patient information shall advise the patient or caregiver that the pharmacist may be contacted for consultation in person at the pharmacy by toll-free telephone or collect telephone call. A combination of oral counseling and alternative forms of counseling is encouraged.

6.14(5) *Exception.* Patient counseling, as described above, shall not be required for inpatients of an institution where other licensed health care professionals are authorized to administer the drugs.

6.14(6) *Refusal of consultation.* A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation. A patient's or caregiver's refusal of consultation shall be documented by the pharmacist. The absence of any record of a refusal of the pharmacist's attempt to counsel shall be presumed to signify that the offer was accepted and that counseling was provided.

[**ARC 8540B**, IAB 2/24/10, effective 4/1/10]

657—6.15(124,126) Return of drugs and other items. For the protection of the public health and safety, prescription drugs and devices, controlled substances, and items of personal contact nature may be returned to the pharmacy for reuse or resale only as herein provided:

6.15(1) *Integrity maintained.* Prescription drugs and devices may be returned, exchanged, or resold only if, in the professional judgment of the pharmacist, the integrity of the prescription drug has not in any way been compromised.

6.15(2) *Controlled substances.* Under no circumstances shall pharmacy personnel accept from a patient or a patient's agent any controlled substances for return, exchange, or resale except to the same patient.

6.15(3) *Unit dose returns.* Prescription drugs dispensed in unit dose packaging, excluding controlled substances, may be returned and reused as authorized in 657—subrule 22.1(6).

6.15(4) *Personal contact items.* Pharmacy personnel shall not accept for reuse or resale any items of personal contact nature that have been removed from the original package or container after sale.

657—6.16(124,155A) Records. Every inventory or other record required to be kept under Iowa Code chapters 124 and 155A or rules of the board shall be kept by the pharmacy and be available for inspection and copying by the board or its representative for at least two years from the date of the inventory or record except as specifically identified by law or rule. Controlled substances records shall be maintained in a readily retrievable manner in accordance with federal requirements and 657—Chapter 10. Original hard-copy prescription and other pharmacy records more than 12 months old may be maintained in a secure storage area outside the licensed pharmacy department unless such remote storage is prohibited under federal law. A remote storage area shall be located within the same physical structure containing the licensed pharmacy department.

6.16(1) *Combined records.* If controlled substances, prescription drugs, or nonprescription drug items are listed on the same record, the controlled substances shall be asterisked, red-lined, or in some other manner made readily identifiable from all other items appearing on the records.

6.16(2) *Prescriptions maintained.* The original prescription drug order shall be maintained for a period of two years following the date of last activity on the prescription.

6.16(3) *Number imprinted.* The original hard-copy prescription shall be imprinted with the prescription or control number assigned to the prescription drug order.

6.16(4) *Alternative data retention system.* Records, except when specifically required to be maintained in original or hard-copy form, may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided:

a. The records maintained in the alternative system contain all of the information required on the manual record;

b. The data processing system is capable of producing a hard copy of the record, within two business days, upon the request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies; and

c. The information maintained in the alternative system is not obscured or rendered illegible due to security features of the original hard-copy record.

[**ARC 7636B**, IAB 3/11/09, effective 4/15/09; **ARC 8539B**, IAB 2/24/10, effective 4/1/10]

These rules are intended to implement Iowa Code sections 124.301, 124.303, 124.306, 126.10, 126.11, 155A.6, 155A.13, 155A.27, 155A.28, 155A.31, and 155A.33 through 155A.36.

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◊ Two or more ARCs

CHAPTER 7
HOSPITAL PHARMACY PRACTICE

[Prior to 2/10/88, see Pharmacy Examiners[620] Ch 12]

657—7.1(155A) Purpose and scope. Hospital pharmacy means and includes a pharmacy licensed by the board and located within any hospital, health system, institution, or establishment which maintains and operates organized facilities for the diagnosis, care, and treatment of human illnesses to which persons may or may not be admitted for overnight stay at the facility. A hospital is a facility licensed pursuant to Iowa Code chapter 135B. This chapter does not apply to a pharmacy located within such a facility for the purpose of providing outpatient prescriptions. A pharmacy providing outpatient prescriptions is and shall be licensed as a general pharmacy subject to the requirements of 657—Chapter 6. The requirements of these rules for hospital pharmacy practice apply to all hospitals, regardless of size or type, and are in addition to the requirements of 657—Chapter 8 and other rules of the board relating to services provided by the pharmacy.

657—7.2(155A) Pharmacist in charge. One professionally competent, legally qualified pharmacist in charge in each pharmacy shall be responsible for, at a minimum, the items identified in this rule. A part-time pharmacist in charge has the same obligations and responsibilities as a full-time pharmacist in charge. Where 24-hour operation of the pharmacy is not feasible, a pharmacist shall be available on an "on call" basis. The pharmacist in charge, at a minimum, shall be responsible for:

1. Ensuring that the pharmacy utilizes an ongoing, systematic program for achieving performance improvement and ensuring the quality of pharmaceutical services.
2. Ensuring that the pharmacy employs an adequate number of qualified personnel commensurate with the size and scope of services provided by the pharmacy and sufficient to ensure adequate levels of quality patient care services. Drug dispensing by nonpharmacists shall be minimized and eliminated wherever possible.
3. Ensuring the availability of any equipment and references necessary for the particular practice of pharmacy.
4. Ensuring that a pharmacist performs therapeutic drug monitoring and drug use evaluation.
5. Ensuring that a pharmacist provides drug information to other health professionals and to patients.
6. Dispensing drugs to patients, including the packaging, preparation, compounding, and labeling functions performed by pharmacy personnel.
7. Delivering drugs to the patient or the patient's agent.
8. Ensuring that patient medication records are maintained as specified in rule 657—7.10(124,155A).
9. Training pharmacy technicians and pharmacy support persons.
10. Ensuring adequate and appropriate pharmacist oversight and supervision of pharmacy technicians and pharmacy support persons.
11. Procuring and storing prescription drugs and devices and other products dispensed from the pharmacy.
12. Distributing and disposing of drugs from the pharmacy.
13. Maintaining records of all transactions of the pharmacy necessary to maintain accurate control over and accountability for all drugs as required by applicable state and federal laws, rules, and regulations.
14. Establishing and maintaining effective controls against the theft or diversion of prescription drugs, controlled substances, and records for such drugs.
15. Preparing a written operations manual governing pharmacy functions; periodically reviewing and revising those policies and procedures to reflect changes in processes, organization, and other pharmacy functions; and ensuring that all pharmacy personnel are familiar with the contents of the manual.

16. Ensuring the legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, and regulations governing the practice of pharmacy.
[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—7.3(155A) Reference library. References may be printed or computer-accessed. A reference library shall be maintained which includes, as a minimum, one current reference from each of the following categories, including access to current periodic updates.

1. The Iowa Pharmacy Law and Information Manual.
2. A patient information reference that includes or provides patient information in compliance with rule 657—6.14(155A).
3. A reference on drug interactions.
4. A general information reference.
5. A drug equivalency reference.
6. An injectable-drug compatibility reference.
7. A drug identification reference to enable identification of drugs brought into the facility by patients.
8. The readily accessible telephone number of a poison control center that serves the area.
9. Additional references as may be necessary for the pharmacist to adequately meet the needs of the patients served. For example, the treatment of pediatric patients and oncology patients would require additional references unique to those specialties.

657—7.4 and **7.5** Reserved.

657—7.6(124,155A) Security. The pharmacy shall be located in an area or areas that facilitate the provision of services to patients and shall be integrated with the facility's communication and transportation systems. The following conditions must be met to ensure appropriate control over drugs and chemicals in the pharmacy:

7.6(1) *Pharmacist responsibility.* Each pharmacist, while on duty, shall be responsible for the security of the pharmacy area, including provisions for effective control against theft of, diversion of, or unauthorized access to drugs or devices, controlled substances, records for such drugs, and patient records as provided in 657—Chapter 21. Policies and procedures shall identify the minimum amount of time that a pharmacist is available at the hospital pharmacy.

7.6(2) *Access when pharmacist absent.* When the pharmacist is absent from the facility, the pharmacy is closed. Policies and procedures shall be established that identify who will have access to the pharmacy when the pharmacy is closed and the procedures to be followed for obtaining drugs, devices, and chemicals to fill an emergent need during the pharmacist's absence.

a. The pharmacist in charge may designate pharmacy technicians or pharmacy support persons who may be present in the pharmacy to perform technical or nontechnical functions, respectively, designated by the pharmacist in charge. Activities identified in paragraph *"d"* of this subrule may not be performed when the pharmacy is closed.

b. If the pharmacist in charge has authorized the presence in the pharmacy of a pharmacy technician or a pharmacy support person to perform designated functions when the pharmacy is closed, only a pharmacy technician may assist another authorized, licensed health care professional to locate a drug or device pursuant to an emergent need. The pharmacy technician or the pharmacy support person may not dispense or deliver the drug, chemical, or device to the licensed health care professional. The licensed health care professional shall comply with established policies and procedures for obtaining drugs, devices, and chemicals when the pharmacy is closed. The licensed health care professional shall not ask or expect the pharmacy technician or the pharmacy support person to verify that the appropriate drug, chemical, or device has been obtained from the pharmacy.

c. A pharmacy technician or a pharmacy support person who is present in the pharmacy when the pharmacy is closed shall prepare and maintain in the pharmacy a log identifying each period of time that the pharmacy technician or pharmacy support person worked in the pharmacy while the pharmacy was

closed and identifying each activity performed during that time period. Each entry shall be dated and each daily record shall be signed by the pharmacy technician or pharmacy support person who prepared the record. The log shall be periodically reviewed by the pharmacist in charge.

d. Activities which shall not be performed by a pharmacy technician or a pharmacy support person when the pharmacist is absent from the facility include:

(1) Dispensing, delivering, or distributing any prescription drugs or devices to patients or others, including health care professionals, prior to pharmacist verification. Verification by a nurse or other licensed health care professional shall not supplant verification by a pharmacist.

(2) Providing the final verification for the accuracy, validity, completeness, or appropriateness of a filled prescription or medication order.

(3) Conducting prospective drug use review or evaluating a patient's medication record for purposes identified in rule 657—8.21(155A).

(4) Providing patient counseling, consultation, or drug information.

(5) Making decisions that require a pharmacist's professional judgment such as interpreting or applying information.

(6) Preparing compounded drug products for immediate administration by other hospital staff or health care professionals without verification by a pharmacist.

7.6(3) *Locked areas.* All pharmacy areas where drugs or devices are maintained or stored and where a pharmacist is not continually present shall be locked.

7.6(4) *Verification by pharmacist.* When the pharmacy is open, patient-specific drugs or devices shall not be distributed prior to the pharmacist's final verification and approval.

7.6(5) *Drugs or devices in patient care areas.* Drugs or devices maintained or stored in patient care areas shall be in locked storage unless the patient care unit is staffed by health care personnel and the medication area is visible to staff at all times.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—7.7(155A) Verification by pharmacist when pharmacy is closed. A hospital pharmacy may contract with another pharmacy for remote pharmacist preview and verification of patient-specific drugs or devices ordered for a patient when the hospital pharmacy is closed. Contracted services may include pharmacist order entry pursuant to subrule 7.8(3). Pharmacies entering into a contract or agreement pursuant to this rule shall comply with the following requirements:

7.7(1) *Nonsupplanting service.* A contract or agreement for remote pharmacist services shall not relieve the hospital pharmacy from employing or contracting with a pharmacist to provide routine pharmacy services within the facility. The activities authorized by this rule are intended to supplement hospital pharmacy services when the pharmacy is closed and are not intended to eliminate the need for an on-site hospital pharmacy or pharmacist.

7.7(2) *Hospital-staff pharmacist.* Nothing in this rule shall prohibit a pharmacist employed by or contracting with a hospital pharmacy for on-site services from also providing remote preview and verification of patient-specific drugs or devices ordered for a patient when the hospital pharmacy is closed. A pharmacist previewing and verifying drug or device orders from a remote location shall have access to patient information pursuant to subrule 7.7(4) or 7.7(5), shall have access to the prescriber as provided in subrule 7.7(6), and shall be identified on the drug or device order as provided in subrule 7.7(7).

7.7(3) *Licenses required.* A pharmacy contracting with a hospital pharmacy to provide services pursuant to this rule shall maintain with the board a current Iowa pharmacy license. A remote pharmacist providing pharmacy services as an employee or agent of a contracting pharmacy pursuant to this rule shall be licensed to practice pharmacy in Iowa.

7.7(4) *Electronic access to patient information.* The remote pharmacist shall have secure electronic access to the hospital pharmacy's patient information system and to all other electronic systems that the on-site pharmacist has access to when the pharmacy is open. The remote pharmacist shall receive training in the use of the hospital's electronic systems.

7.7(5) *Nonelectronic patient information.* If a hospital's patient information is not maintained in an electronic data system or if the hospital pharmacy is not able to provide remote electronic access to the patient information system, the hospital pharmacy may petition for a waiver of subrule 7.7(4) pursuant to 657—Chapter 34 and this subrule. In addition to the information required pursuant to 657—Chapter 34, the petition for waiver shall identify the hospital pharmacy's alternative to the electronic sharing of patient information, shall explain in detail how the alternative method will ensure timely provision of patient information necessary for the remote pharmacist to effectively review the patient's drug regimen and history, and shall detail the processes involved in the alternative proposal including identification of all individuals involved in each of those processes.

7.7(6) *Access to prescriber.* The remote pharmacist shall be able to contact the prescriber to discuss any concerns identified during the pharmacist's review of the patient's information.

7.7(7) *Pharmacist identified.* The record of each patient-specific drug or device order processed pursuant to this rule shall identify, by name or other unique identifier, each pharmacist involved in the preview and verification of the order.

657—7.8(124,126,155A) Drug distribution and control. Policies and procedures governing drug distribution and control shall be developed by the pharmacist in charge with input from other involved hospital staff such as physicians and nurses, from committees such as the pharmacy and therapeutics committee or its equivalent, and from any related patient care committee. It is essential that the pharmacist in charge or designee routinely be available to or on all patient care areas to establish rapport with the personnel and to become familiar with and contribute to medical and nursing procedures relating to drugs.

7.8(1) *Drug preparation.* The pharmacist shall institute the control procedures needed to ensure that patients receive the correct drugs at the proper times. Adequate quality assurance procedures shall be developed.

a. Hospitals shall utilize a unit dose dispensing system pursuant to rule 657—22.1(155A). All drugs dispensed by the pharmacist for administration to patients shall be in single unit or unit dose packages if practicable unless the dosage form or drug delivery device makes it impracticable to package the drug in a unit dose or single unit package.

(1) The pharmacist in charge shall establish policies and procedures that identify situations when drugs may be dispensed in other than unit dose or single unit packages outside the unit dose dispensing system.

(2) The need for nurses to manipulate drugs prior to their administration shall be minimized.

b. Pharmacy personnel shall, except as specified in policies and procedures, prepare all sterile products in conformance with 657—Chapter 13.

c. Pharmacy personnel shall compound or prepare drug formulations, strengths, dosage forms, and packages useful in the care of patients.

7.8(2) *Drug formulary.* The pharmacist in charge shall maintain a current formulary of drug products approved for use in the institution and shall be responsible for specifications for those drug products and for selecting their source of supply.

7.8(3) *Medication orders.* Except as provided in subrule 7.8(14), a pharmacist shall receive a copy of the original medication order for review except when the prescriber directly enters the medication order into an electronic medical record system or when the prescriber issues a verbal medication order directly to a registered nurse or pharmacist who then enters the order into an electronic medical record system. If an individual other than the prescriber enters a medication order into an electronic medical record system, the pharmacist shall review and verify the entry against the original order before the drug is dispensed except for emergency use, when the pharmacy is closed, or when the original order is a verbal order from the prescriber to the registered nurse or pharmacist, or as provided in rule 657—7.7(155A). When the pharmacy is closed, a registered nurse or pharmacist may enter a medication order into an electronic medical record system for the purpose of creating an electronic medication administration record and a pharmacist shall verify the entry against the original medication order as soon as practicable. Hospitalwide and pharmacy stand-alone computer systems shall be secure

against unauthorized entry. The use of abbreviations and chemical symbols on medication orders shall be discouraged but, if used, shall be limited to abbreviations and chemical symbols approved by the appropriate patient care committee.

7.8(4) *Stop order.* A written policy or other system concerning stop orders shall be established to ensure that medication orders are not inappropriately continued.

7.8(5) *Emergency drug supplies and floor stock.* Supplies of drugs for use in medical emergencies shall be immediately available at each nursing unit or service area as specified in policies and procedures. Authorized stocks shall be periodically reviewed in a multidisciplinary manner. All drug storage areas within the hospital shall be routinely inspected to ensure that no outdated or unusable items are present and that all stock items are properly labeled and stored.

7.8(6) *Disaster services.* The pharmacy shall be prepared to provide drugs and pharmaceutical services in the event of a disaster affecting the availability of drugs or internal access to drugs or access to the pharmacy.

7.8(7) *Drugs brought into the institution.* The pharmacist in charge shall determine those circumstances when patient-owned drugs brought into the institution may be administered to a hospital patient and shall establish policies and procedures governing the use and security of drugs brought into the institution. Procedures shall address identification of the drug and methods for ensuring the integrity of the product prior to permitting its use by the patient. The use of patient-owned drugs shall be minimized to the greatest extent possible.

7.8(8) *Samples.* The use of drug samples within the institution shall be eliminated to the extent possible. Sample use is prohibited for hospital inpatient use. If the use of drug samples is permitted for hospital outpatients, that use of samples shall be controlled and the samples shall be distributed through the pharmacy or through a process developed in cooperation with the pharmacy and the institution's appropriate patient care committee, subject to oversight by the pharmacy.

7.8(9) *Investigational drugs.* If investigational drugs are used in the institution:

a. A pharmacist shall be a member of the institutional review board.

b. The pharmacy shall be responsible, in cooperation with the principal investigator, for providing information about investigational drugs used in the institution and for the distribution and control of those drugs.

7.8(10) *Hazardous drugs and chemicals.* The pharmacist, in cooperation with other hospital staff, shall establish policies and procedures for handling drugs and chemicals that are known occupational hazards. The procedures shall maintain the integrity of the drug or chemical and protect hospital personnel.

7.8(11) *Leave meds.* Labeling of prescription drugs for a patient on leave from the facility for a period in excess of 24 hours shall comply with 657—subrule 6.10(1). The dispensing pharmacy shall be responsible for packaging and labeling leave meds in compliance with this subrule.

7.8(12) *Discharge meds.* Drugs authorized for a patient being discharged from the facility shall be labeled in compliance with 657—subrule 6.10(1) before the patient removes those drugs from the facility premises. The dispensing pharmacy shall be responsible for packaging and labeling discharge meds in compliance with this subrule.

7.8(13) *Own-use outpatient prescriptions.* If the hospital pharmacy dispenses own-use outpatient prescriptions, the pharmacy shall comply with all requirements of 657—Chapter 6 except rule 657—6.1(155A).

7.8(14) *Influenza and pneumococcal vaccines.* As authorized by federal law, a written or verbal patient-specific medication administration order shall not be required prior to administration to an adult patient of influenza and pneumococcal polysaccharide vaccines pursuant to physician-approved hospital policy and after the patient has been assessed for contraindications. Administration shall be recorded in the patient's medical record.

[**ARC 8170B**, IAB 9/23/09, effective 10/28/09]

657—7.9(124,155A) Drug information. The pharmacy is responsible for providing the institution's staff and patients with accurate, comprehensive information about drugs and their use and shall serve as its center for drug information.

7.9(1) *Staff education.* The pharmacist shall keep the institution's staff well informed about the drugs used in the institution and their various dosage forms and packagings.

7.9(2) *Patient education.* The pharmacist shall help ensure that all patients are given adequate information about the drugs that they receive. This is particularly important for ambulatory, home care, and discharged patients. These patient education activities shall be coordinated with the nursing and medical staffs and patient education department, if any.

657—7.10(124,155A) Ensuring rational drug therapy. An important aspect of pharmaceutical services is that of maximizing rational drug use. The pharmacist, in concert with the medical staff, shall develop policies and procedures for ensuring the quality of drug therapy.

7.10(1) *Patient profile.* Sufficient patient information shall be collected, maintained, and reviewed by the pharmacist to ensure meaningful and effective participation in patient care. This requires that a drug profile be maintained for each patient receiving care at the hospital. A pharmacist-conducted drug history from patients may be useful in this regard.

a. Appropriate clinical information about patients shall be available and accessible to the pharmacist for use in daily practice.

b. The pharmacist shall review each patient's current drug regimen and directly communicate any suggested changes to the prescriber.

7.10(2) *Adverse drug events.* The pharmacist, in cooperation with the appropriate patient care committee, shall develop a mechanism for the reporting and review, by the committee or other appropriate medical group, of adverse drug events. The pharmacist shall be informed of all reported adverse drug events occurring in the facility. Adverse drug events include but need not be limited to adverse drug reactions and medication errors.

657—7.11 Reserved.

657—7.12(124,126,155A) Drugs dispensed to patients as a result of an emergency room visit. In those facilities with 24-hour pharmacy services, only a pharmacist or prescribing practitioner may dispense any drugs to an outpatient, including emergency department patients. In those facilities without 24-hour pharmacy services, or in those facilities without outpatient pharmacy services or when the facility's outpatient pharmacy is closed, the following procedures shall be observed in dispensing drugs:

7.12(1) *Patients examined in emergency room.* Drugs shall be dispensed only to patients who have been examined in the emergency room.

7.12(2) *Accountability.* Drugs shall be dispensed only in accordance with the system of control and accountability for drugs administered or dispensed from the emergency room.

a. The system shall be developed and supervised by the pharmacist in charge and the facility's emergency department committee, or a similar group or person responsible for policy in that department.

b. The system shall identify drugs of the nature and type to meet the immediate needs of emergency room patients.

c. Controlled substances maintained in the emergency room are kept for use by, or at the direction of, prescribers in the emergency room. In order to receive a controlled substance, a patient must be examined in the emergency room by a prescriber who shall determine the need for the drug. It is not permissible under state and federal requirements for a prescriber to see a patient outside the emergency room setting, or talk to the patient on the telephone, and then proceed to call the emergency room and order the administration of a stocked controlled substance upon the patient's arrival at the emergency room. A prescriber may authorize, without again examining the patient, the administration of additional doses of a previously authorized drug to a patient presenting to the emergency department within 24 hours of the patient's examination and treatment in the emergency department.

d. In an emergency situation when a health care practitioner authorized to prescribe controlled substances is not available on site and regardless of the provisions of paragraph *"c,"* the emergency room nurse may examine the patient in the emergency room and contact the on-call prescriber. The on-call prescriber may then authorize the nurse to administer a controlled substance to the patient pending the arrival of the prescriber. As soon as possible, the prescriber shall examine the patient in the emergency room and determine the patient's further treatment needs.

e. The pharmacist in charge is responsible for maintaining accurate records of dispensing of drugs from the emergency room, and for ensuring the accuracy of prepackaged drugs and the complete and accurate labeling of prepackaged drugs pursuant to subrule 7.12(3).

f. Except as provided in subrule 7.12(6), a practitioner who authorizes dispensing to a patient of a prescription drug from the emergency department drug supply is responsible for the accuracy of the dispensed drug and for the accurate completion of label information pursuant to subrule 7.12(4).

7.12(3) *Prepackaging.* Except as provided in subrule 7.12(6), drugs dispensed in greater than a 24-hour supply may be dispensed only in prepackaged quantities not to exceed a 72-hour supply or the minimum prepackaged quantity in suitable containers. Prepackaged drugs shall be prepared pursuant to the requirements of 657—22.3(126). Drugs dispensed pursuant to this subrule shall be appropriately labeled as required in subrule 7.12(4), including necessary auxiliary labels.

7.12(4) *Labeling.* Except as provided in subrule 7.12(6), at the time of delivery of the drug, the practitioner shall appropriately complete the label, such that the dispensing container bears a label with at least the following information:

a. Name and address of the hospital;

b. Date dispensed;

c. Name of prescriber;

d. Name of patient;

e. Directions for use;

f. Name and strength of drug.

7.12(5) *Delivery of drug to patient.* Except as provided in subrule 7.12(6), the practitioner, or a licensed nurse under the supervision of the practitioner, shall give the appropriately labeled, prepackaged drug to the patient or patient's caregiver. The practitioner, or a licensed nurse under the supervision of the practitioner, shall explain the correct use of the drug and shall explain to the patient that the dispensing is for an emergency or starter supply of the drug. If additional quantities of the drug are required to complete the needed course of treatment, the prescriber shall provide the patient with a prescription for the additional quantities.

