The Iowa Administrative Code Supplement is published biweekly pursuant to Iowa Code sections 2B.5A and 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 or suspension 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)242-6873

Agriculture and Land Stewardship Department[21]
   Replace Chapter 65

Insurance Division[191]
   Replace Chapter 10
   Replace Chapter 35
   Replace Chapter 76

Education Department[281]
   Replace Chapter 17

Pharmacy Board[657]
   Replace Analysis
   Replace Chapter 6
   Replace Chapter 8
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   Replace Chapter 20

Transportation Department[761]
   Replace Chapter 634
CHAPTER 65
ANIMAL AND LIVESTOCK IMPORTATION
[Appeared as Ch 3, 1973 IDR]
[Prior to 7/27/88, see Agriculture Department 30—Ch 17]

21—65.1(163) Definitions.

“Accredited veterinarian” means a veterinarian licensed in the state of origin and approved by the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), to perform certain functions of federal and cooperative state-federal programs in accordance with the provision of Title 9 Code of Federal Regulations (CFR) §160 through §162.

“Avian influenza- or virulent Newcastle disease-affected area” or “AI- or VND-affected area” means the ten-kilometer circle in which avian influenza subtype H5 or H7 or VND virus has been diagnosed in poultry within the last 30 days prior to importation, unless the department has issued an order during the 30 days identifying a different area or time based on epidemiological reasons.

“Domestic fowl” means any member of the class Aves that is propagated or maintained under control of a person for commercial, exhibition, or breeding purposes or as a pet.

“Feral swine” means swine that are free-roaming.

“Official individual identification” means a unique individual identification that is secure and traceable including, but not limited to, a USDA-approved identification ear tag that conforms to the alphanumeric national uniform ear tagging system; a USDA-approved premises tattoo; a registered purebred tattoo; or identification that conforms to the National Animal Identification System. An owner’s private brand or tattoo, even though permanent and registered in the state of origin, is not acceptable official individual identification of an animal for the purpose of entry into Iowa.

“Poultry” means chickens, turkeys, domestic waterfowl, raptors, and domestic game birds, except doves and pigeons.

“Pre-entry permit” means a written or verbal authorization provided by the department prior to the importation of animals into Iowa. If required, a pre-entry permit number must be obtained and listed on the Certificate of Veterinary Inspection accompanying the animals.

“Recognized slaughter establishment” means a slaughtering establishment operating under the provisions of either the Federal Meat Inspection Act (21 U.S.C. 601 et seq.) or an equivalent state meat inspection program.

“Specifically approved auction market” means a stockyard, livestock market, buying station, concentration point, or any other premises under state or federal veterinary supervision where livestock are assembled for sale or sale purposes and which has been approved by USDA as provided in 9 CFR §71.20.

“Transitional swine” means swine that have been, or have had the potential to be, exposed to feral swine.

“Vesicular stomatitis-affected state” or “VS-affected state” means any state in which vesicular stomatitis (VS) virus serotype New Jersey or Indiana has been diagnosed within the last 60 days prior to animal importation.

[ARC 3993C, IAB 9/12/18, effective 10/17/18]

21—65.2(163) Pre-entry permits.

65.2(1) Requests for permits should be directed to the Animal Industry Bureau, Department of Agriculture and Land Stewardship, Wallace State Office Building, Des Moines, Iowa 50319, or may be made by telephoning the bureau at (515)281-5547 during normal business hours.

65.2(2) All permits shall be valid for one shipment only and shall be void 15 days after the date of issuance.

65.2(3) Pre-entry permits are required for:

a. All Cervidae.

b. All domestic fowl or poultry originating from an AI- or VND-affected area.

c. Captive wild-type swine.
d. Cattle and bison originating from states or zones not classified as tuberculosis-free and brucellosis-free.

[ARC 9151B, IAB 10/20/10, effective 9/20/10; ARC 3993C, IAB 9/12/18, effective 10/17/18]

21—65.3(163) General requirements and limitations.

65.3(1) Restricted animals. The following animals are restricted from importation into the state:

a. No animal, including poultry or birds of any species, that is affected with, or that has been recently exposed to, any infectious, contagious or communicable disease or that originates from a quarantined area shall be shipped or in any manner transported or moved into Iowa, unless approved by the state veterinarian.

b. Prairie dogs (Cynomys sp.), tree squirrels (Heliosciurus sp.), rope squirrels (Funisciurus sp.), dormice (Graphiurus sp.), Gambian giant pouched rats (Cricetomys sp.), brush-tailed porcupines (Atherurus sp.), and striped mice (Hybomys sp.) are prohibited from importation into the state.