7.12(6) *Use of InstyMeds dispensing system.* A hospital located in an area of the state where 24-hour outpatient pharmacy services are not available within 15 miles of the hospital may implement the InstyMeds dispensing system in the hospital emergency department only as provided by this subrule.

a. Access to the dispensing machine for the purposes of stocking, inventory, and monitoring shall be limited to pharmacists, pharmacy technicians, and pharmacist-interns.

b. The InstyMeds dispensing system shall be used only in the hospital emergency department for the benefit of patients examined or treated in the emergency department.

c. The dispensing machine shall be located in a secure and professionally appropriate environment.

d. The stock of drugs maintained and dispensed utilizing the InstyMeds dispensing system shall be limited to acute care drugs provided in appropriate quantities for a 72-hour supply or the minimum commercially available package size, except that antimicrobials may be dispensed in a quantity to provide the full course of therapy.

e. Drugs dispensed utilizing the InstyMeds dispensing system shall be appropriately labeled as provided in 657—subrule 6.10(1), paragraphs *"a"* through *"g."*

f. Prior to authorizing the dispensing of a drug utilizing the InstyMeds dispensing system, the prescriber shall offer the patient the option of being provided a prescription that may be filled at the pharmacy of the patient's choice.

g. When appropriate for an acute condition, the prescriber shall provide to the patient or the patient's agent a prescription for the remainder of drug therapy beyond the supply available utilizing the InstyMeds dispensing system. During consultation with the patient or the patient's agent, the prescriber shall clearly explain the appropriate use of the drug supplied, the need to have a prescription for any additional supply of the drug filled at a pharmacy of the patient's choice, and the need to complete the full course of drug therapy.

h. The pharmacy shall, in conjunction with the hospital emergency department, implement policies and procedures to ensure that a patient utilizing the InstyMeds dispensing system has been positively identified.

i. The hospital pharmacist shall review the printout of drugs provided utilizing the InstyMeds dispensing system within 24 hours unless the pharmacy is closed, in which case the printout shall be reviewed during the first day the pharmacy is open following the provision of the drugs. The purpose of the review is to identify any dispensing errors, to determine dosage appropriateness, and to complete a retrospective drug use review of any antimicrobials dispensed in a quantity greater than a 72-hour supply. Any discrepancies found shall be addressed by the pharmacy's continuous quality improvement program.

657—7.13(124,155A) Records. Every inventory or other record required to be kept under this chapter or other board rules or under Iowa Code chapters 124 and 155A shall be kept by the pharmacy and be available for inspection and copying by the board or its representative for at least two years from the date of such inventory or record unless a longer retention period is specified for the particular inventory or record.

7.13(1) *Medication order information.* Each original medication order contained in inpatient records shall bear the following information:

a. Patient name and identification number;

b. Drug name, strength, and dosage form;

c. Directions for use;

d. Date ordered;

e. Practitioner's signature or electronic signature or that of the practitioner's authorized agent.

7.13(2) *Medication order maintained.* The original medication order shall be maintained with the medication administration record in the medical records of the patient following discharge.

7.13(3) *Documentation of drug administration.* Each dose of medication administered shall be properly recorded in the patient's medical record.

These rules are intended to implement Iowa Code sections 124.301, 124.303, 124.306, 126.10, 126.11, 155A.6, 155A.13, 155A.27, 155A.28, 155A.31, and 155A.33 through 155A.36.

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◊ Two or more ARCs

CHAPTER 8
UNIVERSAL PRACTICE STANDARDS
[Prior to 2/10/88, see Pharmacy Examiners[620] Ch 6]

657—8.1(155A) Purpose and scope. The requirements of these rules apply to all Iowa-licensed pharmacists and to all pharmacies providing the services addressed in this chapter to patients in Iowa and are in addition to rules of the board relating to specific types of pharmacy licenses issued by the board.

657—8.2(155A) Pharmaceutical care. Pharmaceutical care is a comprehensive, patient-centered, outcomes-oriented pharmacy practice in which the pharmacist accepts responsibility for assisting the prescriber and the patient in optimizing the patient's drug therapy plan and works to promote health, to prevent disease, and to optimize drug therapy. Pharmaceutical care does not include the prescribing of drugs without the consent of the prescribing practitioner.

8.2(1) *Drug therapy problems.* In providing pharmaceutical care, the pharmacist shall strive to identify, resolve, and prevent drug therapy problems.

8.2(2) *Drug therapy plan.* In providing pharmaceutical care, the pharmacist shall access and evaluate patient-specific information, identify drug therapy problems, and utilize that information in a documented plan of therapy that assists the patient or the patient's caregiver in achieving optimal drug therapy. In concert with the patient, the patient's prescribing practitioner, and the patient's other health care providers, the pharmacist shall assess, monitor, and suggest modifications of the plan as appropriate.

8.2(3) *Eligibility.* Any Iowa-licensed pharmacist may practice pharmaceutical care.

657—8.3(155A) Responsibility.

8.3(1) *Pharmacy operations.* The pharmacy and the pharmacist in charge share responsibility for ensuring that all operations of the pharmacy are in compliance with federal and state laws, rules, and regulations relating to pharmacy operations and the practice of pharmacy.

8.3(2) *Practice functions.* The pharmacist is responsible for all functions performed in the practice of pharmacy. The pharmacist maintains responsibility for any and all delegated functions including functions delegated to pharmacist-interns, pharmacy technicians, and pharmacy support persons.

8.3(3) *Pharmacist-documented verification.* The pharmacist shall provide and document the final verification for the accuracy, validity, completeness, and appropriateness of the patient's prescription or medication order prior to the delivery of the medication to the patient or the patient's representative.
[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—8.4(155A) Pharmacist identification.

8.4(1) *Display of pharmacist license.* During any period the pharmacist is working in a pharmacy, each pharmacist shall display, in a position visible to the public, an original license to practice pharmacy. A current license renewal certificate, which may be a photocopy of an original renewal certificate, shall be displayed with the original license.

8.4(2) *Identification codes.* A permanent log of the initials or codes identifying by name each dispensing pharmacist, pharmacist-intern, and pharmacy technician shall be maintained for a minimum of two years and shall be available for inspection and copying by the board or its representative. The initials or identification code shall be unique to the individual to ensure that each pharmacist, pharmacist-intern, and pharmacy technician can be identified.

8.4(3) *Temporary or intermittent pharmacy staff.* The pharmacy shall maintain a log of all pharmacists, pharmacist-interns, pharmacy technicians, and pharmacy support persons who have worked at that pharmacy and who are not regularly staffed at that pharmacy. Such log shall include the dates and shifts worked by each pharmacist, pharmacist-intern, pharmacy technician, and pharmacy support person and shall be available for inspection and copying by the board or its representative for a minimum of two years following the date of the entry.

8.4(4) *Identification badge.* A pharmacist shall wear a visible identification badge while on duty that clearly identifies the person as a pharmacist and includes at least the pharmacist's first name.
[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—8.5(155A) Environment and equipment requirements. There shall be adequate space, equipment, and supplies for the professional and administrative functions of the pharmacy. Space and equipment in an amount and type to provide secure, environmentally controlled storage of drugs shall be available.

8.5(1) *Refrigeration.* The pharmacy shall maintain one or more refrigeration units. The temperature of the refrigerator shall be maintained within a range compatible with the proper storage of drugs requiring refrigeration, and a thermometer shall be maintained in the refrigerator to verify the temperature.

8.5(2) *Sink.* The pharmacy shall have a sink with hot and cold running water located within the pharmacy department and available to all pharmacy personnel; the sink shall be maintained in a sanitary condition.

8.5(3) *Secure barrier.* The pharmacy department shall be surrounded by a physical barrier capable of being securely locked to prevent entry when the department is closed. A secure barrier may be constructed of other than a solid material with a continuous surface if the openings in the material are not large enough to permit removal of items from the pharmacy department by any means. Any material used in the construction of the barrier shall be of sufficient strength and thickness that it cannot be readily or easily removed, penetrated, or bent. The plans and specifications of the barrier shall be submitted to the board for approval prior to the start of construction. The board may also require on-site inspection of the facility or pharmacy department prior to the pharmacy's opening or relocation. The pharmacy department shall be closed and secured in the absence of the pharmacist except as provided in rule 657—6.7(124,155A) or 657—7.6(124,155A).

8.5(4) *Orderly and clean.* The pharmacy shall be arranged in an orderly fashion and kept clean. All required equipment shall be in good operating condition and maintained in a sanitary manner. Animals shall not be allowed within a licensed pharmacy unless that pharmacy is exclusively providing services for the treatment of animals or unless the animal is a service dog or assistive animal as defined in Iowa Code subsection 216C.11(1).

8.5(5) *Light and ventilation.* The pharmacy shall be properly lighted and ventilated.

8.5(6) *Temperature and humidity.* The temperature and humidity of the pharmacy shall be maintained within a range compatible with the proper storage of drugs.

8.5(7) *Other equipment.* The pharmacist in charge shall ensure the availability of any other equipment necessary for the particular practice of pharmacy and to meet the needs of the patients served by the pharmacy.

8.5(8) *Bulk counting machines.* Unless bar-code scanning is required and utilized to verify the identity of each stock container of drugs utilized to restock a counting machine cell or bin, a pharmacist shall verify the accuracy of the drugs to be restocked prior to filling the counting machine cell or bin. A record identifying the individual who verified the drugs to be restocked, the individual who restocked the counting machine cell or bin, and the date shall be maintained. The pharmacy shall have a method to calibrate and verify the accuracy of the counting device and shall, at least quarterly, verify the accuracy of the device and maintain a dated record identifying the individual who performed the quarterly verification.
[**ARC 8671B**, IAB 4/7/10, effective 5/12/10]

657—8.6(155A) Health of personnel. Only personnel authorized by the responsible pharmacist shall be in the immediate vicinity of the drug dispensing, preparation, compounding, or storage areas. Any person shown, either by medical examination or pharmacist determination, to have an apparent illness or open lesions that may adversely affect the quality or safety of a drug product or another individual shall be excluded from direct contact with components, bulk drug substances, drug product containers, closures, in-process materials, drug products, and patients until the condition is corrected or determined by competent medical personnel not to jeopardize the quality or safety of drug products or patients. All

personnel who normally assist the pharmacist shall be instructed to report to the pharmacist any health conditions that may have an adverse effect on drug products or may pose a health or safety risk to others.

657—8.7(155A) Procurement, storage, and recall of drugs and devices.

8.7(1) *Source.* Procurement of prescription drugs and devices shall be from a drug wholesaler licensed by the board to distribute to Iowa pharmacies or, on a limited basis, from another licensed pharmacy or licensed practitioner located in the United States.

8.7(2) *Sufficient stock.* A pharmacy shall maintain sufficient stock of drugs and devices to fulfill the foreseeable needs of the patients served by the pharmacy.

8.7(3) *Manner of storage.* Drugs and devices shall be stored in a manner to protect their identity and integrity.

8.7(4) *Storage temperatures.* All drugs and devices shall be stored at the proper temperature, as defined by the following terms:

a. *"Controlled room temperature"* means temperature maintained thermostatically between 15 degrees and 30 degrees Celsius (59 degrees and 86 degrees Fahrenheit);

b. *"Cool"* means temperature between 8 degrees and 15 degrees Celsius (46 degrees and 59 degrees Fahrenheit). Drugs and devices may be stored in a refrigerator unless otherwise specified on the labeling;

c. *"Refrigerate"* means temperature maintained thermostatically between 2 degrees and 8 degrees Celsius (36 degrees and 46 degrees Fahrenheit); and

d. *"Freeze"* means temperature maintained thermostatically between -20 degrees and -10 degrees Celsius (-4 degrees and 14 degrees Fahrenheit).

8.7(5) *Product recall.* There shall be a system for removing from use, including unit dose, any drugs and devices subjected to a product recall.

657—8.8(124,155A) Out-of-date drugs or devices. Any drug or device bearing an expiration date shall not be dispensed for use beyond the expiration date of the drug or device. Outdated drugs or devices shall be removed from dispensing stock and shall be quarantined until such drugs or devices are properly disposed of.

657—8.9(124,155A) Records. Every inventory or other record required to be maintained by a pharmacy pursuant to board rules or Iowa Code chapters 124 and 155A shall be maintained and be available for inspection and copying by the board or its representative for at least two years from the date of such inventory or record unless a longer retention period is specified for the particular record or inventory. Original hard-copy prescription and other pharmacy records more than 12 months old may be maintained in a secure storage area outside the licensed pharmacy department unless such remote storage is prohibited under federal law. A remote storage area shall be located within the same physical structure containing the licensed pharmacy department. The following records shall be maintained for at least two years.

8.9(1) *Drug supplier invoices.* All pharmacies shall maintain supplier invoices of prescription drugs and controlled substances upon which the actual date of receipt of the controlled substances by the pharmacist or other responsible individual is clearly recorded.

8.9(2) *Drug supplier credits.* All pharmacies shall maintain supplier credit memos for controlled substances and prescription drugs.

[**ARC 8539B**, IAB 2/24/10, effective 4/1/10]

657—8.10 Reserved.

657—8.11(147,155A) Unethical conduct or practice. The provisions of this rule apply to licensed pharmacies, licensed pharmacists and registered pharmacist-interns.

8.11(1) *Misrepresentative deeds.* A pharmacist shall not make any statement intended to deceive, misrepresent or mislead anyone, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in pharmacy or in the operation or conduct of a pharmacy.

8.11(2) *Undue influence.*

a. A pharmacist shall not accept professional employment or share or receive compensation in any form arising out of, or incidental to, the pharmacist's professional activities from a prescriber of prescription drugs or any other person or corporation in which one or more such prescribers have a proprietary or beneficial interest sufficient to permit them to directly or indirectly exercise supervision or control over the pharmacist in the pharmacist's professional responsibilities and duties or over the pharmacy wherein the pharmacist practices.

b. The prohibition in paragraph *"a"* shall not apply until April 23, 2006, to a pharmacist who is working at a prescriber-owned pharmacy location licensed as of April 23, 1981.

c. A prescriber may employ a pharmacist to provide nondispensing, drug information, or other cognitive services.

8.11(3) *Lease agreements.* A pharmacist shall not lease space for a pharmacy under any of the following conditions:

a. From a prescriber of prescription drugs or a group, corporation, association, or organization of such prescribers on a percentage of income basis;

b. From a group, corporation, association, or organization in which prescribers have majority control or have directly or indirectly a majority beneficial or proprietary interest on a percentage of income basis; or

c. If the rent is not reasonable according to commonly accepted standards of the community in which the pharmacy will be located.

8.11(4) *Nonconformance with law.* A pharmacist shall not knowingly serve in a pharmacy which is not operated in conformance with law, or which engages in any practice which if engaged in by a pharmacist would be unethical conduct.

8.11(5) *Freedom of choice/solicitation/kickbacks/fee-splitting and imprinted prescription blanks or forms.* A pharmacist or pharmacy shall not enter into any agreement which negates a patient's freedom of choice of pharmacy services. A pharmacist or pharmacy shall not participate in prohibited agreements with any person in exchange for recommending, promoting, accepting, or promising to accept the professional pharmaceutical services of any pharmacist or pharmacy. "Person" includes an individual, corporation, partnership, association, firm, or other entity. "Prohibited agreements" includes an agreement or arrangement that provides premiums, "kickbacks," fee-splitting, or special charges as compensation or inducement for placement of business or solicitation of patronage with any pharmacist or pharmacy. "Kickbacks" includes, but is not limited to, the provision of medication carts, facsimile machines, any other equipment, or preprinted forms or supplies for the exclusive use of a facility or practitioner at no charge or billed below reasonable market rate. A pharmacist shall not provide, cause to be provided, or offer to provide to any person authorized to prescribe prescription blanks or forms bearing the pharmacist's or pharmacy's name, address, or other means of identification, except that a hospital may make available to hospital staff prescribers, emergency department prescribers, and prescribers granted hospital privileges for the prescribers' use during practice at or in the hospital generic prescription blanks or forms bearing the name, address, or telephone number of the hospital pharmacy.

8.11(6) *Discrimination.* It is unethical to unlawfully discriminate between patients or groups of patients for reasons of religion, race, creed, color, gender, gender identity, sexual orientation, marital status, age, national origin, physical or mental disability, or disease state when providing pharmaceutical services.

8.11(7) *Claims of professional superiority.* A pharmacist shall not make a claim, assertion, or inference of professional superiority in the practice of pharmacy which cannot be substantiated, or claim an unusual, unsubstantiated capacity to supply a drug or professional service to the community.

8.11(8) *Unprofessional conduct or behavior.* A pharmacist shall not exhibit unprofessional behavior in connection with the practice of pharmacy or refuse to provide reasonable information or answer reasonable questions for the benefit of the patient. Unprofessional behavior shall include, but not be limited to, the following acts: verbal abuse, coercion, intimidation, harassment, sexual advances, threats, degradation of character, indecent or obscene conduct, and theft.

657—8.12(126,147) Advertising. Prescription drug price and nonprice information may be provided to the public by a pharmacy so long as the information is not false or misleading and is not in violation of any federal or state laws applicable to the advertisement of such articles generally and if all of the following conditions are met:

1. All charges for services to the consumer must be stated.
2. The effective dates for the prices listed shall be stated.
3. No reference shall be made to controlled substances listed in Schedules II through V of the latest revision of the Iowa uniform controlled substances Act and the rules of the Iowa board of pharmacy.

657—8.13(135C,155A) Personnel histories. Pursuant to the requirements of Iowa Code section 135C.33, the provisions of this rule shall apply to any pharmacy employing any person to provide patient care services in a patient's home. For the purposes of this rule, "employed by the pharmacy" shall include any individual who is paid to provide treatment or services to any patient in the patient's home, whether the individual is paid by the pharmacy or by any other entity such as a corporation, a temporary staffing agency, or an independent contractor. Specifically excluded from the requirements of this rule are individuals such as delivery persons or couriers who do not enter the patient's home for the purpose of instructing the patient or the patient's caregiver in the use or maintenance of the equipment, device, or drug being delivered, or who do not enter the patient's home for the purpose of setting up or servicing the equipment, device, or drug used to treat the patient in the patient's home.

8.13(1) *Applicant acknowledgment.* The pharmacy shall ask the following question of each person seeking employment in a position that will provide in-home services: "Do you have a record of founded child or dependent adult abuse or have you ever been convicted of a crime, in this state or any other state?" The applicant shall also be informed that a criminal history and dependent adult abuse record check will be conducted. The applicant shall indicate, by signed acknowledgment, that the applicant has been informed that such record checks will be conducted.

8.13(2) *Criminal history check.* Prior to the employment of any person to provide in-home services as described by this rule, the pharmacy shall submit to the department of public safety a form specified by the department of public safety and receive the results of a criminal history check.

8.13(3) *Abuse history checks.* Prior to the employment of any person to provide in-home services as described by this rule, the pharmacy shall submit to the department of human services a form specified by the department of human services and receive the results of a dependent adult abuse record check. The pharmacy may submit to the department of human services a form specified by the department of human services to request a child abuse history check.

a. A person who has a criminal record, founded dependent adult abuse report, or founded child abuse report shall not be employed by a pharmacy to provide in-home services unless the department of human services has evaluated the crime or founded abuse report, has concluded that the crime or founded abuse does not merit prohibition from such employment, and has notified the pharmacy that the person may be employed to provide in-home services.

b. The pharmacy shall keep copies of all record checks and evaluations for a minimum of two years following receipt of the record or for a minimum of two years after the individual is no longer employed by the pharmacy, whichever is greater.

657—8.14(155A) Training and utilization of pharmacy technicians or pharmacy support persons. All Iowa-licensed pharmacies utilizing pharmacy technicians or pharmacy support persons shall develop, implement, and periodically review written policies and procedures for the training and utilization of pharmacy technicians and pharmacy support persons appropriate to the practice of pharmacy at that licensed location. Pharmacy policies shall specify the frequency of review. Pharmacy technician and pharmacy support person training shall be documented and maintained by the pharmacy for the duration of employment. Policies and procedures and documentation of pharmacy technician and pharmacy support person training shall be available for inspection by the board or an agent of the board.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—8.15(155A) Delivery of prescription drugs and devices. Prescription drug orders, prescription devices, and completed prescription drug containers may be delivered, in compliance with all laws, rules, and regulations relating to the practice of pharmacy, to patients at any place of business licensed as a pharmacy.

8.15(1) *Alternative methods.* A licensed pharmacy may, by means of its employee or by use of a common carrier, pick up or deliver prescriptions to the patient or the patient's caregiver as follows:

a. At the office or home of the prescriber.

b. At the residence of the patient or caregiver.

c. At the hospital or medical care facility in which a patient is confined.

d. At an outpatient medical care facility where the patient receives treatment only pursuant to the following requirements:

(1) The pharmacy shall obtain and maintain the written authorization of the patient or patient's caregiver for receipt or delivery at the outpatient medical care facility;

(2) The prescription shall be delivered directly to or received directly from the patient, the caregiver, or an authorized agent identified in the written authorization;

(3) A prescription authorized by a prescriber not treating the patient at the outpatient medical care facility may be transmitted to the pharmacy by the authorized agent via facsimile provided that the means of transmission does not obscure or render the prescription information illegible due to security features of the paper utilized by the prescriber to prepare the prescription and provided that the original written prescription is delivered to the pharmacy prior to delivery of the filled prescription to the patient; and

(4) The outpatient medical care facility shall store the patient's filled prescriptions in a secure area pending delivery to the patient.

e. At the patient's or caregiver's place of employment only pursuant to the following requirements:

(1) The pharmacy shall obtain and maintain the written authorization of the patient or patient's caregiver for receipt or delivery at the place of employment;

(2) The prescription shall be delivered directly to or received directly from the patient, the caregiver, the prescriber, or an authorized agent identified in the written authorization; and

(3) The pharmacy shall ensure the security of confidential information as defined in subrule 8.16(1).

8.15(2) *Policies and procedures required.* Every pharmacy shipping or otherwise delivering prescription drugs or devices to Iowa patients shall develop and implement policies and procedures to ensure accountability, safe delivery, and compliance with temperature requirements as defined by subrule 8.7(4).

[**ARC 7636B**, IAB 3/11/09, effective 4/15/09]

657—8.16(124,155A) Confidential information.

8.16(1) *Definition.* "Confidential information" means information accessed or maintained by the pharmacy in the patient's records which contains personally identifiable information that could be used to identify the patient. This includes but is not limited to patient name, address, telephone number, and social security number; prescriber name and address; and prescription and drug or device information such as therapeutic effect, diagnosis, allergies, disease state, pharmaceutical services rendered, medical information, and drug interactions, regardless of whether such information is communicated to or from the patient, is in the form of paper, is preserved on microfilm, or is stored on electronic media.

8.16(2) *Release of confidential information.* Confidential information in the patient record may be released only as follows:

a. Pursuant to the express written authorization of the patient or the order or direction of a court.

b. To the patient or the patient's authorized representative.

c. To the prescriber or other licensed practitioner then caring for the patient.

d. To another licensed pharmacist when the best interests of the patient require such release.

e. To the board or its representative or to such other persons or governmental agencies duly authorized by law to receive such information.

A pharmacist shall utilize the resources available to determine, in the professional judgment of the pharmacist, that any persons requesting confidential patient information pursuant to this rule are entitled to receive that information.

8.16(3) *Exceptions.* Nothing in this rule shall prohibit pharmacists from releasing confidential patient information as follows:

a. Transferring a prescription to another pharmacy upon the request of the patient or the patient's authorized representative.

b. Providing a copy of a nonrefillable prescription to the person for whom the prescription was issued which is clearly marked as a copy and not to be filled.

c. Providing drug therapy information to physicians or other authorized prescribers for their patients.

d. Disclosing information necessary for the processing of claims for payment of health care operations or services.

8.16(4) *System security and safeguards.* To maintain the integrity and confidentiality of patient records and prescription drug orders, any system or computer utilized shall have adequate security including system safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records and prescription drug orders.

8.16(5) *Record disposal.* Disposal of any materials containing or including patient-specific or confidential information shall be conducted in a manner to preserve patient confidentiality.

657—8.17 and **8.18** Reserved.

657—8.19(124,126,155A) Manner of issuance of a prescription drug or medication order. A prescription drug order or medication order may be transmitted from a prescriber to a pharmacy in written form, orally including telephone voice communication, or by electronic transmission in accordance with applicable federal and state laws and rules. Any prescription drug order or medication order provided to a patient in written or printed form shall include the original, handwritten signature of the prescriber except as provided in rule 657—21.7(124,155A).

8.19(1) *Verification.* The pharmacist shall exercise professional judgment regarding the accuracy, validity, and authenticity of any prescription drug order or medication order consistent with federal and state laws and rules. In exercising professional judgment, the prescribing practitioner and the pharmacist shall take adequate measures to guard against the diversion of prescription drugs and controlled substances through prescription forgeries.

8.19(2) *Transmitting agent.* The prescribing practitioner may authorize an agent to transmit to the pharmacy a prescription drug order or medication order orally or by electronic transmission provided that the name of the transmitting agent is included in the order.

a. New order. A new written or electronically prepared and transmitted prescription drug or medication order shall be manually or electronically signed by the prescriber. If transmitted by the prescriber's agent, the name and title of the transmitting agent shall be included in the order.

b. Refill order or renewal order. An authorization to refill a prescription drug or medication order, or to renew or continue an existing drug therapy, may be transmitted to a pharmacist through oral communication, in writing, or by electronic transmission initiated by or directed by the prescriber.

(1) If the transmission is completed by the prescriber's agent and the name and title of the transmitting agent is included in the order, the prescriber's signature is not required on the fax or alternate electronic transmission.

(2) If the order differs in any manner from the original order, such as a change of the drug strength, dosage form, or directions for use, the prescriber shall sign the order as provided by paragraph *"a."*

8.19(3) *Receiving agent.* Regardless of the means of transmission to a pharmacy, only a pharmacist, a pharmacist-intern, or a pharmacy technician shall be authorized to receive a prescription drug or medication order from a practitioner or the practitioner's agent.

8.19(4) *Legitimate purpose.* The pharmacist shall ensure that the prescription drug or medication order, regardless of the means of transmission, has been issued for a legitimate medical purpose by an

authorized practitioner acting in the usual course of the practitioner's professional practice. A pharmacist shall not dispense a prescription drug if the pharmacist knows or should have known that the prescription was issued solely on the basis of an Internet-based questionnaire, an Internet-based consultation, or a telephonic consultation and without a valid preexisting patient-practitioner relationship.

8.19(5) *Refills.* A prescription for a prescription drug or device that is not a controlled substance may authorize no more than 12 refills within 18 months following the date on which the prescription is issued. A refill is one or more dispensings of a prescription drug or device that results in the patient's receipt of the quantity authorized by the prescriber for a single fill as indicated on the prescription drug order.

[**ARC 8171B**, IAB 9/23/09, effective 10/28/09]

657—8.20(155A) Valid prescriber/patient relationship. Prescription drug orders and medication orders shall be valid as long as a prescriber/patient relationship exists. Once the prescriber/patient relationship is broken and the prescriber is no longer available to treat the patient or oversee the patient's use of a prescription drug, the order loses its validity and the pharmacist, on becoming aware of the situation, shall cancel the order and any remaining refills. The pharmacist shall, however, exercise prudent judgment based upon individual circumstances to ensure that the patient is able to obtain a sufficient amount of the prescribed drug to continue treatment until the patient can reasonably obtain the service of another prescriber and a new order can be issued.

657—8.21(155A) Prospective drug use review. For purposes of promoting therapeutic appropriateness and ensuring rational drug therapy, a pharmacist shall review the patient record, information obtained from the patient, and each prescription drug or medication order to identify:

1. Overutilization or underutilization;
2. Therapeutic duplication;
3. Drug-disease contraindications;
4. Drug-drug interactions;
5. Incorrect drug dosage or duration of drug treatment;
6. Drug-allergy interactions;
7. Clinical abuse/misuse;
8. Drug-prescriber contraindications.

Upon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the problem and shall, if necessary, include consultation with the prescriber. The review and assessment of patient records shall not be delegated to staff assistants but may be delegated to registered pharmacist-interns under the direct supervision of the pharmacist.

657—8.22 to **8.25** Reserved.

657—8.26(155A) Continuous quality improvement program. Each pharmacy licensed to provide pharmaceutical services to patients in Iowa shall implement or participate in a continuous quality improvement program or CQI program. The CQI program is intended to be an ongoing, systematic program of standards and procedures to detect, identify, evaluate, and prevent medication errors, thereby improving medication therapy and the quality of patient care. A pharmacy that participates as an active member of a hospital or corporate CQI program that meets the objectives of this rule shall not be required to implement a new program pursuant to this rule.

8.26(1) *Reportable program events.* For purposes of this rule, a reportable program event or program event means a preventable medication error resulting in the incorrect dispensing of a prescribed drug received by or administered to the patient and includes but is not necessarily limited to:

a. An incorrect drug;
b. An incorrect drug strength;
c. An incorrect dosage form;
d. A drug received by the wrong patient;
e. Inadequate or incorrect packaging, labeling, or directions; or

f. Any incident related to a prescription dispensed to a patient that results in or has the potential to result in serious harm to the patient.

8.26(2) *Responsibility.* The pharmacist in charge is responsible for ensuring that the pharmacy utilizes a CQI program consistent with the requirements of this rule. The pharmacist in charge may delegate program administration and monitoring, but the pharmacist in charge maintains ultimate responsibility for the validity and consistency of program activities.

8.26(3) *Policies and procedures.* Each pharmacy shall develop, implement, and adhere to written policies and procedures for the operation and management of the pharmacy's CQI program. A copy of the pharmacy's CQI program description and policies and procedures shall be maintained and readily available to all pharmacy personnel. The policies and procedures shall address, at a minimum, a planned process to:

a. Train all pharmacy personnel in relevant phases of the CQI program;

b. Identify and document reportable program events;

c. Minimize the impact of reportable program events on patients;

d. Analyze data collected to assess the causes and any contributing factors relating to reportable program events;

e. Use the findings to formulate an appropriate response and to develop pharmacy systems and workflow processes designed to prevent and reduce reportable program events; and

f. Periodically, but at least annually, meet with appropriate pharmacy personnel to review findings and inform personnel of changes that have been made to pharmacy policies, procedures, systems, or processes as a result of CQI program findings.

8.26(4) *Event discovery and notification.* As provided by the procedures of the CQI program, the pharmacist in charge or appropriate designee shall be informed of and review all reported and documented program events. All pharmacy personnel shall be trained to immediately inform the pharmacist on duty of any discovered or suspected program event. When the pharmacist on duty determines that a reportable program event has occurred, the pharmacist shall ensure that all reasonably necessary steps are taken to remedy any problems or potential problems for the patient and that those steps are documented. Necessary steps include, but are not limited to, the following:

a. Notifying the patient or the patient's caregiver and the prescriber or other members of the patient's health care team as warranted;

b. Identifying and communicating directions or processes for correcting the error; and

c. Communicating instructions for minimizing any negative impact on the patient.

8.26(5) *CQI program records.* All CQI program records shall be maintained on site at the pharmacy or shall be accessible at the pharmacy and be available for inspection and copying by the board or its representative for at least two years from the date of the record. When a reportable program event occurs or is suspected to have occurred, the program event shall be documented in a written or electronic storage record created solely for that purpose. Records of program events shall be maintained in an orderly manner and shall be filed chronologically by date of discovery.

a. The program event shall initially be documented as soon as practicable by the staff member who discovers the event or is informed of the event.

b. Program event documentation shall include a description of the event that provides sufficient information to permit categorization and analysis of the event and shall include:

(1) The date and time the program event was discovered and the name of the staff person who discovered the event; and

(2) The names of the individuals recording and reviewing or analyzing the program event information.

8.26(6) *Program event analysis and response.* The pharmacist in charge or designee shall review each reportable program event and determine if follow-up is necessary. When appropriate, information and data collected and documented shall be analyzed, individually and collectively, to assess the cause and any factors contributing to the program event. The analysis may include, but is not limited to, the following:

a. A consideration of the effects on the quality of the pharmacy system related to workflow processes, technology utilization and support, personnel training, and both professional and technical staffing levels;

b. Any recommendations for remedial changes to pharmacy policies, procedures, systems, or processes; and

c. The development of a set of indicators that a pharmacy will utilize to measure its program standards over a designated period of time.

657—8.27 to **8.29** Reserved.

657—8.30(126,155A) Sterile products. Rescinded IAB 6/6/07, effective 7/11/07.

657—8.31 Reserved.

657—8.32(124,155A) Individuals qualified to administer. The board designates the following as qualified individuals to whom a practitioner may delegate the administration of prescription drugs. Any person specifically authorized under pertinent sections of the Iowa Code to administer prescription drugs shall construe nothing in this rule to limit that authority.

1. Persons who have successfully completed a medication administration course.
2. Licensed pharmacists.

657—8.33(147,155A) Supervision of pharmacists who administer adult immunizations. A physician may prescribe via written protocol adult immunizations for influenza and pneumococcal vaccines for administration by an authorized pharmacist if the physician meets these requirements for supervising the pharmacist.

8.33(1) *Definitions.*

a. *"Authorized pharmacist"* means an Iowa-licensed pharmacist who has documented that the pharmacist has successfully completed an organized course of study in a college or school of pharmacy or an Accreditation Council for Pharmacy Education (ACPE)-approved continuing pharmaceutical education program on vaccine administration that:

(1) Requires documentation by the pharmacist of current certification in the American Heart Association or the Red Cross Basic Cardiac Life Support Protocol for health care providers;

(2) Is an evidence-based course that includes study material and hands-on training and techniques for administering vaccines, requires testing with a passing score, complies with current Centers for Disease Control and Prevention guidelines, and provides instruction and experiential training in the following content areas:

1. Standards for immunization practices;
2. Basic immunology and vaccine protection;
3. Vaccine-preventable diseases;
4. Recommended immunization schedules;
5. Vaccine storage and management;
6. Informed consent;
7. Physiology and techniques for vaccine administration;
8. Pre- and post-vaccine assessment and counseling;
9. Immunization record management; and
10. Management of adverse events, including identification, appropriate response, documentation, and reporting.

b. *"Vaccine"* means a specially prepared antigen which, upon administration to a person, will result in immunity and, specifically for the purposes of this rule, shall mean influenza and pneumococcal vaccines.

c. *"Written protocol"* means a physician's order for one or more patients that contains, at a minimum, the following:

(1) A statement identifying the individual physician authorized to prescribe drugs and responsible for the delegation of administration of adult immunizations for influenza and pneumococcus;

(2) A statement identifying the individual authorized pharmacist;

(3) A statement that forbids an authorized pharmacist from delegating the administration of adult immunizations to anyone other than another authorized pharmacist, a registered pharmacist-intern under the direct personal supervision of the authorized pharmacist, or a registered nurse;

(4) A statement identifying the vaccines that may be administered by an authorized pharmacist, the dosages, and the route of administration;

(5) A statement identifying the activities an authorized pharmacist shall follow in the course of administering adult immunizations, including:

1. Procedures for determining if a patient is eligible to receive the vaccine;

2. Procedures for determining the appropriate scheduling and frequency of drug administration in accordance with applicable guidelines;

3. Procedures for record keeping and long-term record storage including batch or identification numbers;

4. Procedures to follow in case of life-threatening reactions; and

5. Procedures for the pharmacist and patient to follow in case of reactions following administration.

(6) A statement that describes how the authorized pharmacist shall report the administration of adult immunizations, within 30 days, to the physician issuing the written protocols and to the patient's primary care physician if one has been designated by the patient. In case of serious complications, the authorized pharmacist shall notify the physicians within 24 hours and submit a VAERS report to the bureau of immunizations, Iowa department of public health. (VAERS is the Vaccine Advisory Event Reporting System.) A serious complication is one that requires further medical or therapeutic intervention to effectively protect the patient from further risk, morbidity, or mortality.

8.33(2) *Supervision.* A physician who prescribes adult immunizations to an authorized pharmacist for administration shall adequately supervise that pharmacist. Physician supervision shall be considered adequate if the delegating physician:

a. Ensures that the authorized pharmacist is prepared as described in subrule 8.33(1), paragraph *"a"*;

b. Provides a written protocol that is updated at least annually;

c. Is available through direct telecommunication for consultation, assistance, and direction, or provides physician backup to provide these services when the physician supervisor is not available;

d. Is an Iowa-licensed physician who has a working relationship with an authorized pharmacist within the physician's local provider service area.

8.33(3) *Administration of other adult immunizations by pharmacists.* A physician may prescribe, for an individual patient by prescription or medication order, other adult immunizations to be administered by an authorized pharmacist.

This rule is intended to implement Iowa Code sections 147.76, 155A.3, 155A.4, and 272C.3.

657—8.34(155A) Collaborative drug therapy management. An authorized pharmacist may only perform collaborative drug therapy management pursuant to protocol with a physician pursuant to the requirements of this rule. The physician retains the ultimate responsibility for the care of the patient. The pharmacist is responsible for all aspects of drug therapy management performed by the pharmacist.

8.34(1) *Definitions.*

"Authorized pharmacist" means an Iowa-licensed pharmacist whose license is in good standing and who meets the drug therapy management criteria defined in this rule.

"Board" means the board of pharmacy.

"Collaborative drug therapy management" means participation by an authorized pharmacist and a physician in the management of drug therapy pursuant to a written community practice protocol or a written hospital practice protocol.

"Collaborative practice" means that a physician may delegate aspects of drug therapy management for the physician's patients to an authorized pharmacist through a community practice protocol. "Collaborative practice" also means that a P&T committee may authorize hospital pharmacists to perform drug therapy management for inpatients and hospital clinic patients through a hospital practice protocol.

"Community practice protocol" means a written, executed agreement entered into voluntarily between an authorized pharmacist and a physician establishing drug therapy management for one or more of the pharmacist's and physician's patients residing in a community setting. A community practice protocol shall comply with the requirements of subrule 8.34(2).

"Community setting" means a location outside a hospital inpatient, acute care setting or a hospital clinic setting. A community setting may include, but is not limited to, a home, group home, assisted living facility, correctional facility, hospice, or long-term care facility.

"Drug therapy management criteria" means one or more of the following:

1. Graduation from a recognized school or college of pharmacy with a doctor of pharmacy (Pharm.D.) degree;
2. Certification by the Board of Pharmaceutical Specialties (BPS);
3. Certification by the Commission for Certification in Geriatric Pharmacy (CCGP);
4. Successful completion of a National Institute for Standards in Pharmacist Credentialing (NISPC) disease state management examination and credentialing by the NISPC;
5. Successful completion of a pharmacy residency program accredited by the American Society of Health-System Pharmacists (ASHP); or
6. Approval by the board of pharmacy.

"Hospital clinic" means an outpatient care clinic operated and affiliated with a hospital and under the direct authority of the hospital's P&T committee.

"Hospital pharmacist" means an Iowa-licensed pharmacist who meets the requirements for participating in a hospital practice protocol as determined by the hospital's P&T committee.

"Hospital practice protocol" means a written plan, policy, procedure, or agreement that authorizes drug therapy management between hospital pharmacists and physicians within a hospital and the hospital's clinics as developed and determined by the hospital's P&T committee. Such a protocol may apply to all pharmacists and physicians at a hospital or the hospital's clinics or only to those pharmacists and physicians who are specifically recognized. A hospital practice protocol shall comply with the requirements of subrule 8.34(3).

"IBM" means the Iowa board of medicine.

"P&T committee" means a committee of the hospital composed of physicians, pharmacists, and other health professionals that evaluates the clinical use of drugs within the hospital, develops policies for managing drug use and administration in the hospital, and manages the hospital drug formulary system.

"Physician" means a person who is currently licensed in Iowa to practice medicine and surgery, osteopathic medicine and surgery, or osteopathy. A physician who executes a written protocol with an authorized pharmacist shall supervise the pharmacist's activities involved in the overall management of patients receiving medications or disease management services under the protocol. The physician may delegate only drug therapies that are in areas common to the physician's practice.

"Therapeutic interchange" means an authorized exchange of therapeutic alternate drug products in accordance with a previously established and approved written protocol.

8.34(2) *Community practice protocol.*

a. An authorized pharmacist shall engage in collaborative drug therapy management with a physician only under a written protocol that has been identified by topic and has been submitted to the board or a committee authorized by the board. A protocol executed after July 1, 2008, will no longer be required to be submitted to the board; however, written protocols executed or renewed after July 1, 2008, shall be made available upon request of the board or the IBM.

b. The community practice protocol shall include:

(1) The name, signature, date, and contact information for each authorized pharmacist who is a party to the protocol and is eligible to manage the drug therapy of a patient. If more than one authorized

pharmacist is a party to the agreement, the pharmacists shall work for a single licensed pharmacy and a principal authorized pharmacist shall be designated in the protocol.

(2) The name, signature, date, and contact information for each physician who may prescribe drugs and is responsible for supervising a patient's drug therapy management. The physician who initiates a protocol shall be considered the main caregiver for the patient respective to that protocol and shall be noted in the protocol as the principal physician.

(3) The name and contact information of the principal physician and the principal authorized pharmacist who are responsible for development, training, administration, and quality assurance of the protocol.

(4) A detailed written protocol pursuant to which the authorized pharmacist will base drug therapy management decisions for patients. The protocol shall authorize one or more of the following:

1. Prescription drug orders. The protocol may authorize therapeutic interchange or modification of drug dosages based on symptoms or laboratory or physical findings defined in the protocol. The protocol shall include information specific to the dosage, frequency, duration, and route of administration of the drug authorized by the patient's physician. The protocol shall not authorize the pharmacist to change a Schedule II drug or to initiate a drug not included in the established protocol.

2. Laboratory tests. The protocol may authorize the pharmacist to obtain or to conduct specific laboratory tests as long as the tests relate directly to the drug therapy management.

3. Physical findings. The protocol may authorize the pharmacist to check certain physical findings, e.g., vital signs, oximetry, or peak flows, that enable the pharmacist to assess and adjust the drug therapy, detect adverse drug reactions, or determine if the patient should be referred back to the patient's physician for follow-up.

4. Patient activities. The protocol may authorize the pharmacist to monitor specific patient activities.

(5) Procedures for securing the patient's written consent. If the patient's consent is not secured by the physician, the authorized pharmacist shall secure such and notify the patient's physician within 24 hours.

(6) Circumstances that shall cause the authorized pharmacist to initiate communication with the physician including but not limited to the need for new prescription orders and reports of the patient's therapeutic response or adverse reaction.

(7) A detailed statement identifying the specific drugs, laboratory tests, and physical findings upon which the authorized pharmacist shall base drug therapy management decisions.

(8) A provision for the collaborative drug therapy management protocol to be reviewed, updated, and reexecuted or discontinued at least every two years.

(9) A description of the method the pharmacist shall use to document the pharmacist's decisions or recommendations for the physician.

(10) A description of the types of reports the authorized pharmacist is to provide to the physician and the schedule by which the pharmacist is to submit these reports. The schedule shall include a time frame within which a pharmacist shall report any adverse reaction to the physician.

(11) A statement of the medication categories and the type of initiation and modification of drug therapy that the physician authorizes the pharmacist to perform.

(12) A description of the procedures or plan that the pharmacist shall follow if the pharmacist modifies a drug therapy.

(13) Procedures for record keeping, record sharing, and long-term record storage.

(14) Procedures to follow in emergency situations.

(15) A statement that prohibits the authorized pharmacist from delegating drug therapy management to anyone other than another authorized pharmacist who has signed the applicable protocol.

(16) A statement that prohibits a physician from delegating collaborative drug therapy management to any unlicensed or licensed person other than another physician or an authorized pharmacist.

(17) A description of the mechanism for the pharmacist and the physician to communicate with each other and for documentation by the pharmacist of the implementation of collaborative drug therapy.

c. Collaborative drug therapy management is valid only when initiated by a written protocol executed by at least one authorized pharmacist and at least one physician.

d. The collaborative drug therapy protocol must be filed with the board, kept on file in the pharmacy, and be made available upon request of the board or the IBM. After July 1, 2008, protocols shall no longer be filed with the board but shall be maintained in the pharmacy and made available to the board and the IBM upon request.

e. A physician may terminate or amend the collaborative drug therapy management protocol with an authorized pharmacist if the physician notifies, in writing, the pharmacist and the board. Notification shall include the name of the authorized pharmacist, the desired change, and the proposed effective date of the change. After July 1, 2008, the physician shall no longer be required to notify the board of changes in a protocol but the written notification shall be maintained in the pharmacy and made available upon request of the board or the IBM.

f. The physician or pharmacist who initiates a protocol with a patient is responsible for securing a patient's written consent to participate in drug therapy management and for transmitting a copy of the consent to the other party within 24 hours. The consent shall indicate which protocol is involved. Any variation in the protocol for a specific patient shall be communicated to the other party at the time of securing the patient's consent. The patient's physician shall maintain the patient consent in the patient's medical record.

8.34(3) *Hospital practice protocol.*

a. A hospital's P&T committee shall determine the scope and extent of collaborative drug therapy management practices that may be conducted by the hospital's pharmacists.

b. Collaborative drug therapy management within a hospital setting or the hospital's clinic setting is valid only when approved by the hospital's P&T committee.

c. The hospital practice protocol shall include:

(1) The names or groups of pharmacists and physicians who are authorized by the P&T committee to participate in collaborative drug therapy management.

(2) A plan for development, training, administration, and quality assurance of the protocol.

(3) A detailed written protocol pursuant to which the hospital pharmacist shall base drug therapy management decisions for patients. The protocol shall authorize one or more of the following:

1. Medication orders and prescription drug orders. The protocol may authorize therapeutic interchange or modification of drug dosages based on symptoms or laboratory or physical findings defined in the protocol. The protocol shall include information specific to the dosage, frequency, duration, and route of administration of the drug authorized by the physician. The protocol shall not authorize the hospital pharmacist to change a Schedule II drug or to initiate a drug not included in the established protocol.

2. Laboratory tests. The protocol may authorize the hospital pharmacist to obtain or to conduct specific laboratory tests as long as the tests relate directly to the drug therapy management.

3. Physical findings. The protocol may authorize the hospital pharmacist to check certain physical findings, e.g., vital signs, oximetry, or peak flows, that enable the pharmacist to assess and adjust the drug therapy, detect adverse drug reactions, or determine if the patient should be referred back to the physician for follow-up.

(4) Circumstances that shall cause the hospital pharmacist to initiate communication with the patient's physician including but not limited to the need for new medication orders and prescription drug orders and reports of a patient's therapeutic response or adverse reaction.

(5) A statement of the medication categories and the type of initiation and modification of drug therapy that the P&T committee authorizes the hospital pharmacist to perform.

(6) A description of the procedures or plan that the hospital pharmacist shall follow if the hospital pharmacist modifies a drug therapy.

(7) A description of the mechanism for the hospital pharmacist and the patient's physician to communicate and for the hospital pharmacist to document implementation of the collaborative drug therapy.

657—8.35(155A) Pharmacy license. A pharmacy license issued by the board is required for all sites where prescription drugs are offered for sale or dispensed under the supervision of a pharmacist. A pharmacy license issued by the board is also required for all sites where drug information or other cognitive pharmacy services, including but not limited to drug use review and patient counseling, are provided by a pharmacist. The board may issue any of the following types of pharmacy licenses: a general pharmacy license, a hospital pharmacy license, a special or limited use pharmacy license, or a nonresident pharmacy license. Nonresident pharmacy license applicants shall comply with board rules regarding nonresident pharmacy practice except when specific exemptions have been granted. Applicants for general or hospital pharmacy practice shall comply with board rules regarding general or hospital pharmacy practice except when specific exemptions have been granted. Any pharmacy located within Iowa that dispenses controlled substances must also register pursuant to 657—Chapter 10.

8.35(1) *Exemptions.* Applicants who are granted exemptions shall be issued a "general pharmacy license with exemption," a "hospital pharmacy license with exemption," a "nonresident pharmacy license with exemption," or a "limited use pharmacy license with exemption" and shall comply with the provisions set forth by that exemption. A written petition for exemption from certain licensure requirements shall be submitted pursuant to the procedures and requirements of 657—Chapter 34 and will be determined on a case-by-case basis.

8.35(2) *Limited use pharmacy license.* Limited use pharmacy license may be issued for nuclear pharmacy practice, correctional facility pharmacy practice, and veterinary pharmacy practice. Applications for limited use pharmacy license for these and other limited use practice settings shall be determined on a case-by-case basis.

8.35(3) *Application form.* Application for licensure and license renewal shall be on forms provided by the board. The application for a pharmacy license shall require an indication of the pharmacy ownership classification. If the owner is a sole proprietorship (100 percent ownership), the name and address of the owner shall be indicated. If the owner is a partnership or limited partnership, the names and addresses of all partners shall be listed or attached. If the owner is a corporation, the names and addresses of the officers and directors of the corporation shall be listed or attached. Any other pharmacy ownership classification shall be further identified and explained on the application. The application form shall require the name, signature, and license number of the pharmacist in charge. The names and license numbers of all pharmacists engaged in practice in the pharmacy, the names and registration numbers of all pharmacy technicians and pharmacy support persons working in the pharmacy, and the average number of hours worked by each pharmacist, pharmacy technician, and pharmacy support person shall be listed or attached. Additional information may be required of specific types of pharmacy license applicants. The application shall be signed by the pharmacy owner or the owner's, partnership's, or corporation's authorized representative.

8.35(4) *License expiration and renewal.* General pharmacy licenses, hospital pharmacy licenses, special or limited use pharmacy licenses, and nonresident pharmacy licenses shall be renewed before January 1 of each year. The fee for a new or renewal license shall be $150.

a. Late payment penalty. Failure to renew the pharmacy license before January 1 following expiration shall require payment of the renewal fee and a penalty fee of $150. Failure to renew the license before February 1 following expiration shall require payment of the renewal fee and a penalty fee of $250. Failure to renew the license before March 1 following expiration shall require payment of the renewal fee and a penalty fee of $350. Failure to renew the license before April 1 following expiration shall require payment of the renewal fee and a penalty fee of $450 and may require an appearance before the board. In no event shall the combined renewal fee and penalty fee for late renewal of a pharmacy license exceed $600.

b. Delinquent license. If a license is not renewed before its expiration date, the license is delinquent and the licensee may not operate or provide pharmacy services to patients in the state of Iowa until the licensee renews the delinquent license. A pharmacy that continues to operate in Iowa without a current license may be subject to disciplinary sanctions pursuant to the provisions of 657—subrule 36.1(4).