65.3(2) Cleaning and disinfection of transportation vehicles. All stock cars and trucks used for hauling into the state of Iowa livestock (cattle, horses, sheep, goats, Cervidae, poultry and swine) for feeding, breeding, or stock purposes must be cleaned and disinfected before such shipments of livestock are loaded.

65.3(3) Certificate of Veterinary Inspection (CVI). Animals imported into the state must be accompanied by a Certificate of Veterinary Inspection, unless specifically exempted by this chapter.

a. A Certificate of Veterinary Inspection is a legible record accomplished on an official form of the state of origin, issued by a licensed accredited veterinarian and approved by the chief livestock health official of the state of origin; or an equivalent form of the United States Department of Agriculture (USDA) issued by a federally employed veterinarian. A Certificate of Veterinary Inspection may be an official paper form or an official approved electronic form.

b. A copy of the approved CVI shall be forwarded immediately to the chief livestock health official of the state of origin for approval and transmittal.

c. An approved CVI shall not be valid more than 30 days from the date of inspection of the animals.

d. The approved CVI must accompany the animals to their final destination in Iowa.

e. All information required on the CVI must be fully completed by the issuing veterinarian and must include the following:

(1) Name and address of the consignor;
(2) Name and address of the consignee;
(3) Point of origin and premises identification, if assigned by the chief livestock health official in the state of origin;
(4) Point of destination of the animals;
(5) Date of examination;
(6) Number of animals examined;
(7) Official individual identification or group identification of all animals;
(8) Sex, age, and breed of each animal;
(9) Test results and herd or state status on diseases specified in this chapter;
(10) Pre-entry permit number, if required; and
(11) A statement by the issuing veterinarian that the animals identified on the CVI are free of signs of infectious or communicable disease.

65.3(4) Certification for vesicular stomatitis (VS). All hoofed animals, including horses, ruminants, swine, and exotic and wild hoofed animals, originating from a VS-affected state must be accompanied by an official Certificate of Veterinary Inspection which, in addition to meeting the requirements of subrule 65.3(3), includes the following statement: “All animals susceptible to Vesicular Stomatitis (VS) identified and included on this certificate have been examined and found to be free from clinical signs of VS, have not been exposed to VS, and, within the past 30 days, have not been within ten (10) miles of any site under quarantine for VS.”

1 Objection filed 1/9/81; see “Objection” at the end of this chapter.
21—65.4(163) Cattle and bison.

65.4(1) General.
   a. Certificate of Veterinary Inspection (CVI). All cattle and bison imported into the state must be accompanied by a CVI, except the following:
      (1) Cattle or bison consigned directly to a specifically approved auction market, and
      (2) Cattle or bison consigned directly to a recognized slaughter establishment.
   b. Identification. All cattle and bison imported into the state must have official individual identification, except as otherwise provided in this rule.

65.4(2) Requirements and limitations, general.
   a. Cattle or bison originating from herds or areas under quarantine shall not be admitted into the state.
   b. Cattle or bison known to be infected with Johnne’s disease shall not be imported except to a recognized slaughter establishment and shall be accompanied by an owner-shipper statement that identifies the animals as positive to an official Johnne’s disease test. Such statement shall be delivered to the consignee, unless prior approval is obtained from the state veterinarian.
   c. Cattle (beef-type) and bison steers and heifers more than 6 months of age but less than 18 months of age may be imported for feeding purposes without official individual identification and quarantined to the premises of destination. However, cattle and bison originating from a state which is not a tuberculosis-free state and heifers originating from a state which is not a brucellosis-free state are not eligible for this identification exemption. The CVI must contain the statement: “These animals are quarantined to the premises of destination until moved to slaughter.”