8.35(5) *Inspection of new pharmacy location.* If the new pharmacy location within Iowa was not a licensed pharmacy immediately prior to the proposed opening of the new pharmacy, the pharmacy location shall require an on-site inspection by a pharmacy board inspector prior to the issuance of the pharmacy license. The purpose of the inspection is to determine compliance with requirements pertaining to space, library, equipment, security, temperature control, and drug storage safeguards. Inspection may be scheduled anytime following submission of necessary license and registration applications and prior to opening for business as a pharmacy. Prescription drugs, including controlled substances, may not be delivered to a new pharmacy location prior to satisfactory completion of the opening inspection.

8.35(6) *Pharmacy license changes.* When a pharmacy changes its name, location, ownership, or pharmacist in charge, a new pharmacy license application with a license fee as provided in subrule 8.35(4) shall be submitted to the board office. Upon receipt of the fee and properly completed application, the board will issue a new pharmacy license certificate. The old license certificate shall be returned to the board office within ten days of the change of name, location, ownership, or pharmacist in charge.

a. A change of pharmacy location in Iowa shall require an on-site inspection of the new location as provided in subrule 8.35(5) if the new location was not a licensed pharmacy immediately prior to the relocation.

b. A change of ownership of a currently licensed Iowa pharmacy, or a change of pharmacy location to another existing Iowa pharmacy location, shall not require on-site inspection pursuant to subrule 8.35(5). A new pharmacy license is required as provided above. In those cases in which the pharmacy is owned by a corporation, the sale or transfer of all stock of the corporation does not constitute a change of ownership provided the corporation that owns the pharmacy continues to exist following the stock sale or transfer.

c. A change of pharmacist in charge shall require completion and submission of the application and fee for new pharmacy license . If a permanent pharmacist in charge has not been identified by the time of the vacancy, a temporary pharmacist in charge shall be identified. Written notification identifying the temporary pharmacist in charge, signed by the pharmacy owner or corporate officer and the temporary pharmacist in charge, shall be submitted to the board within 10 days following the vacancy. Within 90 days following the vacancy, a permanent pharmacist in charge shall be identified, and an application for pharmacy license, including the license fee as provided in subrule 8.35(4), shall be submitted to the board office.

8.35(7) *Pharmacy closing.* At least two weeks prior to the closing of a pharmacy, a written notice shall be sent to the board and to the Drug Enforcement Administration (DEA) notifying those agencies of the intent to discontinue business or sell the pharmacy including the anticipated date of sale or closing.

a. Prior notification shall include the name, address, DEA registration number, Iowa pharmacy license number, and Iowa controlled substances Act (CSA) registration number of the closing pharmacy and of the pharmacy to which prescription drugs will be transferred. Notification shall also include the name, address, DEA registration number, Iowa pharmacy license number, and CSA registration number of the location at which prescription files, patient profiles, and controlled substance receipt and disbursement records will be maintained.

b. Pharmacy patients with active prescriptions on file with a pharmacy that intends to close permanently shall be notified by that pharmacy, via direct mail or public notice at least two weeks prior to the closure of the pharmacy, that each patient has the right to transfer the patient's active prescriptions to a pharmacy of the patient's choosing. This paragraph shall not apply in the case of an emergency or unforeseeable closure including, but not limited to, emergency board action, foreclosure, fire, or natural disaster.

c. A complete inventory of all prescription drugs being transferred shall be taken as of the close of business. The inventory shall serve as the ending inventory for the closing pharmacy as well as a record of additional or starting inventory for the pharmacy to which the drugs are transferred. A copy of the inventory shall be included in the records of each licensee.

(1) DEA Form 222 is required for transfer of Schedule II controlled substances.

(2) The inventory of controlled substances shall be completed pursuant to the requirements in 657—10.35(124,155A).

(3) The inventory of all noncontrolled prescription drugs may be estimated.

(4) The inventory shall include the name, strength, dosage form, and quantity of all prescription drugs transferred.

(5) Controlled substances requiring destruction or other disposal shall be transferred in the same manner as all other drugs. The new owner is responsible for the disposal of these substances as provided in rule 657—10.18(124).

d. The license certificate and CSA certificate of the closing or selling pharmacy shall be returned to the board office within ten days of closing or sale. The DEA registration certificate and all unused DEA Forms 222 shall be returned to the DEA.

e. A location that no longer houses a licensed pharmacy shall not display any sign, placard, or other notification, visible to the public, which identifies the location as a pharmacy. A sign or other public notification that cannot feasibly be removed shall be covered so as to conceal the identification as a pharmacy.

8.35(8) *Failure to complete licensure.* An application for a pharmacy license, including an application for registration pursuant to 657—Chapter 10, if applicable, will become null and void if the applicant fails to complete the licensure process within six months of receipt by the board of the required applications. The licensure process shall be complete upon the pharmacy's opening for business at the licensed location following an inspection rated as satisfactory by an agent of the board if such an inspection is required pursuant to this rule. When an applicant fails to timely complete the licensure process, fees submitted with applications will not be transferred or refunded.

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◊ Two or more ARCs

CHAPTER 14
PUBLIC INFORMATION AND INSPECTION OF RECORDS

657—14.1(22,124,155A) Definitions. As used in this chapter:

"Board" means the Iowa board of pharmacy examiners.

"Confidential record" means a record which is not available as a matter of right for examination and copying by members of the public under applicable provisions of law. Confidential records include records or information contained in records that the board is prohibited by law from making available for examination by members of the public, and records or information contained in records that are specified as confidential by Iowa Code section 22.7 or other provision of law, but that may be disclosed upon order of a court, order of the lawful custodian of the record, or order of another person duly authorized to release the record. Mere inclusion in a record of information declared confidential by an applicable provision of law does not necessarily make that entire record a confidential record.

"Custodian" means the executive secretary/director of the board.

"Open record" means a record other than a confidential record.

"Personally identifiable information" means information about or pertaining to an individual or business entity in a record which identifies the individual or entity and which is contained in a record system.

"Record" means the whole or a part of a "public record," as defined in Iowa Code section 22.1, that is owned by or in the physical possession of the board.

"Record system" means any group of records under the control of the board from which a record may be retrieved by a personal identifier such as the name of an individual or business entity, number, symbol, or other unique retriever assigned to an individual or business entity.

657—14.2(22,124,155A) Purpose and scope. The purpose of this chapter is to facilitate broad public access to open records. It seeks to facilitate rational board determinations with respect to the handling of confidential records and the implementation of the fair information practices Act. Board staff shall cooperate with members of the public in implementing the provisions of this chapter.

This chapter does not:

1. Require the board to index or retrieve records that contain information about individuals by that person's name or other personal identifier.
2. Make available to the general public records that would otherwise not be available under Iowa Code chapter 22.
3. Govern the maintenance or disclosure of, notification of or access to records in the possession of the board that are governed by rules of another board or agency.
4. Apply to grantees, including local governments or subdivisions, administering state-funded programs, unless otherwise provided by law or agreement.
5. Make available records compiled by the board in reasonable anticipation of court litigation or formal administrative proceedings. Applicable legal and constitutional principles, statutes, rules of discovery, evidentiary privileges, and rules of the board shall govern the availability of the records to the general public or to any subject individual or party to litigation or proceedings.

657—14.3(22,124,155A) Requests for access to records.

14.3(1) *Location of record.* A request for access to a record should be directed to Executive Secretary/Director, Iowa Board of Pharmacy Examiners, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688.

14.3(2) *Office hours.* Open records shall be made available during all customary office hours, which are 8 a.m. to 4:30 p.m. daily, excluding Saturdays, Sundays, and official state holidays.

14.3(3) *Request for access.* Requests for access to open records shall be made in writing. Requests shall identify the particular records sought, by name or description, in order to facilitate determining the location of the record. All requests shall include the name, address, and telephone number of the person requesting the information.

14.3(4) *Response to requests.* Access to an open record shall be provided in a timely manner upon request. If the size or nature of the request for access to an open record requires time for processing, the custodian shall comply with the request as soon as feasible. Access to an open record may be delayed for one of the purposes authorized by Iowa Code section 22.8(4) or 22.10(4). The custodian shall promptly give notice to the requester of the reason for any delay in access to an open record and an estimate of the length of that delay and, upon request, shall promptly provide that notice to the requester in writing.

The custodian of a record may deny access to the record by members of the public only on the grounds that such a denial is warranted under Iowa Code section 22.8(4) or 22.10(4), or that it is a confidential record, or that its disclosure is prohibited by a court order. Access by members of the public to a confidential record is limited by law and, therefore, may generally be provided only in accordance with the provisions of rule 657—14.4(22,124,155A) and other applicable provisions of law.

14.3(5) *Security of record.* No unauthorized person may search or remove any record from board files. The custodian or a designee of the custodian shall supervise examination and copying of board records. The integrity of board records shall not be compromised during such examination or handling.

14.3(6) *Copying.* A reasonable number of copies of an open record may be made in the board office.

14.3(7) *Fees.*

a. Copying and postage costs. Price schedules for published materials and for photocopies of records supplied by the board shall be prominently posted in the board office. Copies of records may be made by or for members of the public on board photocopy machines or from electronic storage systems at cost as determined by the custodian and posted in the board office. When the mailing of copies of records is requested, the costs of such mailing may also be charged to the requester.

b. Supervisory and retrieval fees. An hourly fee may be charged for board expenses in supervising the examination of and for the copying of requested records, or for the search and retrieval of such records, when the time required exceeds 15 minutes. The custodian shall prominently post in the board office the hourly fees to be assessed. Hourly fees shall not be in excess of the compensation rate of a board employee who ordinarily would be appropriate and suitable to perform the function.

c. Advance payments. The custodian may require payment of assessed or estimated fees before the custodian processes a request.

657—14.4(22,124,155A) Access to confidential records. Under Iowa Code section 22.7 or other applicable provisions of law, the lawful custodian may disclose certain confidential records to one or more members of the public. Other provisions of law authorize or require the custodian to release specified confidential records under certain circumstances or to particular persons. In requesting the custodian to permit the examination and copying of such a confidential record, the following procedures apply and are in addition to those specified for requests for access to records in rule 657—14.3(22,124,155A).

14.4(1) *Proof of identity.* A person requesting access to a confidential record shall be required to provide proof of identity or authority to secure access to the record.

14.4(2) *Requests.* The custodian shall require that a request to examine and copy a confidential record be in writing. A person requesting access to such a record shall be required to sign a certified statement or affidavit enumerating the specific reasons justifying access to the confidential record and to provide any proof necessary to establish relevant facts.

14.4(3) *Notice to subject of record and opportunity to obtain injunction.* If the custodian receives a request for access to a confidential record, the custodian may make reasonable efforts to notify any person who is the subject of the record, who is identified in the record, or whose address or telephone number is contained in the record about the request. If it is practicable and in the public interest to delay releasing the information, the custodian may, before releasing the record, give the notified persons an opportunity to seek a court order under Iowa Code section 22.8 or other applicable provision of law prohibiting the custodian from releasing the confidential information. If the custodian gives a notified person this opportunity, the custodian shall give the notified person a specific deadline to obtain a court order prohibiting release of the confidential information and shall not release the confidential information during that time. If the deadline passes and the notified person has not obtained a court order prohibiting

the custodian from releasing the confidential information, the custodian shall release the information to the requester.

14.4(4) *Request denied.* When the custodian denies a request for access to a confidential record, the custodian shall promptly notify the requester. If the requester indicates to the custodian that a written notification of the denial is desired, the custodian shall promptly provide such a notification. Written notification shall be signed by the custodian and shall include:

a. The name and title of the custodian responsible for the denial;

b. A citation to the provision of law vesting authority in the custodian to deny disclosure of the record; and

c. A brief statement of the reasons the requester is being denied access to the record.

14.4(5) *Request granted.* When the custodian grants a request for access to a confidential record to a particular person, the custodian shall notify that person and indicate any lawful restrictions imposed by the custodian on that person's examination and copying of the record.

657—14.5(22,124,155A) Requests for treatment of a record as a confidential record and its withholding from examination. The custodian may treat a record as a confidential record and withhold it from examination only to the extent that the custodian is authorized, by Iowa Code section 22.7, another applicable provision of law, or a court order, to refuse to disclose that record to members of the public.

14.5(1) *Persons who may request.* Any person who would be aggrieved or adversely affected by disclosure of a record, and who identifies a provision of law or court order that authorizes the treatment of the record as a confidential record, may request that the custodian treat the record as such and withhold it from public inspection.

14.5(2) *Request.* A request that a record be treated as a confidential record shall be in writing and shall be filed with the custodian. The request shall set forth the legal and factual basis justifying such confidential record treatment for that record, and the name, address, and telephone number of the person authorized to respond to any inquiry or action of the custodian concerning the request. A person requesting treatment of a record as a confidential record shall also be required to sign a certified statement or affidavit enumerating the specific reasons justifying the treatment of that record as a confidential record and to provide any proof necessary to establish relevant facts. Requests for treatment of a record as a confidential record for a limited time period shall also specify the precise period of time for which that treatment is requested.

A person filing a request for treatment of a record or a portion of a record as a confidential record shall, if possible, accompany the request with a copy of that record from which those portions for which confidential record treatment is being requested have been deleted. If the original record is being submitted to the board by the person requesting confidential treatment at the time the request is filed, the person shall conspicuously indicate on the original record that all or portions of the record are confidential.

14.5(3) *Failure to request.* Failure of a person to request confidential record treatment for a record does not preclude the custodian from treating it as a confidential record. However, if a person who submits business information to the board does not request that it be withheld from public inspection under Iowa Code section 22.7(3) or 22.7(6), the custodian may assume that the person has no objection to disclosure of the record to members of the public.

14.5(4) *Timing of decision.* A decision by the custodian with respect to disclosure of a record to members of the public may be made when a request for its treatment as a confidential record is filed or upon receipt of a request for access to the record by a member of the public.

14.5(5) *Request granted or deferred.* If a request for confidential record treatment is granted or if action on a request is deferred, a copy of the record from which the matter in question has been deleted and a copy of the decision to grant or defer action on the request will be made available for public inspection in lieu of the original record. If the custodian subsequently receives a request for access to the original record, the custodian will make reasonable and timely efforts to notify any person who has filed a request for its treatment as a confidential record of the pendency of that subsequent request.

14.5(6) *Request denied and opportunity to seek injunction.* If the custodian denies a request to treat a record as confidential and to withhold it from public inspection, the custodian shall notify the requester in writing of the denial and the reasons for the denial. If the requester asks, the custodian may delay allowing examination of the record if the delay is reasonable and in good faith, to permit the requester to seek a court order under the provisions of Iowa Code section 22.8 or other applicable provision of law prohibiting public inspection of the record. The custodian shall notify the requester in writing of the deadline for obtaining such a court order. The custodian may continue to delay allowing public inspection only if no request for examination of the record has been received, if the court directs the custodian not to allow public inspection of the record, or to the extent permitted by another applicable provision of law and with the consent of the party requesting access. However, the custodian shall not withhold the record from public inspection for any period of time if the custodian determines the requester has no reasonable grounds to justify treatment of the record as confidential.

657—14.6(22,124,155A) Procedure by which additions, dissents, or objections may be entered into certain records. Except as otherwise provided by law, a person may file a request with the custodian to review, and to have a written statement of additions, dissents, or objections entered into, a record containing personally identifiable information pertaining to that person. This does not authorize a person who is a subject of such a record to alter the original copy of that record or to expand the official record of any board proceeding. A requester shall send the request to review such a record or the written statement of additions, dissents, or objections to Executive Secretary/Director, Iowa Board of Pharmacy Examiners, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. A request to review such a record or the written statement of additions, dissents, or objections to the record shall be dated and signed by the requester and shall include the current address and telephone number of the requester or the requester's representative.

657—14.7(22,124,155A) Consent to disclosure by the subject of a confidential record. To the extent permitted by any applicable provision of law, a person who is the subject of a confidential record may have a copy of the portion of that record concerning the subject disclosed to a third party. A request for such a disclosure shall be in writing and shall identify the particular record or records that may be disclosed, the particular person or class of persons to whom the record may be disclosed, and any applicable time period during which the record may be disclosed. The person who is the subject of the record and, where applicable, the person to whom the record is to be disclosed shall be required to provide proof of identity. Appearance of counsel before the board on behalf of a person who is the subject of a confidential record is deemed to constitute consent for the board to disclose records about that person to the person's attorney. This rule does not authorize the subject of a record that is confidential under Iowa Code section 272C.6(4) to consent to the release of the record.

657—14.8(22,124,155A) Notice to suppliers of information. When the board requests that a person supply information about that person, the board shall notify the person of the use that will be made of the information, which persons outside the board may routinely be provided this information, which parts of the requested information are required and which are optional, and the consequences of failure to provide the requested information. This notice may be given in these rules, on the written form used to collect the information, on a separate fact sheet or letter, in brochures, in formal agreements, in contracts, in handbooks, in manuals, verbally, or by other appropriate means.

657—14.9(22,124,155A) Disclosures without the consent of the subject.

14.9(1) Open records are routinely disclosed without the consent of the subject.

14.9(2) To the extent allowed by law, disclosure of confidential records may occur without the consent of the subject. Following are instances when disclosure, if lawful, will generally occur without notice to the subject:

a. For a routine use as defined in rule 657—14.10(22,124,155A) or in the notice for a particular record system.

b. To a recipient who has provided the board with advance written assurance that the record will be used solely as a statistical research or reporting record, provided that the record is transferred in a form that does not identify the subject.

c. To another government agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States for a civil or criminal law enforcement activity if the activity is authorized by law. An authorized representative of the government agency or instrumentality shall have submitted a written request to the board specifying the record desired and the law enforcement activity for which the record is sought.

d. To an individual pursuant to a showing of compelling circumstances affecting the health or safety of any individual, provided a notice of the disclosure is transmitted to the last-known address of the subject.

e. To the legislative services agency as provided in Iowa Code section 2A.3.

f. In the course of employee disciplinary proceedings.

g. In response to a court order or subpoena.

657—14.10(22,124,155A) Routine use. "Routine use" means the disclosure of a record without the consent of the subject or subjects, for a purpose that is compatible with the purpose for which the record was collected, and includes disclosures required to be made by statute other than the public records law, Iowa Code chapter 22.

To the extent allowed by law, the following uses are considered routine uses of all board records:

1. Disclosure to those officers, employees, investigators, members, and agents of the board who have a need for the record in the performance of their duties. The custodian of the record may, upon request of any officer, employee, investigator, member, or agent of the board or on the custodian's own initiative, determine what constitutes legitimate need to use confidential records.

2. Disclosure of information that indicates an apparent violation of law to appropriate law enforcement authorities for investigation and possible criminal prosecution, civil court action, or regulatory order.

3. Disclosure to the attorney general's office for use in performing its official function.

4. Transfers of information among board staff and members; to other state agencies, boards, and departments; to federal agencies; to agencies in other states; to the National Association of Boards of Pharmacy; or to local units of government as appropriate to carry out the board's statutory authority.

5. Information released to the staff of federal or state entities for audit purposes or for purposes of determining whether the board is lawfully operating a program.

6. Any disclosure specifically authorized by the statute under which the record was collected or maintained.

657—14.11(22,124,155A) Consensual disclosure of confidential records.

14.11(1) *Consent to disclosure by a subject individual.* To the extent permitted by law, the subject may consent in writing to board disclosure of confidential records as provided in rule 657—14.7(22,124,155A).

14.11(2) *Complaints to public officials.* A letter from a subject of a confidential record to a public official that seeks the official's intervention on behalf of the subject in a matter involving the board may, to the extent permitted by law, be treated as an authorization to release to the official sufficient information about the subject to resolve the matter.

657—14.12(22,124,155A) Release to subject.

14.12(1) The subject of a confidential record may file a written request to review confidential records about that person as provided in rule 657—14.6(22,124,155A). However, the board need not release the following records to the subject:

a. The identity of a person providing information to the board need not be disclosed directly or indirectly to the subject of the information when the information is authorized to be held confidential pursuant to Iowa Code section 22.7(18) or other provision of law.

b. Records need not be disclosed to the subject when they are the work product of an attorney or are otherwise privileged.

c. Peace officers' investigative reports may be withheld from the subject, except as required by the Iowa Code. See Iowa Code section 22.7(5).

d. All information in licensee complaint and investigation files maintained by the board for the purposes of licensee discipline are required to be withheld from the subject prior to the filing of formal charges and the notice of hearing in a licensee disciplinary action.

e. As otherwise authorized by law.

14.12(2) When a record has multiple subjects with interest in the confidentiality of the record, the board may take reasonable steps to protect confidential information relating to another subject.

657—14.13(22,124,155A) Availability of records.

14.13(1) *Open records.* Board records are open for public inspection and copying unless otherwise provided by rule or law.

14.13(2) *Confidential records.* The following records may be withheld from public inspection. Records are listed by category, according to the legal basis for withholding them from public inspection.

a. Tax records made available to the board (Iowa Code sections 422.20 and 422.72);

b. All information in complaint and investigation files maintained by the board for purposes of licensee discipline, except that the information may be released to the licensee once a licensee disciplinary proceeding has been initiated by the filing of formal charges and a notice of hearing (Iowa Code section 272C.6(4));

c. Records of controlled substances disposed of or destroyed (Iowa Code section 124.506);

d. Criminal history or prior misconduct of an applicant for licensure (Iowa Code section 147.21(1));

e. Information relating to the contents of an examination for licensure (Iowa Code section 147.21(2));

f. Information relating to the results of an examination for licensure, other than final score, except that information about the results of an examination may be provided to the person who took the examination (Iowa Code section 147.21(3));

g. Information contained in investigative reports relating to the abuse of controlled substances (Iowa Code section 124.504);

h. Minutes of closed meetings of the board (Iowa Code section 21.5(4));

i. Records of closed-session board disciplinary hearings (Iowa Code sections 272C.6(1) and 21.5(4));

j. Information or records received from a restricted source and any other information or records made confidential by law;

k. Identifying details in final orders, decisions, and opinions to the extent required to prevent a clearly unwarranted invasion of personal privacy or trade secrets under Iowa Code section 17A.3(1)*"d"*;

l. Those portions of board staff manuals, instructions, or other statements issued by the board that set forth criteria or guidelines to be used by board staff in conducting audits, making inspections, negotiating settlements, or selecting or handling cases. This includes operational tactics or allowable tolerances or criteria for the defense, prosecution, or settlement of cases, when disclosure of these statements would:

(1) Enable law violators to avoid detection;

(2) Facilitate disregard of requirements imposed by law; or

(3) Give a clearly improper advantage to persons who are in an adverse position to the board (Iowa Code sections 17A.2 and 17A.3);

m. Personal information in personnel files including, but not limited to, evaluations, discipline, social security number, home address, gender, birth date, and medical and psychological evaluations;

n. Any other records made confidential by law.

14.13(3) *Authority to release confidential records.* The board may in its discretion disclose some confidential records that the board is authorized to refuse to disclose under Iowa Code section 22.7 or

other discretionary provision of law. Any person may request permission to inspect such records. If the board determines that it will release such records, the board may, where appropriate, notify interested parties before releasing the records and withhold the records from inspection as provided in subrule 14.4(3).

657—14.14(22,124,155A) Personally identifiable information. This rule describes the nature and extent of personally identifiable information which is collected, maintained, and retrieved by the board by personal identifier in record systems as defined in rule 657—14.1(22,124,155A). For each record system, this rule describes the legal authority for the collection of that information and the means of storage of that information. Indication that information in a record system is stored in or on more than one media format should not be interpreted to mean that all information is stored in all such formats. Some information comprising a record may be maintained in or on one type of media while other related information is maintained in or on another. The description also indicates whether the record system contains any confidential information, and includes the legal authority for confidentiality. The record systems maintained by the board are:

14.14(1) *Records of board disciplinary hearings.* These records contain information about licensees, permit holders, and registrants who are the subject of a board disciplinary proceeding or other action. This information is collected by the board pursuant to the authority granted in Iowa Code chapters 17A, 124, 155A, and 272C and is stored electronically, in computer, and on paper. The information contained in "closed session" board hearing records is confidential in whole or in part pursuant to Iowa Code sections 21.5(4) and 272C.6(1).

14.14(2) *Complaint reports.* Complaint and investigative files maintained by the board for purposes of licensee discipline contain information about licensees, permit holders, registrants, and the persons that they serve. This information is collected by the board pursuant to the authority granted in Iowa Code chapters 124 and 155A and is stored electronically, in computer, and on paper. The information contained in these records is confidential in whole or in part pursuant to Iowa Code sections 22.7(18) and 272C.6(4).

14.14(3) *Continuing pharmaceutical education records.* These records contain educational information about pharmacists licensed by the board. This information is collected pursuant to the authority granted in Iowa Code chapter 272C and is stored on paper only.

14.14(4) *Controlled drug samples records.* These records contain information about controlled substance registrants who receive samples of controlled drugs from drug manufacturers. The records include the name, strength, and quantity of controlled drugs received by the registrant, and the identity of the manufacturer or distributor. This information is collected by the board pursuant to the authority granted in Iowa Code chapter 124 and is stored on paper.

14.14(5) *Controlled substance registration records.* These records contain information about pharmacies; individual practitioners including doctors of medicine and surgery, osteopathic medicine and surgery, dentistry, veterinary medicine, podiatry, and optometry; physician assistants; advanced registered nurse practitioners; drug manufacturers, distributors, importers, and exporters; researchers; hospitals and clinics; other health care facilities such as long-term care and nursing care facilities; analytical laboratories; and teaching institutions. This information is collected by the board pursuant to the authority granted in Iowa Code chapter 124 and is stored on paper and in computer.

14.14(6) *Controlled drug destruction reports.* These records contain information about the disposal or destruction of controlled substances in the possession of registrants. The records include the name, strength, quantity, and form of all controlled substances disposed of or destroyed, and the identity of the registrant. This information is collected by the board pursuant to the authority granted in Iowa Code chapter 124 and is stored in computer and on paper. The information contained in these records is confidential pursuant to Iowa Code section 124.506.

14.14(7) *Examination records.* These records contain information about applicants for any of the following examinations: National Association of Boards of Pharmacy Licensure Examination, North American Pharmacist Licensure Examination, Multistate Pharmacy Jurisprudence Examination, Federal Drug Law Examination, and Iowa Drug Law Examination. These records may also contain information

about applicants licensed or pursuing licensure by reciprocity, score transfer, or other means. This information is collected by the board pursuant to the authority granted in Iowa Code chapters 147 and 155A and is stored on paper, electronically, and in computer. The information contained in these records is confidential in part pursuant to Iowa Code sections 147.21, 22.7(1), and 22.7(19).

14.14(8) *Pharmacist-intern records.* These records contain information about pharmacist-interns and their preceptors. This information is collected by the board pursuant to the authority granted in Iowa Code section 155A.6 and is stored on paper, electronically, and in computer. The information contained in these records may be confidential in part pursuant to Iowa Code section 22.7(1).

14.14(9) *Investigative reports.* These records contain information about the subjects of board investigations and the activities of board investigators. The records include a variety of attachments such as interviews, drug audits, medical records, pharmacy records, exhibits, police reports, incident reports, and investigators' observations. This information is collected by the board pursuant to the authority granted in Iowa Code chapters 124, 126, 147, and 155A and is stored electronically, in computer, and on paper. The information contained in these records is confidential pursuant to Iowa Code sections 22.7(2), 22.7(5), 22.7(6), 22.7(9), and 22.7(19); 147.21(1); 124.504; and 272C.6(4).

14.14(10) *Licensure records.* These records contain information about pharmacists, pharmacies, and wholesalers that are licensed by the board. This information is collected by the board pursuant to the authority granted in Iowa Code chapters 126, 147, and 155A and is stored electronically, on paper, in computer, and in the state archives.

14.14(11) *Personnel records.* These records contain personal information about board members and staff. This information is stored on paper and microfiche. The personal information contained in these records may be confidential in whole or in part pursuant to Iowa Code section 22.7(11).

14.14(12) *Nonlicensee investigation files.* These records contain information about nonlicensees, nonregistrants, or non-permit holders. This information is a public record except to the extent that certain information may be exempt from disclosure under Iowa Code section 22.7 or other provision of law.

14.14(13) *Routine inspection reports.* These records contain information about pharmacies, controlled substance registrant offices, manufacturers and distributors, and wholesalers that are inspected by agents of the board to determine compliance with state and federal law. This information is collected by the board pursuant to the authority granted in Iowa Code chapters 124 and 155A and is stored on paper, in computer, and electronically.

14.14(14) *Notifications to the board.* These records contain reports of theft or loss of controlled substances; of pharmacy or drug wholesaler openings, closings, and changes of ownership, location, or responsible person; of the sale or transfer of prescription drugs including controlled substances; of disasters, accidents, or emergencies affecting drugs; and of pharmacists', pharmacist-interns', pharmacy technicians', and pharmacy support persons' names, addresses, or employment changes. This information is collected by the board pursuant to the authority granted in Iowa Code sections 155A.6, 155A.6A and 155A.19 and 2009 Iowa Code Supplement section 155A.6B and is stored on paper, electronically, and in computer.

14.14(15) *Precursor substances permit and distribution records.* These records contain information about precursor substances handlers, both vendors and recipients, and information about the distribution, disposal, or destruction of precursor substances. This information is collected by the board pursuant to the authority granted in Iowa Code chapter 124B and is stored in computer and on paper.

14.14(16) *Pharmacy technician records.* These records contain information about pharmacy technicians who are registered by the board. This information is collected by the board pursuant to the authority granted in Iowa Code chapter 155A and is stored on paper and in computer.

14.14(17) *Pharmacy support person records.* These records contain information about pharmacy support persons who are registered with the board. This information is collected by the board pursuant to the authority granted in Iowa Code chapter 155A and is stored on paper, electronically, and in computer.
[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—14.15(22,124,155A) Other groups of records. This rule describes groups of records maintained by the board other than record systems as defined in rule 657—14.1(22,124,155A). These records are

routinely available to the public and may be accessible via the Internet. The board's files of these records do not contain confidential information except where indicated. These records may contain information about individuals and include:

14.15(1) *Board calendars, agenda, news releases, statistical reports and compilations, newsletters, publications, correspondence, and other information intended for the public.* These records may contain information about individuals, including board members and staff, and are stored on paper, electronically, and in computer.

14.15(2) *Minutes of open meetings of the board.* These records contain information about people who participate in board meetings. This information is collected pursuant to Iowa Code section 21.3 and is stored electronically, in computer, and on paper, and may be accessed via the Internet.

14.15(3) *Records of board rule-making proceedings.* These records may contain information about individuals making written or oral comments on rules proposed by the board. This information is collected pursuant to Iowa Code section 17A.4 and is stored electronically, in computer, and on paper. Information may be accessible via the Internet.

14.15(4) *Board decisions, findings of fact, final orders, advisory opinions, declaratory orders, and other statements of law or policy issued by the board in the performance of its function.* These records are open to the public pursuant to Iowa Code section 272C.6(4), except for information that is confidential, and are stored on paper, electronically, and in computer.

657—14.16(22,124,155A) Computer. The board uses an in-house network of file and print servers and personal computers. This network system permits the comparison of personally identifiable information in one computerized record system with personally identifiable information in another computerized record system.

These rules are intended to implement Iowa Code section 22.11.

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CHAPTER 15
CORRECTIONAL PHARMACY PRACTICE

657—15.1(155A) Purpose and scope. It is the intent of these rules to authorize the department of corrections to distribute prescription drugs to patients in correctional facilities from one or more correctional pharmacies. Each correctional pharmacy shall be responsible for the provision of pharmacy services for a specific number of correctional facilities. The correctional pharmacies may be located on the grounds of a correctional facility or may be located off site from all facilities. The correctional pharmacies shall be licensed by the board with limited-use pharmacy licenses designated as correctional pharmacy licenses. Pharmacists shall be responsible for any delegated act performed by supportive personnel under the pharmacists' supervision. The requirements of these rules for correctional pharmacy practice are in addition to the requirements of 657—Chapter 8 and other rules of the board relating to the services provided by the pharmacies.
[**ARC 8670B**, IAB 4/7/10, effective 5/12/10]

657—15.2(126,155A) Definitions. For purposes of this chapter, the following definitions shall apply:

"Board" means the Iowa board of pharmacy.

"Department" means the Iowa department of corrections.

"Emergency/first dose drug supply" means a limited inventory of drugs stored outside the correctional pharmacy and accessible to designated health care staff for the purpose of initiating emergency or first dose prescription drug orders issued during periods when the pharmacist is unavailable.

"Medication administration record" means the record of the administration of drugs to patients.

"Med-pak" means a customized patient medication package prepared for a specific patient which comprises a series of immediate containers containing prescribed solid oral dosage forms, each container being labeled with the time or the appropriate period for the patient to take its contents.

"Prescription drug order" means an order that is for a drug or device for a patient in custody status in a correctional facility, that is originated by a practitioner authorized to prescribe, and that meets the information requirements for a prescription drug order but is recorded, distributed, and administered as though it were a medication order.

"Qualified individual" means a pharmacist, a person who has successfully completed a medication administration course, or a person specifically authorized under pertinent sections of the Iowa Code to administer prescription drugs.

"Single unit package" means a package that contains one discrete pharmaceutical dosage form.

"Unit dose dispensing system" means a drug distribution system utilizing single unit, unit dose, or unit of issue packaging in a manner that helps reduce or remove traditional drug stocks from resident care areas and enables the selection and distribution of drugs to be pharmacy-based and controlled.

"Unit dose package" means a package that contains that particular dose of a drug ordered for the patient for one administration time. A unit dose package is not always a single unit package.

"Unit of issue package" means a package that provides multiple units or doses attached to each other but separated in a card or specifically designed container.
[**ARC 8670B**, IAB 4/7/10, effective 5/12/10]

657—15.3(155A) Pharmacist in charge. One professionally competent, legally qualified pharmacist who is licensed to practice pharmacy in Iowa shall be the pharmacist in charge of the correctional pharmacy and shall be responsible for, at a minimum, the following:

1. Ensuring that the pharmacy utilizes an ongoing, systematic program for achieving performance improvement and ensuring the quality of pharmaceutical services;
2. Ensuring that the pharmacy employs an adequate number of qualified personnel commensurate with the size and scope of services provided by the pharmacy;
3. Ensuring that a quarterly inspection of all pharmaceuticals located at the correctional facility, including any emergency/first dose drug supply located outside the confines of the pharmacy, is completed and documented;

4. Ensuring the availability of any equipment and references necessary for the particular practice of pharmacy;

5. Preparing written policies and procedures governing pharmacy functions; periodically reviewing and revising those policies and procedures to reflect changes in processes, organization, and other pharmacy functions; ensuring that policies and procedures are consistent with board rules; and ensuring that all pharmacy personnel are familiar with the policies and procedures;

6. Ensuring that a pharmacist performs prospective drug use reviews as specified in rule 657—8.21(155A);

7. Ensuring that a pharmacist provides drug information to other health professionals, to other caregivers, and to patients as required or requested;

8. Dispensing drugs to patients, including the packaging, preparation, compounding, and labeling functions performed by pharmacy personnel;

9. Delivering drugs to the patient or the patient's agent;

10. Ensuring that patient drug records are maintained as specified in rule 657—15.8(124,126,155A);

11. Training pharmacy technicians and pharmacy support persons;

12. Establishing policies and procedures for the procurement and storage of prescription drugs and devices and other products dispensed from the pharmacy;

13. Disposing of and distributing drugs from the pharmacy;

14. Maintaining records of all transactions of the pharmacy necessary to maintain accurate control over and accountability for all drugs as required by applicable state and federal laws, rules, and regulations;

15. Establishing and maintaining effective controls against the theft or diversion of prescription drugs and records for such drugs;

16. Ensuring the legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, and regulations governing the practice of pharmacy.

[**ARC 8670B**, IAB 4/7/10, effective 5/12/10]

657—15.4(155A) Reference library. References may be printed or computer-accessed. Each correctional pharmacy shall have on site, at a minimum, one current reference from each of the following categories, including access to current periodic updates.

1. The Iowa Pharmacy Law and Information Manual.

2. A patient information reference that includes or provides patient information in compliance with rule 657—6.14(155A).

3. A reference on drug interactions.

4. A general information reference.

5. A drug equivalency reference.

6. A reference on natural or herbal medicines.

7. The readily accessible telephone number of a poison control center that serves the area.

8. Additional references as may be necessary for the pharmacist to adequately meet the needs of the patients served.

[**ARC 8670B**, IAB 4/7/10, effective 5/12/10]

657—15.5(124,155A) Security. The pharmacy shall be located in an area or areas that provide for effective control against theft of, diversion of, and unauthorized access to prescription drugs and pharmacy records. The following conditions shall be met to ensure appropriate control over drugs and chemicals in the pharmacy:

15.5(1) *Locked areas.* All areas occupied by the correctional pharmacy or where drugs or devices are maintained or stored shall be lockable by a key, combination, or electronic device so as to prevent access by unauthorized personnel and shall be locked when unoccupied or unattended.

15.5(2) *Access when pharmacist absent.* The pharmacist in charge, with the concurrence of the department, shall establish and implement policies and procedures for the security of the correctional pharmacy. Policies and procedures shall identify who will have access to the pharmacy, what areas may

be accessed, and the procedures to be followed for obtaining drugs and chemicals when the pharmacist is absent from the pharmacy.

15.5(3) *Pharmacist responsibility.* Each pharmacist, while on duty, shall be responsible for the security of the correctional pharmacy. This responsibility includes provisions for effective control against theft of, diversion of, or unauthorized access to prescription drugs or devices, controlled substances, records for such drugs and devices, and patient records as provided in 657—Chapter 21 and rule 657—8.16(124,155A). Policies and procedures shall identify the days and hours the pharmacy shall be open. A pharmacist shall be on site during all times that the pharmacy is open.

15.5(4) *Drugs in the correctional facility.* All drugs distributed from the pharmacy to areas of the correctional facility for subsequent administration to patients shall be kept in locked storage when not in use. Policies and procedures shall identify the qualified individuals who are authorized to access these drugs and the process to be followed for their removal.

[**ARC 8670B**, IAB 4/7/10, effective 5/12/10]

657—15.6 Reserved.

657—15.7(124,126,155A) Training and utilization of pharmacy technicians or pharmacy support persons. All correctional pharmacies utilizing pharmacy technicians or pharmacy support persons shall develop, implement, and periodically review written policies and procedures for the training and utilization of pharmacy technicians and pharmacy support persons appropriate to the practice of pharmacy at that licensed location. Pharmacy policies shall specify the frequency of the review. Pharmacy technician and pharmacy support person training shall be documented and maintained by the pharmacy for the duration of employment. Policies and procedures and documentation of pharmacy technician and pharmacy support person training shall be available for inspection by the board or an agent of the board.

[**ARC 8670B**, IAB 4/7/10, effective 5/12/10]

657—15.8(124,126,155A) Drug distribution and dispensing controls. Prescription drugs shall be distributed or dispensed only from the original or a properly verified prescription drug order. There shall be no transcribing of prescription drug orders by nursing staff or clerical staff except for their own records.

15.8(1) *Required information.* Prescription drug orders written in patient health records shall include the following information:

a. Patient name, identification number, and correctional facility location;

b. Drug name, strength, dosage form, and quantity or duration;

c. Directions for use of the drug;

d. Date the prescription drug order is authorized;

e. Prescriber's name, signature, and office address;

f. Prescriber's DEA number for controlled substances.

15.8(2) *Original maintained.* The original prescription drug order and the medication administration record shall be maintained for a minimum of two years in the patient's health record.

15.8(3) *Effect upon transfer of patient.* Current prescription drug orders remain in effect when a patient is transferred to another correctional facility.

15.8(4) *Unit dose dispensing.* Drugs dispensed in a unit dose dispensing system for subsequent administration by nurses or other qualified individuals shall be packaged and labeled by pharmacy staff in compliance with the provisions of rule 657—22.1(155A). Policies and procedures shall be implemented that include, but are not limited to, the following:

a. Return and reuse of drugs;

b. Expiration dating;

c. Record keeping.

15.8(5) *Med-pak dispensing.* Drugs may be dispensed in med-pak dispensing systems for subsequent administration by nurses or other qualified individuals. Policies and procedures shall be

implemented that are in accordance with rule 657—22.5(155A) and include, but are not limited to, the following:

a. Return and reuse of containers;

b. Expiration dating;

c. Record keeping.

15.8(6) *Drug administration.* Only a licensed health care professional authorized to administer drugs or a qualified individual shall administer to a patient prepackaged drugs from the supply distributed by the pharmacy. Documentation of administration shall be recorded in the medication administration record. The single unit, unit dose, or med-pak packaging shall remain intact to the point of administration.

15.8(7) *Dispensing for patient self-administration.* Drugs dispensed for self-administration by a patient shall be packaged and labeled in accordance with rule 657—6.10(126,155A).

15.8(8) *Labeling of drugs under special circumstances.*

a. Insulin, ophthalmics, otic preparations, inhalers, nasal sprays, topicals, and other similarly packaged drugs. A label shall be affixed to the immediate container showing at least the patient's name and ID number. A label that complies with 657—subrule 6.10(1) shall be affixed to the outer container.

b. Leave and release drugs. Labeling of prescription drugs for patients leaving the correctional facility for temporary absences in excess of 24 hours, such as court appearances, and for patients being released from custody shall comply with 657—subrule 6.10(1) before the drug is removed from the facility. The dispensing pharmacy shall be responsible for packaging and labeling leave and release drugs in compliance with this paragraph.

15.8(9) *Drug product selection.* Correctional pharmacies shall be exempt from the patient notification requirements of Iowa Code section 155A.32 when exercising drug product selection.

15.8(10) *Emergency/first dose drug supply.* An emergency/first dose drug supply of prescription drugs may be supplied to a correctional facility for use by authorized personnel pursuant to rule 657—22.7(124,155A). Only pharmacists, pharmacist-interns, and pharmacy technicians may restock, replace, or return drugs to the emergency/first dose drug supply. A drug shall be removed from the emergency/first dose drug supply only pursuant to a valid prescription drug order. The pharmacy shall be notified of the removal and administration of a drug from the emergency/first dose drug supply. The pharmacist shall perform drug use review prior to the administration of a second dose. All drugs removed from the emergency/first dose drug supply that are not administered, including any wastage, shall be returned to the pharmacy. A written or electronic record shall be made of all removals from the emergency/first dose drug supply. The record shall include the following information:

a. Patient's name and identification number;

b. Prescriber;

c. Name, strength, dosage form, and quantity of the drug removed;

d. Signature, unique identification, or initials of the authorized person removing the drug;

e. Date and time the drug was removed;

f. Returns of unused drugs to the pharmacy.

[**ARC 8670B**, IAB 4/7/10, effective 5/12/10]

657—15.9 Reserved.

657—15.10(124,126,155A) Policies and procedures. The pharmacist in charge shall develop and implement written policies and procedures for the pharmacy drug distribution system consistent with board rules and department policies and procedures pertaining to pharmaceutical services. Pharmacy policies and procedures shall address, but not be limited to, the following:

1. Controlled substances;
2. Formulary or drug list;
3. Stop orders;
4. Drug sample use and distribution;
5. Drug recalls;
6. Outdated drugs;

7. Patient records;
8. Inspection of drug inventories;
9. Adverse reaction reports;
10. Leave and release drugs;
11. Emergency/first dose drug supply;
12. Drugs brought into the facility;
13. Medication administration and records;
14. Drug compounding;
15. Sterile products;
16. Access to the pharmacy in the absence of the pharmacist;
17. Transfers of drugs between facilities and correctional pharmacies;
18. Transfers of prescription drug orders between correctional pharmacies;
19. Delivery of drugs;
20. Notification when a drug or device is not available;
21. Drug destruction within the pharmacy;
22. Return of unused drugs.

[**ARC 8670B**, IAB 4/7/10, effective 5/12/10]

These rules are intended to implement Iowa Code sections 124.301, 124.303, 124.306, 124.308, 126.10, 126.11, 155A.6A, 155A.13, 155A.27, 155A.28, 155A.31, 155A.32, and 155A.34 through 155A.36 and 2009 Iowa Code Supplement section 155A.6B.

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CHAPTER 16
NUCLEAR PHARMACY PRACTICE

[Prior to 12/14/88, see Pharmacy Examiners Board 657—8.8(155A)]

657—16.1(155A) Purpose and scope. It is unlawful to receive, possess or transfer radioactive drugs except in accordance with the provisions of Iowa Code chapter 155A. It is also unlawful for any person to provide radiopharmaceutical services unless the person is a pharmacist or a person acting under the direct supervision of a pharmacist acting in accordance with the provisions of Iowa Code chapter 155A, board rules and rules of the environmental protection commission. It is not unlawful for a medical practitioner to receive, possess, or transfer radioactive drugs for administration to patients as provided in Iowa Code chapter 148. No person may receive, acquire, possess, use, transfer, or dispose of any radioactive material except in accordance with the conditions set forth by the environmental protection commission pursuant to the provisions of Iowa Code chapter 455B. The requirements of these nuclear pharmacy rules are in addition to and not in substitution for 657—Chapter 8 and other applicable provisions of rules of the board and the environmental protection commission or the public health department.

657—16.2(155A) Definitions.

"Authentication of product history" means, but is not limited to, identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical.

"Board" means the Iowa board of pharmacy examiners.

"Internal test assessment" means, but is not limited to, conducting those tests of quality assurance necessary to ensure the integrity of the test.

"Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

"Qualified nuclear pharmacist" means a person currently licensed to practice pharmacy in Iowa who meets the qualifications established by rule 657—16.3(155A).

"Radiopharmaceutical quality assurance" means, but is not limited to, the performance of appropriate chemical, biological and physical tests on potential radiopharmaceuticals and the interpretation of the resulting data to determine the radiopharmaceuticals' suitability for use in humans and animals, including internal test assessment authentication of product history and the keeping of proper records.

"Radiopharmaceutical service" means, but is not limited to, the preparation, dispensing, labeling and delivery of radiopharmaceuticals; the compounding of radiopharmaceuticals; the participation in radiopharmaceutical selection and radiopharmaceutical utilization reviews; the proper and safe storage and distribution of radiopharmaceuticals; the maintenance of radiopharmaceutical quality assurance; the responsibility for advising, as necessary or required, of the therapeutic values, hazards and use of radiopharmaceuticals; and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management and control of a nuclear pharmacy.

657—16.3(155A) General requirements for qualified nuclear pharmacist. A qualified nuclear pharmacist shall meet all requirements of either alternative one or alternative two established in subrules 16.3(1) and 16.3(2), respectively.

16.3(1) *Alternative one.* A qualified nuclear pharmacist shall:

a. Meet minimum standards of training for medical uses of radioactive materials; and

b. Be a currently licensed pharmacist in the state of Iowa; and

c. Submit an affidavit of experience and training to the board; and

d. Have completed one of the following nuclear pharmacy training alternatives:

(1) Received a minimum of 90 contact hours of didactic instruction in nuclear pharmacy from an accredited college of pharmacy. In addition, the pharmacist shall have attained a minimum of 160 hours of clinical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist in a nuclear pharmacy that provides nuclear pharmacy services or in a structured clinical nuclear pharmacy training program of an accredited college of pharmacy.

(2) Successfully completed a nuclear pharmacy residency accredited by the American Society of Health-System Pharmacists (ASHP).

(3) Successfully completed a certificate program in nuclear pharmacy accredited by the American Council on Pharmaceutical Education (ACPE).

16.3(2) *Alternative two.* A qualified nuclear pharmacist shall:

a. Be a currently licensed pharmacist in the state of Iowa; and

b. Be certified by the Board of Pharmaceutical Specialties as a board-certified nuclear pharmacist (BCNP); and

c. Submit an affidavit of BCNP credentials to the board.

657—16.4(155A) General requirements for pharmacies providing radiopharmaceutical services.

16.4(1) *Qualified nuclear pharmacist.* A license to operate a pharmacy providing radiopharmaceutical services shall be issued only to a qualified nuclear pharmacist who shall be the pharmacist in charge of the pharmacy. The pharmacist in charge shall be responsible for, at a minimum, the requirements in rule 657—6.2(155A). All personnel performing tasks in the preparation and distribution of radioactive drugs shall be under the direct personal supervision of a qualified nuclear pharmacist. A qualified nuclear pharmacist is responsible for all operations of the pharmacy and, except in emergency situations, shall be in personal attendance at all times that the pharmacy is open for business.

16.4(2) *Space requirements.* Nuclear pharmacies shall have adequate space, commensurate with the scope of services required and provided. The nuclear pharmacy area shall be separate from the pharmacy areas for nonradioactive drugs and shall be secured from unauthorized personnel. All pharmacies handling radiopharmaceuticals shall provide a radioactive storage and product decay area, occupying at least 25 square feet of space, separate from and exclusive of the hot laboratory, compounding, dispensing, quality assurance, and office areas.

16.4(3) *Personnel appropriately trained.* The pharmacist in charge shall be responsible for ensuring that all pharmacy personnel have been appropriately and adequately trained for their assigned tasks.

16.4(4) *Pharmacy support persons.* A pharmacy support person shall register with the board pursuant to the registration requirements of 657—Chapter 5. Alternatively, a pharmacy support person may register with the board as a pharmacy technician pursuant to the registration and national certification requirements of 657—Chapter 3.

16.4(5) *Records required.* Nuclear pharmacies shall maintain records of acquisition and disposition of all radioactive drugs in accordance with rules of the board and the environmental protection commission.

16.4(6) *Compliance with laws.* Nuclear pharmacies shall comply with all applicable laws and regulations of federal and state agencies, including those laws and regulations governing nonradioactive drugs.

16.4(7) *Prescription and office use.* Radioactive drugs shall be dispensed only upon a prescription order from a licensed medical practitioner authorized to possess, use and administer radiopharmaceuticals. A nuclear pharmacy may also furnish radiopharmaceuticals to practitioners for office use.

16.4(8) *Outer-container label.* In addition to any of the board's labeling requirements for nonradioactive drugs, the immediate outer container of a radioactive drug to be dispensed shall also be labeled with:

a. The standard radiation symbol;

b. The words "Caution — Radioactive Material";

c. The name of the radionuclide;

d. The chemical form;

e. The amount of radioactive material contained, in millicuries or microcuries;

f. If the radioactive drug is a liquid, the volume in cubic centimeters;

g. The requested calibration time for the amount of radioactivity contained.

16.4(9) *Immediate-container label.* The immediate container shall be labeled with:

a. The standard radiation symbol;
b. The words "Caution — Radioactive Material";
c. The name of the pharmacy; and
d. The prescription number.

16.4(10) *Radioactivity.* The amount of radioactivity for each individual preparation shall be determined by radiometric methods immediately prior to dispensing.

16.4(11) *Redistribution.* A nuclear pharmacy may redistribute to another nuclear pharmacy or authorized party radioactive drugs that are the subject of an approved new drug application if the pharmacy does not process the radioactive drugs in any manner or violate the product packaging.
[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—16.5(155A) Library. Each nuclear pharmacy shall have access to the following references. References may be printed or computer-accessed and shall be current editions or revisions.

1. United States Pharmacopoeia/National Formulary, with supplements;
2. The Iowa Pharmacy Law and Information Manual;
3. State rules and federal regulations governing the use of applicable radioactive materials;
4. Additional references as may be necessary for the pharmacist to adequately meet the needs of the patients served.

657—16.6(155A) Minimum equipment requirements. Each nuclear pharmacy shall maintain the following equipment for use in the provision of radiopharmaceutical services:

1. Laminar flow hood;
2. Dose calibrator;
3. Refrigerator;
4. Single-channel scintillation counter;
5. Microscope;
6. Autoclave, or access to one;
7. Incubator, or access to one;
8. Radiation survey meter;
9. Other equipment necessary for the radiopharmaceutical services provided as required by the board.

A pharmacy may request waiver or variance from a provision of this rule pursuant to the procedures and requirements of 657—Chapter 34.

657—16.7(155A) Training and utilization of pharmacy support persons. Nuclear pharmacies utilizing pharmacy support persons shall develop, implement, and periodically review written policies and procedures for the training and utilization of pharmacy support persons. Pharmacy policies shall specify the frequency of review. Pharmacy support person training shall be documented and maintained by the pharmacy for the duration of employment. Such policies and procedures and documentation of pharmacy support person training shall be available for inspection by the board or an agent of the board.
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These rules are intended to implement Iowa Code sections 155A.4, 155A.13, 155A.28, and 155A.31.

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CHAPTER 17
WHOLESALE DRUG LICENSES

657—17.1(155A) Definitions.

"Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

"Blood component" means that part of blood separated by physical or mechanical means.

"Board" means the Iowa board of pharmacy.

"Distribute" means the delivery of a prescription drug or device.

"Drug sample" means a drug that is distributed without monetary consideration to a pharmacist or practitioner. "Drug sample" does not include drugs intended for patients who would otherwise not receive needed drugs due to their inability to pay.

"Manufacturer" means a person or business engaged in the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis and includes packaging or repackaging of the substances or labeling or relabeling of the substances' containers.

"Prescription drug" means any of the following:

1. A substance for which federal or state law requires a prescription before it may be legally dispensed to the public.

2. A drug or device that under federal law is required, prior to being dispensed or delivered, to be labeled with one of the following statements:

- Caution: Federal law prohibits dispensing without a prescription.
- Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.
- Rx only.

3. A drug or device that is required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by a practitioner only.

"Proprietary medicine" or *"over-the-counter (OTC) medicine"* means a nonnarcotic drug or device that may be sold without a prescription and that is labeled and packaged in compliance with applicable state or federal law.

"Reverse distribution" means the receipt of prescription drugs including controlled substances, whether received from Iowa locations or shipped to Iowa locations, for the purposes of destroying the drugs or returning the drugs to their original manufacturers or distributors.

"Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

1. The sale, purchase, or trade of a drug or an offer to sell, purchase or trade a drug for emergency medical reasons. For purposes of this chapter, "emergency medical reasons" includes transfers of prescription drugs by a pharmacy to another pharmacy to alleviate a temporary shortage;

2. The sale, purchase or trade of a drug, an offer to sell, purchase or trade a drug, or the dispensing of a drug pursuant to a prescription;

3. The lawful distribution of drug samples by manufacturers' representatives or wholesale salespersons;

4. The sale, purchase or trade of blood and blood components intended for transfusion; or

5. Intracompany sales.

"Wholesale distributor" or *"wholesaler"* means a person or business operating or maintaining, either within or outside this state, a manufacturing plant, wholesale distribution center, wholesale business, or any other business in which prescription drugs, medicinal chemicals, medicines, or poisons are sold, manufactured, dispensed, stocked, exposed, or offered for sale at wholesale in this state. "Wholesaler" includes, but is not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; reverse distributors; and pharmacies that conduct wholesale distributions exceeding 5 percent of gross annual sales of prescription drugs. "Wholesaler" does not include those wholesalers who sell

only OTC medicines or manufacturers' representatives lawfully distributing drug samples to authorized practitioners.

"Wholesale salesperson" or *"manufacturer's representative"* means an individual who takes purchase orders on behalf of a wholesaler for prescription drugs, medicinal chemicals, medicines, or poisons. "Manufacturer's representative" also means a person designated by a pharmaceutical manufacturer to lawfully distribute drug samples to authorized practitioners.

657—17.2 Reserved.

657—17.3(155A) Wholesale drug license. Every wholesaler as defined in rule 17.1(155A), wherever located, that engages in wholesale distribution into, out of, or within this state must be licensed by the board in accordance with the laws and rules of Iowa before engaging in wholesale distribution of prescription drugs. Where operations are conducted at more than one location by a single wholesaler, each such location shall be separately licensed in Iowa. A wholesaler located within Iowa that engages in wholesale distribution of controlled substances shall also register pursuant to 657—Chapter 10.

17.3(1) *Application form.* Application for licensure and license renewal shall be on forms provided by the board. Application for wholesale drug licensure shall require an indication of the type of wholesale operation and the wholesaler ownership classification. If the owner is a sole proprietorship (100 percent ownership), the name and address of the owner shall be indicated. If the owner is a partnership or limited partnership, the names and addresses of all partners shall be listed or attached. If the owner is a corporation, the names and addresses of the officers and directors of the corporation shall be listed or attached. Any other wholesaler ownership classification shall be further identified and explained on the application. The name, address, and telephone numbers of at least one contact person for the licensed facility shall be identified. A list of all states in which the wholesaler is licensed and all trade or business names used by the wholesaler shall be included on or with the application. The application shall identify, if the wholesaler is located outside Iowa, applicable home state license information and DEA and FDA license or registration information. The application shall also provide information regarding any past criminal convictions or adverse actions against licenses or registrations held by the licensee or facility managers.

17.3(2) *License expiration and renewal.* A wholesale drug license shall be renewed before January 1 of each year. The fee for a new or renewal license shall be $300.

a. Late payment penalty. Failure to renew the license before January 1 shall require payment of the renewal fee and a penalty fee of $300. Failure to renew the license before February 1 following expiration shall require payment of the renewal fee and a penalty fee of $400. Failure to renew the license before March 1 following expiration shall require payment of the renewal fee and a penalty fee of $500. Failure to renew the license before April 1 following expiration shall require payment of the renewal fee and a penalty fee of $600 and may require an appearance before the board. In no event shall the combined renewal fee and penalty fee for late renewal of a wholesale drug license exceed $900.

b. Delinquent license. If a license is not renewed before its expiration date, the license is delinquent and the licensee may not operate or do business in Iowa until the licensee renews the delinquent license. A drug wholesaler who continues to do business in Iowa without a current license may be subject to disciplinary sanctions pursuant to the provisions of 657—subrule 36.1(4).

17.3(3) *Inspection of new wholesale drug distribution facility.* If a new wholesale drug distribution location within Iowa was not a licensed wholesale drug distribution site immediately prior to the proposed opening of the new wholesale facility, the location shall require an on-site inspection by a pharmacy board inspector prior to the issuance of the wholesale drug license. The purpose of the inspection is to determine compliance with requirements pertaining to space, equipment, drug storage safeguards, and security. Inspection may be scheduled anytime following submission of necessary license and registration applications and prior to beginning wholesale drug distribution. Prescription drugs, including controlled substances, may not be delivered to a new wholesale drug distribution facility prior to satisfactory completion of the opening inspection.

17.3(4) *Wholesale drug license changes.*

a. Ownership change. When ownership of a licensed drug wholesaler changes, the licensee shall submit to the board written notification including the name, address, and license number of the wholesaler and the effective date of the change. Notification shall also identify the new ownership classification and the owners, partners, or corporate officers as indicated in subrule 17.3(1). In those cases in which the wholesaler is owned by a corporation, the sale or transfer of all stock of the corporation does not constitute a change of ownership provided the corporation that owns the wholesaler continues to exist following the stock sale or transfer. A new license shall not be required for a change of ownership.

b. Name or location change. When a licensed drug wholesaler changes its name or location, a new wholesale drug license application with a license fee as provided in 17.3(2) shall be submitted to the board office. Upon receipt of the fee and properly completed application, the board will issue a new license certificate. The old license certificate shall be returned to the board office within ten days of the change of name or location. A change of wholesaler location within Iowa, if the new location was not a licensed drug wholesaler immediately prior to the relocation, shall require an on-site inspection of the new location as provided in subrule 17.3(3).

17.3(5) *Drug wholesaler closing.* A licensee discontinuing wholesale distribution of prescription drugs in or into Iowa shall submit to the board, with the current wholesale drug license certificate, written notification indicating the effective date of closing or discontinuing business in Iowa. If the drug wholesaler had been engaged in the distribution of controlled substances in Iowa, the written notification shall identify by name, address, and appropriate license numbers the facility or facilities to which controlled substances records and any final inventory of controlled substances have been transferred.

17.3(6) *Failure to complete licensure process.* An application for a wholesale drug license, including an application for registration pursuant to 657—Chapter 10, if applicable, will become null and void if the applicant fails to complete the licensure process within six months of receipt by the board of the required applications. The licensure process shall be complete upon the wholesaler's opening for business at the licensed location following an inspection rated as satisfactory by an agent of the board if such an inspection is required pursuant to this rule. When an applicant fails to timely complete the licensure process, fees submitted with applications will not be transferred or refunded.

657—17.4(155A) Minimum qualifications. The board will consider the following factors in determining eligibility for licensure of persons or businesses that engage in the wholesale distribution of prescription drugs:

1. Any convictions of the applicant under federal, state, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;
2. Any felony convictions of the applicant under federal, state, or local laws;
3. The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;
4. The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;
5. Suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;
6. Compliance with licensing requirements under previously granted licenses, if any;
7. Compliance with the requirements to maintain or make available to the board, its agents or authorized personnel, or to federal, state, or local law enforcement officials those records required to be maintained by wholesalers; and
8. Any other factors or qualifications the board considers relevant to and consistent with public health and safety.

657—17.5(155A) Personnel. Licensed wholesalers shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling,

including a description of their duties and a summary of their qualifications. The wholesaler shall employ personnel with the education or experience appropriate to the responsibilities of the position held by the individual.

657—17.6(155A) Responsibility for conduct. A licensed drug wholesaler shall be held responsible for actions of the wholesaler's managerial agent when the conduct of the agent may fairly be assumed to represent the policy of the wholesaler. "Managerial agent" includes, but is not necessarily limited to, an officer or director of a corporation or an association or a partner of a partnership, and includes a person having management responsibility for submissions to the FDA regarding the development or approval of any drug product; the production, quality assurance, or quality control of any drug product; or research and development of any drug product.

17.6(1) *Misrepresentative deeds.* A managerial agent shall not make any statement intended to deceive, misrepresent, or mislead anyone, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in the manufacture, distribution, or marketing of prescription drugs.

17.6(2) *Unethical conduct or behavior.* A managerial agent shall not exhibit unethical behavior in connection with the manufacture, distribution, or marketing of prescription drugs or refuse to provide reasonable information or answer reasonable questions for the benefit of a health professional or a patient. Unethical behavior shall include, but not be limited to, the following acts: verbal abuse, coercion, intimidation, harassment, sexual advances, threats, degradation of character, indecent or obscene conduct, and theft.

657—17.7(124,155A) Distribution to authorized licensees. A wholesaler shall be responsible for verifying, prior to the distribution of a prescription drug, the authority of the person or business to whom the distribution is intended. Such verification may include, but is not limited to, obtaining a copy of the license under which the person or business claims authority to possess the prescription drug or contacting the appropriate licensing authority for verification of the licensee's authority to possess the prescription drug.

657—17.8(124,155A) Written policies and procedures. Wholesalers shall establish, maintain, and adhere to written policies and procedures for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Wholesalers shall also include in their written policies and procedures the following:

17.8(1) *Oldest stock distributed first.* A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement if such deviation is temporary and appropriate.

17.8(2) *Recalls and market withdrawals.* A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

a. Any action initiated at the request of the Food and Drug Administration or other federal, state, or local law enforcement agency or other government agency, including the board;

b. Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

c. Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design.

17.8(3) *Emergency and disaster plan.* A procedure to ensure that wholesalers prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

17.8(4) *Outdated drugs.* A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs.

17.8(5) *Exception.* The procedure required by subrule 17.8(1) does not apply to reverse distribution operations. All other procedures addressed in this rule are required of reverse distribution operations.

17.8(6) *Drugs supplied to salesperson/representative.* If supplying drugs to wholesale salespersons or manufacturers' representatives, a procedure directing that the security, storage, and record-keeping requirements contained in these rules shall be maintained by those wholesale salespersons or manufacturers' representatives.

657—17.9(155A) Facilities. All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

1. Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
2. Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
3. Have a quarantine area for storage of outdated, damaged, unsafe, deteriorated, misbranded, or adulterated prescription drugs; for drugs that are in immediate or sealed outer or sealed secondary containers that have been opened; for drugs that have been identified as being defective or are believed to be defective; and for drugs that do not meet the FDA-approved criteria for the product;
4. Be maintained in a clean and orderly condition;
5. Be free from infestation by insects, rodents, birds, or vermin of any kind.

657—17.10(124,155A) Security.

17.10(1) *Secure from unauthorized entry.* All facilities used for wholesale drug distribution shall be secure from unauthorized entry.

a. Access from outside the premises shall be kept to a minimum and be well controlled.

b. The outside perimeter of the premises shall be well lighted.

c. Entry into areas where prescription drugs are held shall be limited to authorized personnel.

17.10(2) *Alarm.* All facilities shall be equipped with an alarm system to deter entry after hours.

17.10(3) *Security system.* All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

657—17.11(155A) Storage. All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs or with requirements in the current edition of an official compendium.

17.11(1) *Controlled room temperature.* If no storage requirements are established for a prescription drug, the drug may be held at "controlled room temperature" to help ensure that its identity, strength, quality, and purity are not adversely affected. "Controlled room temperature" means the room temperature is maintained thermostatically between 15 degrees and 30 degrees Celsius (59 degrees and 86 degrees Fahrenheit).

17.11(2) *Documentation.* Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs shall be utilized to document proper storage of prescription drugs.

17.11(3) *Exception.* The storage requirements of this rule do not apply to reverse distribution operations.

657—17.12 Reserved.

657—17.13(155A) Drugs in possession of representatives. If a wholesaler is supplying samples or other forms of prescription drugs to wholesale salespersons or manufacturers' representatives, the wholesaler shall be responsible for ensuring that those representatives maintain distribution records and maintain the drugs under appropriate security and storage conditions pursuant to the requirements of these rules.

657—17.14(155A) Examination of materials.

17.14(1) *Receipt shipment.* Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

17.14(2) *Outgoing shipment.* Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

17.14(3) *Type of inspection.* Examination or inspection shall be completed in a manner to ensure the stated intent of this rule. Inspection may be completed by use of electronic surveillance or personal examination.

657—17.15(155A) Returned, damaged, and outdated prescription drugs.

17.15(1) *Quarantine required.* Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to the supplier.

17.15(2) *Seal opened.* Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such and shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

17.15(3) *Drug safety, purity uncertain.* Unless examination, testing, or other investigation proves that a drug meets appropriate standards of safety, identity, strength, quality, and purity, a prescription drug that has been returned under conditions that cast doubt on the drug's safety, identity, strength, quality, or purity shall be destroyed or returned to the supplier. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesaler shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the conditions of the drug and its container, carton, or labeling as a result of storage or shipping.

17.15(4) *Exception.* The requirements of this rule do not apply to reverse distribution operations.

657—17.16(124,155A) Record keeping. Wholesalers shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs, including outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

17.16(1) *Transaction records.* Transaction records shall include the following information:

a. The source of the drugs, including the name and principal address of the seller or transferor and the address of the location from which the drugs were shipped;

b. The identity and quantity of the drugs received and distributed or disposed of;

c. The dates of receipt and distribution or other disposition of the drugs; and

d. If a distribution transaction, the recipient of the drugs, including the name and principal address of the purchaser or transferee and the address to which the drugs were shipped.

17.16(2) *Records maintained.* Inventories and records shall be made available for inspection and photocopying by any authorized official of the board or of any governmental agency charged with enforcement of these rules for a period of two years following disposition of the drugs. The annual inventory of controlled substances shall be maintained for a minimum of two years from the date of the inventory.

17.16(3) *Inspection of records.* Records described in this rule that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be available for inspection within two working days of a request by an authorized official of the board or of any governmental agency charged with enforcement of these rules.

17.16(4) *Confidentiality of patient information.* A wholesaler shall obtain and maintain patient-specific data only as necessary for the health and safety of the patient. Any patient-specific

information in the possession of a wholesaler shall be maintained in compliance with the patient confidentiality and security requirements of rules 657—8.16(124,155A) and 657—21.2(124,155A).
[**ARC 8669B**, IAB 4/7/10, effective 5/12/10]

657—17.17(124,155A) Compliance with federal, state, and local laws. Wholesalers shall operate in compliance with applicable federal, state, and local laws, rules, and regulations.

17.17(1) *Access by authorized officials.* Wholesalers shall permit the board and authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law. Such officials shall be required to show appropriate identification prior to being permitted access to wholesalers' premises and delivery vehicles.

17.17(2) *Controlled substance registrations.* Wholesalers that deal in controlled substances shall register with the appropriate state controlled substance authority and with the Drug Enforcement Administration (DEA) and shall comply with all applicable federal, state, and local laws, rules, and regulations.

657—17.18(155A) Discipline. Pursuant to 657—Chapters 35 and 36, the board may deny, suspend, or revoke a wholesale drug license for any violation of Iowa Code chapter 124, 124A, 124B, 126, 155A, or 205 or a rule of the board promulgated thereunder.

These rules are intended to implement Iowa Code sections 124.301 through 124.303, 124.306, 155A.4, and 155A.17.

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CHAPTER 18
CENTRALIZED PRESCRIPTION FILLING AND PROCESSING

657—18.1(155A) Purpose and scope. The purpose of this chapter is to provide standards for centralized prescription drug order filling or centralized prescription processing by a pharmacy. Any facility established for the purpose of filling or processing prescription drug orders on behalf of other pharmacies shall be licensed as a pharmacy and shall hold all necessary registrations. A hospital pharmacy may participate in centralized prescription filling only of prescription drug orders for noncontrolled substances pursuant to these rules. A hospital pharmacy may engage in centralized prescription processing pursuant to the requirements of rule 657—7.7(155A). Except as specifically identified in the rules, the requirements of these rules for centralized prescription filling or centralized prescription processing are in addition to the requirements of 657—Chapters 6, 7, and 8, and other rules of the board relating to services provided by pharmacies.

657—18.2(155A) Definitions. For the purposes of this chapter, the following definitions shall apply:

"Central fill pharmacy" means a pharmacy contracting with an originating pharmacy, or having the same owner as an originating pharmacy, that provides centralized prescription drug order filling on behalf of the originating pharmacy pursuant to these rules.

"Centralized prescription drug order filling" or *"centralized filling"* means the filling of a prescription drug order by a pharmacy on behalf of another pharmacy. "Centralized filling" does not include the processing or dispensing of a prescription drug order but may include any of the following filling functions:

1. Receiving prescription drug orders from the originating pharmacy;
2. Interpreting or clarifying prescription drug orders;
3. Entering prescription drug order information into a pharmacy's prescription record system;
4. Selecting, counting, and placing the prescribed drug into an appropriate prescription container;
5. Affixing the prescription label, including any auxiliary labels, to the prescription container;
6. Obtaining refill and substitution authorizations;
7. Verifying all filling processes performed by the central fill pharmacy.

"Centralized prescription drug order processing" or *"centralized processing"* means the processing of a prescription drug order by a pharmacy on behalf of another pharmacy. "Centralized processing" does not include the filling or dispensing of a prescription drug order but may include any of the following processing functions:

1. Interpreting or clarifying prescription drug orders;
2. Entering prescription drug order information into a pharmacy's prescription record system;
3. Interpreting clinical data for prior authorization for dispensing;
4. Performing formulary-directed therapeutic interchange.

"Central processing pharmacy" means a pharmacy contracting with an originating pharmacy, or having the same owner as an originating pharmacy, that provides centralized prescription drug order processing on behalf of the originating pharmacy pursuant to these rules.

"DEA" means the U.S. Department of Justice, Drug Enforcement Administration.

"Dispense" means the delivery of a prescription drug or device to an ultimate user or the ultimate user's agent by or pursuant to the lawful order of a practitioner. "Dispense" includes:

1. Receiving the prescription drug order from the patient, the patient's agent, or the prescriber;
2. Delivering the filled prescription to the patient or the patient's agent;
3. Providing drug information concerning a patient's drug therapy;
4. Providing patient counseling;
5. Providing medication therapy management.

"Hospital" means a facility licensed pursuant to Iowa Code chapter 135B.

"Hospital pharmacy" means and includes a pharmacy licensed by the board and located within any hospital, health system, institution, or establishment which maintains and operates organized facilities

for the diagnosis, care, and treatment of human illnesses to which persons may or may not be admitted for overnight stay at the facility.

"Mail order pharmacy" means a pharmacy located within a United States jurisdiction whose primary business is to dispense a prescription drug or device pursuant to a valid prescription drug order and to deliver the drug or device to a patient, including a patient in this state, via the United States Postal Service, a common carrier, or a delivery service. "Mail order pharmacy" includes a pharmacy that does business via the Internet or other electronic media.

"Medication therapy management" means the review of drug therapy regimens of a patient by a pharmacist for the purpose of evaluating and rendering advice to a practitioner, or for the purpose of evaluating and modifying the drug regimen in accordance with a collaborative drug therapy management protocol pursuant to rule 657—8.34(155A).

"Originating pharmacy" means a pharmacy that receives a prescription drug order from a patient, the patient's agent, or a prescriber, outsources prescription filling or processing functions to another pharmacy, and ultimately dispenses the prescription drug or device to the patient or the patient's agent.

657—18.3(155A) General requirements.

18.3(1) *Essential qualifications.* An originating pharmacy may outsource prescription drug filling to a central fill pharmacy or prescription drug order processing to a central processing pharmacy provided the pharmacies:

a. Have the same owner or have entered into a written contract or agreement that outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws, rules, and regulations; and

b. Share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to perform the contracted functions.

18.3(2) *Legal compliance.* An originating pharmacy, a central fill pharmacy, and a central processing pharmacy shall comply with all provisions applicable to the pharmacy contained in federal and state laws, rules, and regulations to the extent applicable for the specific filling or processing activity and these rules, including but not limited to the following:

a. Each pharmacy located within Iowa shall maintain Iowa pharmacy licensure and, if the pharmacy dispenses controlled substances, the pharmacy shall maintain DEA and Iowa controlled substances registrations.

b. Each pharmacy located outside Iowa shall maintain Iowa nonresident pharmacy licensure in addition to the licensure requirements of the pharmacy's home state.

c. Each pharmacist providing centralized prescription drug order processing or filling functions as an employee or agent of a central processing or central fill pharmacy located within Iowa shall maintain active licensure to practice pharmacy in Iowa.

d. Pharmacies shall comply with Iowa board rules relating to the duties that must be performed by a pharmacist.

e. Pharmacies shall comply with Iowa requirements for supervision of pharmacy technicians and pharmacy support persons.

18.3(3) *Originating pharmacy responsibility.* Except as specifically provided by this subrule, the originating pharmacy shall be responsible for all dispensing functions as the term "dispense" is defined in rule 18.2(155A). An originating pharmacy contracting only for centralized filling shall retain responsibility for all processing functions, and an originating pharmacy contracting only for centralized processing shall retain responsibility for all filling functions.

a. A mail order pharmacy engaged in the centralized filling of prescription drug orders may deliver a filled prescription directly to the patient and shall not be required to return the filled prescription to the originating pharmacy.

b. A central fill or a central processing pharmacy that shares a common central processing unit with the originating pharmacy may perform prospective drug use review (DUR) pursuant to rule 657—8.21(155A). Only a pharmacist shall perform the DUR; the review shall not be delegated to a pharmacy technician, registered nurse, or other pharmacy support person. The pharmacist performing

the DUR shall document in the shared patient record all concerns, recommendations, observations, and comments resulting from that review. The pharmacist at the originating pharmacy shall utilize the DUR notes in counseling the patient pursuant to rule 657—6.14(155A).

18.3(4) *Central fill label requirements.* The label affixed to the prescription container filled by a central fill pharmacy on behalf of an originating pharmacy shall include the following:

a. A unique identifier indicating that the prescription was filled at the central fill pharmacy;

b. Serial number (a unique identification number of the prescription) as assigned by the originating pharmacy;

c. The name, address, and telephone number of the originating pharmacy;

d. The name of the patient or, if such drug is prescribed for an animal, the species of the animal and the name of its owner;

e. The name of the prescribing practitioner;

f. The date the prescription is filled by the central fill pharmacy;

g. The directions or instructions for use, including precautions to be observed;

h. Unless otherwise directed by the prescriber, the name, strength, and quantity of the drug dispensed.

(1) If a pharmacist selects an equivalent drug product for a brand name drug product prescribed by a practitioner, the prescription container label shall identify the generic drug and may identify the brand name drug for which the selection is made, such as "(generic name) Generic for (brand name product)".

(2) If a pharmacist selects a brand name drug product for a generic drug product prescribed by a practitioner, the prescription container label shall identify the brand name drug product dispensed and may identify the generic drug product ordered by the prescriber, such as "(brand name product) for (generic name)";

i. The initials or other unique identification of the pharmacist in the originating pharmacy who performed drug use review and transmitted the prescription drug order to the central fill pharmacy.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—18.4 Reserved.

657—18.5(155A) Patient notification and authorization.

18.5(1) *Prior notification and authorization.* A pharmacy that outsources prescription drug order filling or prescription drug order processing to another pharmacy shall, prior to outsourcing a patient's prescription:

a. Notify the patient or the patient's agent that prescription filling or processing may be outsourced to another pharmacy.

b. Provide the name of the pharmacy that will be filling or processing the prescription or, if the pharmacy is part of a network of pharmacies under common ownership and any of the network pharmacies may fill or process the prescription, the patient shall be notified of this fact. Notification shall be provided through a notice to the patient or the patient's agent by means of a sign prominently displayed in the originating pharmacy and through written notice provided to the patient or the patient's agent prior to implementation of the program or upon commencement of services to a new patient, as applicable.

c. If a patient provides the originating pharmacy with notification that the patient no longer authorizes the originating pharmacy to outsource the patient's prescription drug orders, the originating pharmacy shall discontinue outsourcing the filling or processing of the patient's prescription drug orders.

18.5(2) *Exception.* The provisions of this rule do not apply to a patient in a facility, such as a hospital or long-term care facility, where Iowa law requires that drugs be administered to the patient by a health care professional.

657—18.6 to **18.9** Reserved.

657—18.10(155A) Policy and procedures.

18.10(1) *Manual maintained.* A policy and procedure manual relating to centralized filling or centralized processing activities shall be maintained at all pharmacies involved in centralized filling or centralized processing and shall be available for inspection and copying by the board or an agent of the board.

18.10(2) *Manual contents.* The manual shall:

a. Outline the responsibilities of each of the pharmacies;

b. Include a list of the names, addresses, telephone numbers, and all license and registration numbers of the pharmacies involved in centralized filling or centralized processing;

c. Include evidence that all licenses and registrations have been verified to be current and in good standing, identifying the individual verifying license and registration status and the method used to verify status; and

d. Include, but not necessarily be limited to, policies and procedures for:

(1) Protecting the confidentiality and integrity of patient information;

(2) Protecting each patient's freedom of choice of pharmacy services;

(3) Maintaining appropriate records to identify the name, the initials or unique identification code, and the specific activities of each pharmacist or pharmacy technician who performed any centralized filling or centralized processing function;

(4) Complying with federal and state laws, rules, and regulations;

(5) Operating a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems; and

(6) Reviewing, at least annually, the written policies and procedures and documenting that review.

657—18.11 to **18.14** Reserved.

657—18.15(155A) Records. Central fill or central processing pharmacies shall maintain appropriate records that identify, by prescription drug order, the name and initials or unique identification code of each pharmacist or pharmacy technician who performs a centralized filling or centralized processing function for a prescription drug order. Originating pharmacies shall maintain appropriate records that identify, by prescription drug order, the name and initials or unique identification code of the pharmacist who performed drug use review and the pharmacist who transmitted the prescription drug order to the central fill or central processing pharmacy. These records may be maintained separately by each pharmacy or in a common electronic file as long as the data processing system is capable of producing a printout that lists the functions performed by each pharmacy and pharmacist or technician and identifies the pharmacist or technician who performed each function.

These rules are intended to implement Iowa Code sections 124.301, 124.306, 124.308, 155A.13, and 155A.28.

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CHAPTER 25
CHILD SUPPORT NONCOMPLIANCE

657—25.1(252J) Definitions. For the purpose of this chapter the following definitions shall apply:

"Act" means Iowa Code chapter 252J.

"Board" means the Iowa board of pharmacy examiners.

"Certificate" means a document known as a certificate of noncompliance which is provided by the child support unit certifying that the named licensee is not in compliance with a support order or with a written agreement for payment of support entered into by the child support unit and the licensee.

"Child support unit" means the child support recovery unit of the Iowa department of human services.

"Denial notice" means a board notification denying an application for the issuance or renewal of a license as required by the Act.

"License" means a license to practice pharmacy, a registration to practice as a pharmacist-intern, a registration to practice as a pharmacy technician, a registration to practice as a pharmacy support person, or a registration to possess, prescribe, dispense, administer, distribute, or otherwise handle controlled substances under Iowa Code chapter 124.

"Licensee" means an individual to whom a license has been issued or who is seeking the issuance of a license.

"Revocation or suspension notice" means a board notification suspending a license for an indefinite or specified period of time or a notification revoking a license as required by the Act.

"Withdrawal certificate" means a document known as a withdrawal of a certificate of noncompliance provided by the child support unit certifying that the certificate is withdrawn and that the board may proceed with issuance, reinstatement, or renewal of a license.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—25.2(252J) Issuance or renewal of license—denial. The board shall deny the issuance or renewal of a license upon the receipt of a certificate from the child support unit. This rule shall apply in addition to the procedures set forth in the Act.

25.2(1) *Service of denial notice.* Notice shall be served upon the licensee by certified mail, return receipt requested; by personal service; or through authorized counsel.

25.2(2) *Effective date of denial.* The effective date of the denial of issuance or renewal of a license, as specified in the notice, shall be 60 days following service of the notice upon the licensee.

25.2(3) *Preparation and service of denial notice.* The executive secretary/director of the board is authorized to prepare and serve the notice upon the licensee.

25.2(4) *Licensee responsible to inform board.* Licensees shall keep the board informed of all court actions and all child support unit actions taken under or in connection with the Act and shall provide the board with copies, within seven days of filing or issuance, of all applications filed with the district court pursuant to the Act, all court orders entered in such actions, and any withdrawal certificates issued by the child support unit.

25.2(5) *Reinstatement following license denial.* All board fees required for application, license renewal, or license reinstatement shall be paid by licensees before a license will be issued, renewed, or reinstated after the board has denied the issuance or renewal of a license pursuant to the Act.

25.2(6) *Effect of filing in district court.* In the event a licensee files a timely district court action following service of a notice, the board shall continue with the intended action described in the notice upon the receipt of a court order lifting the stay, dismissing the action, or otherwise directing the board to proceed. For purposes of determining the effective date of the denial of the issuance or renewal of a license, the board shall count the number of days before the action was filed and the number of days after the action was disposed of by the court.

25.2(7) *Final notification.* The board shall notify the licensee in writing through regular first-class mail, or such other means as the board determines appropriate in the circumstances, within ten days

of the effective date of the denial of the issuance or renewal of a license and shall similarly notify the licensee if the license is issued or renewed following the board's receipt of a withdrawal certificate.

657—25.3(252J) Suspension or revocation of a license. The board shall suspend or revoke a license upon the receipt of a certificate from the child support unit according to the procedures set forth in the Act. This rule shall apply in addition to the procedures set forth in the Act.

25.3(1) *Service of revocation or suspension notice.* Revocation or suspension notice shall be served upon the licensee by certified mail, return receipt requested; by personal service; or through authorized counsel.

25.3(2) *Effective date of revocation or suspension.* The effective date of the suspension or revocation of a license, as specified in the revocation or suspension notice, shall be 60 days following service of the revocation or suspension notice upon the licensee.

25.3(3) *Preparation and service of revocation or suspension notice.* The executive secretary/director of the board is authorized to prepare and serve the revocation or suspension notice upon the licensee and is directed to notify the licensee that the license will be suspended unless the license is already suspended on other grounds. In the event that the license is on suspension, the executive secretary/director shall notify the licensee of the board's intention to revoke the license.

25.3(4) *Licensee responsible to inform board.* The licensee shall keep the board informed of all court actions and all child support unit action taken under or in connection with the Act and shall provide the board with copies, within seven days of filing or issuance, of all applications filed with the district court pursuant to the Act, all court orders entered in such actions, and any withdrawal certificates issued by the child support unit.

25.3(5) *Reinstatement following license suspension, revocation, or denial of renewal.* A licensee shall pay all board fees required for license renewal or license reinstatement, and all continuing education requirements shall be met, before a license will be reinstated after the board has suspended a license pursuant to the Act. A licensee whose license to practice pharmacy has been revoked shall complete the examination components as indicated in rule 657—2.10(155A) and shall pay all required examination fees pursuant to rule 657—2.2(147). A licensee whose registration to practice as a pharmacist-intern, as a pharmacy technician, or as a pharmacy support person or whose registration to handle controlled substances under Iowa Code chapter 124 has been revoked shall complete application and pay all board fees required for new registration.

25.3(6) *Effect of filing in district court.* In the event a licensee files a timely district court action pursuant to the Act and following service of a revocation or suspension notice, the board shall continue with the intended action described in the revocation or suspension notice upon the receipt of a court order lifting the stay, dismissing the action, or otherwise directing the board to proceed. For purposes of determining the effective date of the suspension or revocation, the board shall count the number of days before the action was filed and the number of days after the action was disposed of by the court.

25.3(7) *Final notification.* The board shall notify the licensee in writing through regular first-class mail, or such other means as the board determines appropriate in the circumstances, within ten days of the effective date of the suspension or revocation of a license and shall similarly notify the licensee if a license is reinstated following the board's receipt of a withdrawal certificate.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—25.4(17A,22,252J) Share information. Notwithstanding any statutory confidentiality provision, the board may share information with the child support unit through manual or automated means for the sole purpose of identifying applicants or licensees subject to enforcement under the Act.

These rules are intended to implement Iowa Code chapter 252J.

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CHAPTER 31
STUDENT LOAN DEFAULT OR NONCOMPLIANCE WITH AGREEMENT FOR PAYMENT OF OBLIGATION

657—31.1(261) Definitions. For the purpose of this chapter, the following definitions shall apply:

"Act" means Iowa Code sections 261.121 to 261.127.

"Board" means the Iowa board of pharmacy examiners.

"Certificate" means a document known as a certificate of noncompliance from the college student aid commission certifying that the named licensee is not in compliance with the terms of an agreement for payment of a student loan obligation.

"Commission" means the college student aid commission.

"Denial notice" means a board notification denying an application for the issuance or renewal of a license as required by the Act.

"License" means a license to practice pharmacy, a registration to practice as a pharmacist-intern, a registration to practice as a pharmacy technician, a registration to practice as a pharmacy support person, or a registration to possess, prescribe, dispense, administer, distribute, or otherwise handle controlled substances under Iowa Code chapter 124.

"Licensee" means an individual to whom a license has been issued or who is seeking the issuance of a license.

"Revocation or suspension notice" means a board notification suspending a license for an indefinite or specified period of time or a notification revoking a license as required by the Act.

"Withdrawal certificate" means a document known as a withdrawal of a certificate of noncompliance provided by the commission certifying that the certificate is withdrawn and that the board may proceed with issuance, reinstatement, or renewal of a license.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—31.2(261) Issuance or renewal of a license—denial. The board shall deny the issuance or renewal of a license upon receipt of a certificate from the commission according to the procedures set forth in Iowa Code sections 261.121 to 261.127.

31.2(1) *Service of denial notice.* Notice shall be served upon the licensee by restricted certified mail, return receipt requested, or by personal service in accordance with the Iowa Rules of Civil Procedure. Alternatively, the licensee may accept service personally or through authorized counsel.

31.2(2) *Effective date of denial.* The effective date of the denial of issuance or renewal of a license, as specified in the notice, shall be 60 days following service of the notice upon the licensee.

31.2(3) *Preparation and service of denial notice.* The executive secretary/director of the board is authorized to prepare and serve the notice upon the licensee.

31.2(4) *Licensee responsible to inform board.* Licensees shall keep the board informed of all court actions and all commission actions taken under or in connection with the Act and shall provide the board copies, within seven days of filing or issuance, of all applications filed with the district court pursuant to Iowa Code section 261.127, all court orders entered in such actions, and any withdrawal certificates issued by the commission.

31.2(5) *Reinstatement following license denial.* All board fees required for application, license renewal, or license reinstatement shall be paid by licensees, and all continuing education requirements shall be met, before a license will be issued, renewed, or reinstated after the board has denied the issuance or renewal of a license pursuant to the Act.

31.2(6) *Effect of filing in district court.* In the event a licensee timely files a district court action following service of a board notice pursuant to Iowa Code sections 261.126 and 261.127, the board shall continue with the intended action described in the notice upon the receipt of a court order lifting the stay, dismissing the action, or otherwise directing the board to proceed. For purposes of determining the effective date of the denial of the issuance or renewal of a license, the board shall count the number of days before the action was filed and the number of days after the action was disposed by the court.

31.2(7) *Final notification.* The board shall notify the licensee in writing through regular first-class mail, or such other means as the board deems appropriate in the circumstances, within ten days of the effective date of the denial of the issuance or renewal of a license and shall similarly notify the licensee when the license is issued or renewed following the board's receipt of a withdrawal certificate.

657—31.3(261) Suspension or revocation of a license. The board shall suspend or revoke a license upon receipt of a certificate from the commission according to the procedures set forth in the Act. This rule shall apply in addition to the procedures set forth in the Act.

31.3(1) *Service of revocation or suspension notice.* Notice shall be served upon the licensee by restricted certified mail, return receipt requested, or by personal service in accordance with the Iowa Rules of Civil Procedure. Alternatively, the licensee may accept service personally or through authorized counsel.

31.3(2) *Effective date of revocation or suspension.* The effective date of the revocation or suspension of a license, as specified in the notice, shall be 60 days following service of the notice upon the licensee.

31.3(3) *Preparation and service of revocation or suspension notice.* The executive secretary/director of the board is authorized to prepare and serve the notice upon the licensee and is directed to notify the licensee that the license will be suspended unless the license is already suspended on other grounds. In the event that the license is on suspension, the executive secretary/director shall notify the licensee of the board's intention to revoke the license.

31.3(4) *Licensee responsible to inform board.* Licensees shall keep the board informed of all court actions and all commission actions taken under or in connection with the Act and shall provide the board copies, within seven days of filing or issuance, of all applications filed with the district court pursuant to Iowa Code section 261.127, all court orders entered in such actions, and any withdrawal certificates issued by the commission.

31.3(5) *Reinstatement following license suspension, revocation, or denial of renewal.* All board fees required for license renewal or license reinstatement shall be paid by licensees, and all continuing education requirements shall be met, before a license will be renewed or reinstated after the board has suspended a license pursuant to the Act. A licensee whose license to practice pharmacy has been revoked shall complete the examination components as indicated in rule 657—2.10(155A) and shall pay all required examination fees pursuant to rule 657—2.2(147). A licensee whose registration to practice as a pharmacist-intern, as a pharmacy technician, or as a pharmacy support person or whose registration to handle controlled substances under Iowa Code chapter 124 has been revoked shall complete application and pay all board fees required for new registration.

31.3(6) *Effect of filing in district court.* In the event a licensee timely files a district court action following service of a board notice pursuant to Iowa Code sections 261.126 and 261.127, the board shall continue with the intended action described in the notice upon the receipt of a court order lifting the stay, dismissing the action, or otherwise directing the board to proceed. For purposes of determining the effective date of the suspension or revocation of a license, the board shall count the number of days before the action was filed and the number of days after the action was disposed by the court.

31.3(7) *Final notification.* The board shall notify the licensee in writing through regular first-class mail, or such other means as the board deems appropriate in the circumstances, within ten days of the effective date of the suspension or revocation of a license and shall similarly notify the licensee when the license is reinstated following the board's receipt of a withdrawal certificate.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—31.4(17A,22,261) Share information. Notwithstanding any statutory confidentiality provision, the board may share information with the commission through manual or automated means for the sole purpose of identifying applicants or licensees subject to enforcement under the Act.

These rules are intended to implement Iowa Code sections 261.121 to 261.127.

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CHAPTER 32
NONPAYMENT OF STATE DEBT

657—32.1(272D) Definitions. For the purpose of this chapter, the following definitions shall apply:

"Act" means Iowa Code chapter 272D.

"Board" means the Iowa board of pharmacy.

"Certificate" means a document known as a certificate of noncompliance provided by the unit certifying that the named licensee has outstanding liability placed with the unit and has not entered into an approved payment plan to pay the liability.

"Denial notice" means a board notification denying an application for the issuance or renewal of a license as required by the Act.

"Liability" means a debt or obligation placed with the unit for collection that is greater than $1000. For purposes of this chapter, "liability" does not include support payments collected pursuant to Iowa Code chapter 252J.

"License" means a license to practice pharmacy, a registration to practice as a pharmacist-intern, a registration to practice as a pharmacy technician, a registration to practice as a pharmacy support person, or a registration to possess, prescribe, dispense, administer, distribute, or otherwise handle controlled substances under Iowa Code chapter 124.

"Licensee" means an individual to whom a license has been issued or who is seeking the issuance of a license.

"Revocation or suspension notice" means a board notification suspending a license for an indefinite or specified period of time or a notification revoking a license as required by the Act.

"Unit" means the centralized collection unit of the department of revenue.

"Withdrawal certificate" means a document known as a withdrawal of a certificate of noncompliance provided by the unit certifying that the certificate is withdrawn and that the board may proceed with issuance, reinstatement, or renewal of a license.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—32.2(272D) Issuance or renewal of a license—denial. The board shall deny the issuance or renewal of a license upon receipt of a certificate from the unit according to the procedures set forth in the Act.

32.2(1) *Service of denial notice.* Notice shall be served upon the licensee by restricted certified mail, return receipt requested, or by personal service in accordance with the Iowa Rules of Civil Procedure. Alternatively, the licensee may accept service personally or through authorized counsel.

32.2(2) *Effective date of denial.* The effective date of the denial of issuance or renewal of a license, as specified in the notice, shall be 60 days following service of the notice upon the licensee.

32.2(3) *Preparation and service of denial notice.* The executive director of the board is authorized to prepare and serve the notice upon the licensee.

32.2(4) *Licensee responsible to inform board.* Licensees shall keep the board informed of all court actions and all unit actions taken under or in connection with the Act and shall provide the board copies, within seven days of filing or issuance, of all applications filed with the district court pursuant to Iowa Code section 272D.9, all court orders entered in such actions, and any withdrawal certificates issued by the unit.

32.2(5) *Reinstatement following license denial.* All board fees required for application, license renewal, or license reinstatement shall be paid by the licensee and all continuing education requirements shall be met before a license will be issued, renewed, or reinstated after the board has denied the issuance or renewal of a license pursuant to the Act.

32.2(6) *Effect of filing in district court.* In the event a licensee timely files a district court action following service of a board notice pursuant to Iowa Code sections 272D.8 and 272D.9, the board shall continue with the intended action described in the notice upon the receipt of a court order lifting the stay, dismissing the action, or otherwise directing the board to proceed. For purposes of determining the

effective date of the denial of the issuance or renewal of a license, the board shall count the number of days before the action was filed and the number of days after the action was disposed of by the court.

32.2(7) *Final notification.* The board shall notify the licensee in writing through regular first-class mail, or such other means as the board deems appropriate in the circumstances, within ten days of the effective date of the denial of the issuance or renewal of a license and shall similarly notify the licensee when the license is issued or renewed following the board's receipt of a withdrawal certificate.

657—32.3(272D) Suspension or revocation of a license. The board shall suspend or revoke a license upon receipt of a certificate from the unit according to the procedures set forth in the Act. This rule shall apply in addition to the procedures set forth in the Act.

32.3(1) *Service of revocation or suspension notice.* Notice shall be served upon the licensee by restricted certified mail, return receipt requested, or by personal service in accordance with the Iowa Rules of Civil Procedure. Alternatively, the licensee may accept service personally or through authorized counsel.

32.3(2) *Effective date of revocation or suspension.* The effective date of the revocation or suspension of a license, as specified in the notice, shall be 60 days following service of the notice upon the licensee.

32.3(3) *Preparation and service of revocation or suspension notice.* The executive director of the board is authorized to prepare and serve the notice upon the licensee and is directed to notify the licensee that the license will be suspended unless the license is already suspended on other grounds. In the event that the license is on suspension, the executive director shall notify the licensee of the board's intention to revoke the license.

32.3(4) *Licensee responsible to inform board.* Licensees shall keep the board informed of all court actions and all unit actions taken under or in connection with the Act and shall provide the board copies, within seven days of filing or issuance, of all applications filed with the district court pursuant to Iowa Code section 272D.9, all court orders entered in such actions, and any withdrawal certificates issued by the unit.

32.3(5) *Reinstatement following license suspension, revocation, or denial of renewal.* All board fees required for license renewal or license reinstatement shall be paid by the licensee and all continuing education requirements shall be met before a license will be renewed or reinstated after the board has suspended a license pursuant to the Act. A licensee whose license to practice pharmacy has been revoked shall complete the examination components as indicated in rule 657—2.10(155A) and shall pay all required examination fees pursuant to rule 657—2.2(155A). A licensee whose registration to practice as a pharmacist-intern, as a pharmacy technician, or as a pharmacy support person or whose registration to handle controlled substances under Iowa Code chapter 124 has been revoked shall complete application and pay all board fees required for new registration.

32.3(6) *Effect of filing in district court.* In the event a licensee timely files a district court action following service of a board notice pursuant to Iowa Code sections 272D.8 and 272D.9, the board shall continue with the intended action described in the notice upon the receipt of a court order lifting the stay, dismissing the action, or otherwise directing the board to proceed. For purposes of determining the effective date of the suspension or revocation of a license, the board shall count the number of days before the action was filed and the number of days after the action was disposed of by the court.

32.3(7) *Final notification.* The board shall notify the licensee in writing through regular first-class mail, or such other means as the board deems appropriate in the circumstances, within ten days of the effective date of the suspension or revocation of a license and shall similarly notify the licensee when the license is reinstated following the board's receipt of a withdrawal certificate.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—32.4(17A,22,272D) Share information. Notwithstanding any statutory confidentiality provision, the board may share information with the unit through manual or automated means for the sole purpose of identifying applicants or licensees subject to enforcement under the Act.

These rules are intended to implement Iowa Code chapter 272D.

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CHAPTER 36
DISCIPLINE

657—36.1(147,155A,272C) Authority and grounds for discipline.

36.1(1) *Jurisdiction of the board.* The board has the authority to impose discipline for any violations of Iowa Code chapters 124, 124A, 124B, 126, 147, 155A, 205, and 272C or the rules promulgated thereunder.

36.1(2) *Disciplinary sanctions.* The board has the authority to impose the following disciplinary sanctions:

a. Revocation of a registration, a permit, or a license issued by the board.

b. Suspension of a registration, a permit, or a license issued by the board until further order of the board or for a specified period.

c. Nonrenewal of a registration, a permit, or a license issued by the board.

d. Prohibit permanently, until further order of the board, or for a specified period, the engaging in specified procedures, methods or acts.

e. Probation.

f. Require a pharmacist or a pharmacist-intern to complete additional education or training.

g. Require a pharmacist to successfully complete any reexamination for licensure.

h. Order a pharmacist, pharmacist-intern, pharmacy technician, or pharmacy support person to undergo a physical or mental examination.

i. Impose civil penalties not to exceed $25,000.

j. Issue citation and warning.

k. Such other sanctions allowed by law as may be appropriate.

36.1(3) *Considerations in determining sanctions.* The board may consider the following factors in determining the nature and severity of the disciplinary sanction to be imposed:

a. The relative seriousness of the violation as it relates to assuring the citizens of this state a high standard of professional care.

b. The facts of the particular violation.

c. Any extenuating circumstances or other countervailing considerations.

d. Number of prior violations or complaints.

e. Seriousness of prior violations or complaints.

f. Whether remedial action has been taken.

g. Any other factors as may reflect upon the competency, ethical standards, and professional conduct of the licensee, registrant, or permittee.

36.1(4) *Grounds for discipline.* The board may impose any of the disciplinary sanctions set out in subrule 36.1(2) when the board determines that the licensee, registrant, or permittee is guilty of the following acts or offenses:

a. Fraud in procuring a license. Fraud in procuring a license includes but is not limited to an intentional perversion of the truth in making application for a license to practice pharmacy, to operate a pharmacy doing business in this state, or to operate as a wholesale drug distributor doing business in this state, or in making application for a registration to practice as a pharmacist-intern, a pharmacy technician, or a pharmacy support person. It includes false representations of a material fact, whether by word or conduct, by false or misleading allegations, or by concealment of that which should have been disclosed when making application, or attempting to file or filing with the board any false or forged diploma, certificate, affidavit, identification, or qualification in making application for a license or registration in this state.

b. Professional incompetency. Professional incompetency includes but is not limited to:

(1) A substantial lack of knowledge or ability to discharge professional obligations within the scope of the pharmacist's practice.

(2) A substantial deviation by a pharmacist from the standards of learning or skill ordinarily possessed and applied by other pharmacists in the state of Iowa acting in the same or similar circumstances.

(3) A failure by a pharmacist to exercise in a substantial respect that degree of care which is ordinarily exercised by the average pharmacist in the state of Iowa acting under the same or similar circumstances.

(4) A willful or repeated departure from, or the failure to conform to, the minimal standard or acceptable and prevailing practice of pharmacy in the state of Iowa.

c. Knowingly making misleading, deceptive, untrue or fraudulent representations in the practice of pharmacy or engaging in unethical conduct or practice harmful or detrimental to the public. Proof of actual injury need not be established.

d. Habitual intoxication or addiction to the use of drugs. Habitual intoxication or addiction to the use of drugs includes, but is not limited to:

(1) The inability of a licensee or registrant to practice with reasonable skill and safety by reason of the excessive use of alcohol on a continuing basis.

(2) The excessive use of drugs which may impair a licensee's or registrant's ability to practice with reasonable skill or safety.

e. Conviction of a felony related to the profession or occupation of the licensee or registrant, or a conviction of a felony that would affect the licensee's or registrant's ability to practice within the licensee's or registrant's profession. A copy of the record of conviction or a plea of guilty shall be conclusive evidence.

f. Fraud in representations as to skill or ability. Fraud in representations as to skill or ability includes, but is not limited to, a pharmacist having made deceptive or untrue representations as to competency to perform professional services which the pharmacist is not qualified to perform by virtue of training or experience.

g. Use of untrue or improbable statements in advertisements.

h. Distribution of drugs for other than lawful purposes. The distribution of drugs for other than lawful purposes includes, but is not limited to, the disposition of drugs in violation of Iowa Code chapters 124, 126, and 155A.

i. Willful or repeated violations of the provisions of Iowa Code chapter 147 or Iowa Code chapter 272C. Willful or repeated violations of these Acts include, but are not limited to, a pharmacist's, pharmacist-intern's, pharmacy technician's, or pharmacy support person's intentionally or repeatedly violating a lawful rule or regulation promulgated by the board of pharmacy or the state department of public health, violating a lawful order of the board in a disciplinary hearing, or violating the provisions of Title IV (Public Health) of the Code of Iowa.

j. Violating a statute or law of this state, another state, or the United States, without regard to its designation as either a felony or misdemeanor, which statute or law relates to the practice of pharmacy or the distribution of controlled substances, prescription drugs, or nonprescription drugs.

k. Failure to notify the board within 30 days after a final decision entered by the licensing authority of another state, territory, or country which decision resulted in a license or registration revocation, suspension, or other disciplinary sanction.

l. Knowingly aiding, assisting, procuring, or advising another person to unlawfully practice pharmacy or to unlawfully perform the functions of a pharmacist-intern, a pharmacy technician, or a pharmacy support person.

m. Inability of a licensee or registrant to practice with reasonable skill and safety by reason of mental or physical impairment or chemical abuse.

n. Being adjudged mentally incompetent by a court of competent jurisdiction. Such adjudication shall automatically suspend a license or registration for the duration of the license or registration unless the board otherwise orders.

o. Submission of a false report of continuing education or failure to submit biennial reports of continuing education.

p. Failure to notify the board within 30 days after occurrence of any judgment or settlement of a malpractice court claim or action.

q. Failure to file the reports required by subrule 36.2(3) concerning acts or omissions committed by another licensee or registrant.

r. Willful or repeated malpractice.

s. Willful or gross negligence.

t. Obtaining any fee by fraud or misrepresentation.

u. Violating any of the grounds for revocation or suspension of a license or registration listed in Iowa Code sections 147.55, 155A.12, and 155A.15 or any of the rules of the board.

v. Practicing pharmacy without an active and current Iowa pharmacist license, operating a pharmacy without a current pharmacy license, operating a prescription drug wholesale facility without a current wholesale drug license, practicing as a pharmacist-intern without a current pharmacist-intern registration, assisting a pharmacist with technical functions associated with the practice of pharmacy without a current pharmacy technician registration except as provided in rule 657—3.3(155A), introductory paragraph, or assisting a pharmacist with nontechnical functions associated with the practice of pharmacy without a current pharmacy support person registration.

w. Attempting to circumvent the patient counseling requirements, or discouraging patients from receiving patient counseling concerning their prescription drug orders.

x. Noncompliance with a child support order or with a written agreement for payment of child support as evidenced by a certificate of noncompliance issued pursuant to Iowa Code chapter 252J.

y. Student loan default or noncompliance with the terms of an agreement for payment of a student loan obligation as evidenced by a certificate of noncompliance issued pursuant to Iowa Code chapter 261 or default on a repayment or service obligation under any federal or state educational loan or service-conditional scholarship program upon certification by the program of such a default.

z. Engaging in any conduct that subverts or attempts to subvert a board investigation.

aa. Employing or continuing to employ as a practicing pharmacist any person whose Iowa pharmacist license is not current and active, employing or continuing to employ a person to assist a pharmacist with technical functions associated with the practice of pharmacy who is not currently registered as a pharmacy technician except as provided in rule 657—3.3(155A), introductory paragraph, or employing or continuing to employ a person to assist a pharmacist with nontechnical functions associated with the practice of pharmacy who is not currently registered as a pharmacy support person.

ab. Retaliatory action. Retaliating against a pharmacist, pharmacist-intern, pharmacy technician, or pharmacy support person for making allegations of illegal or unethical activities, making required reports to the board, or cooperating with a board investigation or survey.

ac. Failing to create and maintain complete and accurate records as required by state or federal law, regulation, or rule of the board.

ad. Violating the pharmacy or drug laws or rules of another state while under the jurisdiction of that state.

ae. Having a license to practice pharmacy issued by another state canceled, revoked, or suspended for conduct substantially equivalent to any of the grounds for disciplinary action in Iowa. A copy of the record from the state taking the disciplinary action shall be conclusive evidence of the action taken by that state.

af. Failure to comply with mandatory child or dependent adult abuse reporter training requirements.

ag. Failure to timely provide to the board or a representative of the board prescription fill data or other required pharmacy or controlled substances records.

ah. Nonpayment of a state debt as evidenced by a certificate of noncompliance issued pursuant to Iowa Code chapter 272D.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—36.2(155A,272C) Investigations.

36.2(1) *General.* The board may, upon receipt of a written or verbal complaint or upon its own motion pursuant to other evidence received by the board, review and investigate alleged acts or omissions that the board reasonably believes constitute cause under applicable law or administrative rules for licensee, registrant, or permittee discipline.

36.2(2) *Reporting of judgments or settlements.* Each licensee or registrant shall report to the board every adverse judgment in a malpractice action to which the pharmacy, pharmacist, pharmacist-intern,

pharmacy technician, or pharmacy support person is a party, and every settlement of a claim alleging malpractice. The report must be filed within 30 days from the date of the judgment or settlement.

36.2(3) *Reporting of acts or omissions.* Each licensee or registrant having firsthand knowledge of acts or omissions set forth in subrule 36.1(4) shall report to the board within 30 days of initially acquiring the information those acts or omissions committed by another person licensed to practice pharmacy or registered to practice as a pharmacist-intern, as a pharmacy technician, or as a pharmacy support person. The report shall include the name and other available information identifying the licensee or registrant and the date, time, and place of the incident.

36.2(4) *Confidentiality of investigative files.* Complaint files, investigation files, and all other investigation reports and investigative information in the possession of the board or its employees or agents that relate to licensee, permittee, or registrant discipline shall be privileged and confidential pursuant to Iowa Code section 272C.6(4).

36.2(5) *Investigation of allegations.* In order to determine if probable cause exists for a disciplinary hearing, the board, the executive secretary/director, or someone designated by the executive secretary/director shall cause an investigation to be made into the allegations of the complaint. The licensee, registrant, or permittee complained of shall be given the opportunity to present to the investigator a position or defense respecting the allegations of the complaint prior to the commencement of a contested case.

36.2(6) *Investigatory subpoena powers.* The board is authorized by law to subpoena books, papers, records, and any other real evidence, whether or not privileged or confidential under law, to help determine whether a contested case proceeding (hearing) should be commenced.

36.2(7) *Investigative report.* Upon completion of the investigation, the investigator(s) shall prepare a report for the board's consideration. The report may contain the position or defense of the respondent, discuss jurisdiction, and set forth any legal arguments and authorities that appear applicable to the case.

36.2(8) *Board consideration.* The board shall review all investigations. Participation in the review shall not bar any board member from participating in any subsequent disciplinary proceeding.

a. *Board action.* After reviewing an investigation, the board may either institute a disciplinary proceeding by filing one or more statements of charges, send a confidential letter of education or administrative warning to the licensee, registrant or permittee, request additional investigation, or close the case without further investigation.

b. *Confidential action.* If the board determines that formal disciplinary action is not warranted, the board may send a confidential letter of education or administrative warning to the licensee, registrant or permittee. The purpose of a confidential letter of education or administrative warning is to alert the licensee, registrant or permittee to possible violations of Iowa law or board rules so that the licensee, registrant or permittee may address the issues. Confidential letters of education and administrative warnings do not constitute formal disciplinary action and are not public records. The board shall maintain a copy of the confidential letter of education or administrative warning in the confidential investigative file regarding the licensee, registrant or permittee. Confidential letters of education and administrative warnings may be used as evidence against a licensee, registrant or permittee in future administrative hearings.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—36.3(147,272C) Peer review committees.

36.3(1) *Establish committee.* The board may establish and register peer review committees.

36.3(2) *Referral to committee.* The board shall determine which complaints or other matters shall be referred to a peer review committee for investigation, review, and report to the board.

36.3(3) *Services to committee.* The board may provide investigatory and related services to a peer review committee upon request.

36.3(4) *Investigation by committee.* A peer review committee may determine the method to be used in making its investigation, or that it is unable to investigate the report upon a complaint and return the complaint, together with an explanation, to the board.

36.3(5) *Confidentiality.* A peer review committee shall observe the requirements of confidentiality imposed by Iowa Code section 272C.6.

36.3(6) *Immunity from civil liability.* Members of a peer review committee shall not be liable for acts, omissions, or decisions made in connection with service on a peer review committee. However, immunity from civil liability shall not apply if the act is done with malice.

36.3(7) *Committee procedures.* A peer review committee shall submit to the board for approval the procedures to be used for review, investigation, and handling of all complaints.

657—36.4(17A,124,124B,126,147,155A,272C) Disciplinary proceedings. The proceeding for revocation, suspension, or other disciplinary sanctions against a pharmacy license, a wholesale drug license, a pharmacy technician registration, a pharmacy support person registration, a pharmacist-intern registration, or a license to practice pharmacy, or the denial of or refusal to issue or renew a license or registration, or the suspension, denial, or revocation of a permit to handle precursor substances shall be substantially in accordance with the procedures set forth in 657—Chapter 35 and these rules, which are in addition to the procedures stated in Iowa Code sections 147.58 et seq., and 155A.16.
[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—36.5(17A,124,124B,126,147,155A,272C) Notice of disciplinary hearing.

36.5(1) *Preparation of notice.* The executive secretary/director shall prepare the notice of hearing upon direction to do so by the board upon a probable cause determination.

36.5(2) *Contents.* The notice of hearing shall contain the information set forth in 657—subrule 35.5(2).

36.5(3) *Delivery.* Delivery of the notice shall constitute the commencement of the contested case proceeding, and delivery may be executed by one of the methods provided for in 657—subrule 35.5(1).

36.5(4) *Timely service – denial of renewal.* Notice of a hearing involving denial of license, permit, or registration renewal shall be served no later than 30 days before the expiration of the license, permit, or registration.

36.5(5) *Timely service – revocation or suspension.* Notice of a hearing involving revocation or suspension of a license, permit, or registration shall be served no less than 30 days before the time set for the hearing.

657—36.6(17A,124B,147,155A,272C) Informal settlement.

36.6(1) *Negotiating parties.*

a. A contested case may be resolved by informal settlement. The respondent or the board may initiate negotiation of an informal settlement.

b. The board chairperson may designate the executive secretary/director or one or more board members with authority to negotiate on behalf of the board.

36.6(2) *Waiver of notice and opportunity to be heard.* The decision to enter into informal settlement negotiations is voluntary on the part of the respondent. By entering into informal settlement negotiations, the respondent waives the right to seek disqualification of a board member pursuant to Iowa Code section 17A.17 and 657—35.9(17A) based on that board member's participation in the settlement negotiations. Upon initiation of negotiation, the assistant attorney general is authorized to discuss informal settlement with the board's designee. Consent to negotiation by the respondent also constitutes a waiver of notice and opportunity to be heard pursuant to Iowa Code section 17A.17 during informal settlement negotiation.

36.6(3) *Board approval.* All informal settlements are subject to approval of a majority of the full board. If the board fails to approve an informal settlement, it shall be of no force or effect to either party.

36.6(4) *Participation of designee.* A board member who is designated to act in negotiation of an informal settlement may review investigative material in the course of conducting the negotiation. The designated board member is not disqualified from participating in the adjudication of the contested case by virtue of reviewing the investigative material or having participated in negotiation discussions.

657—36.7(272C) Appearance. The respondent shall have the right to appear before the board in person or by attorney at the respondent's expense.

657—36.8(17A,124B,147,155A,272C) Order of proceedings. Before testimony is presented, the record shall show the identity of any board members present, the presiding hearing officer, the primary parties and their representatives, and the fact that all testimony is being recorded.

Hearings before the board generally follow the order established by this rule.

1. The presiding officer may read the specification of charges and the answer thereto, or other responsive pleading, filed by the respondent prior to the hearing.
2. The assistant attorney general representing the public interest before the board may make an opening statement.
3. Each respondent shall be offered the opportunity to make an opening statement. A respondent may elect to reserve an opening statement until just prior to the presentation of evidence by the respondent.
4. Evidence is presented on behalf of the public.
5. Evidence is presented on behalf of the respondent(s).
6. Rebuttal evidence is presented on behalf of the public.
7. Rebuttal evidence is presented on behalf of the respondent(s).
8. The parties are offered the opportunity to make closing arguments, first on behalf of the public, then on behalf of the respondent, and then on behalf of the public.

657—36.9(272C) Confidentiality. At no time prior to the release of the final decision by the board shall any portion or the whole thereof be made public or be distributed to any persons other than the parties.

657—36.10(17A,272C) Notification of decision. All parties to a proceeding hereunder shall be promptly furnished with a copy of any final decision or order either in person or by first-class mail, or by telephone if necessary to ensure that the parties learn of the decision or order first.

657—36.11(272C) Board decision. The board's decision and order to discipline a licensee, registrant, or permittee, or to revoke or suspend a license to practice pharmacy, a wholesale drug license, a license to operate a pharmacy, a registration to practice as a pharmacist-intern, a pharmacy technician, or a pharmacy support person, or a permit to handle precursor substances, shall remain in force and effect until the appeal is finally determined and disposed of upon its merit unless the board grants a stay of its decision as provided for in rule 657—35.28(17A).

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—36.12(17A,272C) Publication of decisions. Final decisions of the board relating to disciplinary proceedings are public records subject to Iowa Code chapter 22, examination of public records, and may be transmitted to the appropriate professional association and a newspaper of general circulation to be selected by the board.

657—36.13(17A,124B,147,155A,272C) Reinstatement. Any person whose license to practice pharmacy or to operate a pharmacy or whose wholesale drug license or permit to handle precursor substances or whose pharmacist-intern registration, pharmacy technician registration, or pharmacy support person registration has been revoked or suspended shall meet the following eligibility requirements for reinstatement:

36.13(1) *Prerequisites.* The individual shall satisfy all terms of the order of revocation or suspension or court proceedings as they apply to that revocation or suspension. If the order of revocation or suspension did not establish terms and conditions upon which reinstatement might occur, or if the license, registration, or permit was voluntarily surrendered, an initial application for reinstatement may not be made until one year has elapsed from the date of the board's order or the date of voluntary surrender.

36.13(2) *Pharmacist license revoked or surrendered—examinations required.* A person whose license to practice pharmacy was revoked or voluntarily surrendered must successfully pass the North American Pharmacist Licensure Examination (NAPLEX) or an equivalent examination as determined by NABP and the Multistate Pharmacy Jurisprudence Examination (MPJE), Iowa Edition.

36.13(3) *Proceedings.* The respondent shall initiate all proceedings for reinstatement by filing with the board an application for reinstatement of the license, registration, or permit. The application shall be docketed in the original case in which the license, registration, or permit was revoked, suspended, or surrendered. All proceedings upon petition for reinstatement, including all matters preliminary and ancillary thereto, shall be subject to the same rules of procedure as other cases before the board. The board and the respondent may informally settle the issue of reinstatement. The respondent may choose to have an informal reinstatement conference before the board, as provided in rule 657—36.14(17A,124B,147,155A,272C).

36.13(4) *Burden of proof.* An application for reinstatement shall allege facts which, if established, will be sufficient to enable the board to determine that the basis for the revocation or suspension no longer exists and that it will be in the public interest for the license, registration, or permit to be reinstated. The burden of proof to establish such facts shall be on the respondent.

36.13(5) *Order.* An order for reinstatement shall be based upon a decision that incorporates findings of facts and conclusions of law and shall be based upon the affirmative vote of a quorum of the board. This order shall be available to the public as provided in 657—Chapter 14.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—36.14(17A,124B,147,155A,272C) Informal reinstatement conference.

36.14(1) *Request.* Upon written request of the respondent and approval by the executive secretary/director of the board, an informal reinstatement conference may be held before the board.

36.14(2) *Confidentiality.* The conference shall be open to the public except as provided in Iowa Code chapter 21 and Iowa Code section 272C.6. Material submitted to the board regarding a licensee, registrant, or permittee subject to suspension or revocation and received prior to the filing of an application for reinstatement shall be deemed to be investigatory in nature and therefore confidential. If a request for an informal settlement conference is made and approved, all material submitted by the respondent to the board for its consideration shall be deemed public records and is not confidential. Upon filing a request for an informal reinstatement conference, the respondent consents to the provision of relevant materials to board members prior to the time of the informal reinstatement conference.

36.14(3) *Disposition.* After conducting an informal reinstatement conference, the board may issue a proposed order for reinstatement, may issue a proposed order denying reinstatement, or may order a formal hearing on the application.

36.14(4) *Appeal—formal hearing.* Upon appeal of a proposed order or upon the board's order for formal hearing, application for reinstatement shall be set for formal hearing subject to the same rules of procedure as other cases before the board. By consenting to the informal settlement conference, respondent waives any objection to any board member participating in a formal hearing by virtue of the board member's participation at the informal settlement conference. All materials submitted and statements made by the respondent at the informal settlement conference shall be admissible at a subsequent formal hearing.

36.14(5) *Final order.* A proposed order resulting from an informal reinstatement conference becomes the final decision of the board without further proceedings unless there is an appeal to, or review on motion of, the board within the time provided in rule 657—35.26(17A,124B,126,147,155A,205,272C).

657—36.15(17A,124B,147,155A,272C) Voluntary surrender of a license, permit, or registration. The voluntary surrender of a license to practice pharmacy, a license to operate a pharmacy, a wholesale drug license, a permit to handle precursor substances, a pharmacy technician registration, a pharmacy support person registration, or a pharmacist-intern registration shall be

considered a revocation of license, permit, or registration. A request for reinstatement shall be handled under the terms established by rule 657—36.13(17A,124B,147,155A,272C).
[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—36.16(17A,124B,147,155A,272C) License, permit, or registration denial. Any request for a hearing before the board concerning the denial of a license, permit, or registration shall be submitted by the applicant in writing to the board by certified mail, return receipt requested, within 30 days of a mailing of a notice of denial of license, permit, or registration.

657—36.17(155A,272C) Order for mental or physical examination. A pharmacist, pharmacist-intern, pharmacy technician, or pharmacy support person who is licensed or registered by the board is, as a condition of licensure or registration, under a duty to submit to a mental or physical examination within a time period specified by order of the board. Such examination may be ordered upon a showing of probable cause and shall be at the expense of the pharmacist, pharmacist-intern, pharmacy technician, or pharmacy support person.

36.17(1) *Content of order.* A board order for mental or physical examination shall include the following items:

a. A description of the type of examination to which the pharmacist, pharmacist-intern, pharmacy technician, or pharmacy support person must submit.

b. The name and address of the examiner or treatment facility that the board has identified to perform the examination on the pharmacist, pharmacist-intern, pharmacy technician, or pharmacy support person.

c. The time period in which the pharmacist, pharmacist-intern, pharmacy technician, or pharmacy support person must schedule the required examination.

d. The amount of time in which the pharmacist, pharmacist-intern, pharmacy technician, or pharmacy support person is required to complete the examination.

e. A requirement that the pharmacist, pharmacist-intern, pharmacy technician, or pharmacy support person cause a report of the examination results to be provided to the board within a specified period of time.

f. A requirement that the pharmacist, pharmacist-intern, pharmacy technician, or pharmacy support person communicate with the board regarding the status of the examination.

g. A provision allowing the pharmacist, pharmacist-intern, pharmacy technician, or pharmacy support person to request additional time to schedule or complete the examination or to request that the board approve an alternative examiner or treatment facility. The board shall, in its sole discretion, determine whether to grant such a request.

36.17(2) *Objection to order.* A licensee or registrant who is the subject of a board order and who objects to the order may file a request for hearing. The request for hearing shall specifically identify the factual and legal issues upon which the licensee or registrant bases the objection. The hearing shall be considered a contested case proceeding and shall be governed by the provisions of 657—Chapter 35. A contested case involving an objection to an examination order will be captioned in the name of Jane or John Doe in order to maintain the licensee's or registrant's confidentiality.

36.17(3) *Closed hearing.* Any hearing on an objection to the board order shall be closed pursuant to Iowa Code section 272C.6(4).

36.17(4) *Order and reports—confidential.* An examination order and any subsequent examination reports issued in the course of a board investigation are confidential investigative information pursuant to Iowa Code section 272C.6(4).
[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—36.18(272C) Disciplinary hearings—fees and costs.

36.18(1) *Definitions.* As used in this chapter in relation to a formal disciplinary action filed by the board against a licensee or registrant:

"Deposition" means the testimony of a person pursuant to subpoena or at the request of the state of Iowa taken in a setting other than a hearing.

"Expenses" means costs incurred by persons appearing pursuant to subpoena or at the request of the state of Iowa for purposes of providing testimony on the part of the state of Iowa in a hearing or other official proceeding and shall include mileage reimbursement at the rate specified in Iowa Code section 70A.9 or, if commercial air or ground transportation is used, the actual cost of transportation to and from the proceeding. Also included are actual costs incurred for meals and necessary lodging.

"Medical examination fees" means actual costs incurred by the board in a physical, mental, chemical abuse, or other impairment-related examination or evaluation of a licensee or registrant when the examination or evaluation is conducted pursuant to an order of the board.

"Transcript" means a printed verbatim reproduction of everything said on the record during a hearing or other official proceeding.

"Witness fees" means compensation paid by the board to persons appearing pursuant to subpoena or at the request of the state of Iowa, for purposes of providing testimony on the part of the state of Iowa. For the purposes of this rule, compensation shall be the same as outlined in Iowa Code section 622.69 or 622.72 as the case may be.

36.18(2) *Hearing fee and recoverable costs.* The board may charge a fee not to exceed $75 for conducting a disciplinary hearing that results in disciplinary action taken by the board against the license or registration. In addition to the fee, the board may recover from the licensee or registrant costs for the following procedures and personnel:

a. Transcript.

b. Witness fees and expenses.

c. Depositions.

d. Medical examination fees incurred relating to a person licensed or registered under Iowa Code chapter 147 or 169.

36.18(3) *Fees, costs are part of disciplinary order.* Fees and costs assessed by the board pursuant to subrule 36.18(2) shall be calculated by the board's executive secretary/director and shall be entered as part of the board's final disciplinary order. The board's final disciplinary order shall specify the time period in which the licensee or registrant shall pay the assessed fees and costs.

36.18(4) *Board treatment of collected fees, costs.* Fees and costs collected by the board pursuant to subrule 36.18(2) shall be allocated to the expenditure category of the board in which the hearing costs were incurred. The fees and costs shall be considered repayment receipts as defined in Iowa Code section 8.2.

36.18(5) *Failure to pay assessed fees, costs.* Failure of a licensee or registrant to pay the fees and costs assessed herein within the time period specified in the board's final disciplinary order shall constitute a violation of a lawful order of the board.

These rules are intended to implement Iowa Code sections 17A.10 to 17A.23, 124.301, 124.304, 124B.12, 126.16 to 126.18, 155A.6, 155A.12, 155A.13, 155A.13A, 155A.15 to 155A.18, 155A.25, 205.11, 272C.3 to 272C.6, 272C.9, and 272C.10.

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See ADMINISTRATIVE SERVICES DEPARTMENT (DAS); TOURISM

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