65.4(3) Testing.
   a. Tuberculosis test. Testing requirements for tuberculosis are as follows:
      (1) A tuberculosis test is not required for importation of cattle or bison provided that:
         1. The cattle or bison are native to, and originate from, an accredited tuberculosis-free herd (accredited herd number and date of last test must be listed on the CVI), state, or zone; or
         2. The cattle (beef-type) and bison are between the ages of 6 months and 18 months and are being imported for feeding purposes.
      (2) A negative tuberculosis test is required within 60 days prior to importation for cattle or bison six months of age or older that are not exempted by 65.4(3)’a’(1).
      (3) Cattle and bison less than 6 months of age that originate from a herd, state, or zone that is not accredited as tuberculosis-free or as modified accredited advanced must originate from a herd which has been whole-herd tested negative for tuberculosis within 12 months prior to importation.
   b. Brucellosis test.
      (1) A brucellosis test is not required for importation of cattle or bison provided that:
         1. The cattle or bison are native to, and originate from, a certified brucellosis-free herd (herd number and date of last test shall be listed on the CVI), state, or area; or
         2. The cattle and bison are official calfhood vaccines under 18 months of age; or
         3. The cattle and bison are steers or spayed heifers.
      (2) A negative brucellosis test is required within 30 days prior to importation for cattle or bison six months of age or older that are not exempted by 65.4(3)’b’(1).
      (3) Cattle and bison less than 6 months of age that originate from a herd, state or zone that is not certified brucellosis-free must originate from a herd which has been whole-herd tested negative for brucellosis within 12 months prior to importation.
      (4) All brucellosis tests of cattle and bison shall be conducted by state or federal laboratories or by approved laboratories under the supervision of the chief livestock health official of the state of origin.
   c. Trichomoniasis test. A bull must have a negative trichomoniasis test within 30 days prior to importation and have no subsequent sexual exposure. The trichomoniasis test is either one negative polymerase chain reaction (PCR) test or three consecutive weekly negative trichomoniasis foetus cultures. This testing requirement does not apply if the bull is:
      (1) Under the age of 24 months and listed on the Certificate of Veterinary Inspection as “virgin” or not having been sexually exposed to any female;
(2) Being sent directly to slaughter or to an auction market and directly to slaughter; or
(3) Temporarily in the state for a rodeo or exhibition and leaves after the event.

65.4(4) Rodeo bulls.

a. Tuberculosis test. A negative tuberculosis test is required within 12 months prior to importation.

b. Brucellosis test. A negative brucellosis test is required within 12 months prior to importation.

[ARC 9151B, IAB 10/20/10, effective 9/20/10; ARC 0230C, IAB 7/25/12, effective 8/29/12; ARC 1278C, IAB 1/8/14, effective 2/12/14]

21—65.5(163,166D) Swine.

65.5(1) General.

a. Certificate of Veterinary Inspection (CVI). All swine imported into the state, except swine consigned directly to a recognized slaughter establishment, swine consigned to a specifically approved auction market, or swine that are moved in accordance with an approved swine production health plan (SPHP), must be accompanied by a CVI.

b. All swine imported into the state, except swine consigned directly to a recognized slaughter establishment, swine consigned to a specifically approved auction market, or swine that are moved in accordance with an approved swine production health plan (SPHP), must have official individual identification.

c. All swine imported into the state must originate from a herd or area not under quarantine.

d. Feral swine are not eligible for importation into the state.

e. Transitional swine must meet the requirements of 65.5(4) in addition to the general requirements. Transitional swine are swine that have been, or have had the potential to be, exposed to feral swine.

65.5(2) Breeding swine.

a. Brucellosis test. All breeding swine imported into the state must:

(1) Originate from herds not known to be infected with, or exposed to, brucellosis and be accompanied by proof of a negative brucellosis test conducted within 30 days prior to importation; or

(2) Originate directly from a validated brucellosis-free state; or

(3) Originate directly from a validated brucellosis-free herd. The date of the last test and herd validation number must be included on the CVI.

b. Pseudorabies test. All breeding swine imported into the state must:

(1) Originate from a herd not known to be infected with, or exposed to, pseudorabies and be accompanied by proof of a negative pseudorabies test conducted within 30 days of importation; or

(2) Originate from a qualified pseudorabies negative (QN) herd (the date of last test and herd number shall be listed on the CVI); or

(3) Originate from a pseudorabies Stage IV or Stage V state.

65.5(3) Feeder swine.

a. Brucellosis test. Swine imported into the state for further feeding must originate from herds not known to be infected with, or exposed to, brucellosis.

b. Pseudorabies test. Swine imported into the state for further feeding must:

(1) Originate from herds not known to be infected with, or exposed to, pseudorabies and be accompanied by proof of a negative pseudorabies test conducted within 30 days prior to importation; or

(2) Originate from a qualified pseudorabies negative (QN) herd; or

(3) Originate from a pseudorabies Stage III, Stage IV or Stage V state.

65.5(4) Captive wild-type and transitional swine. Captive wild-type and transitional swine imported into the state must:

a. Originate from herds not known to be infected with, or exposed to, brucellosis and be accompanied by proof of a negative brucellosis test conducted within 30 days prior to importation; and

b. Originate from herds not known to be infected with, or exposed to, pseudorabies and be accompanied by proof of a negative pseudorabies test conducted within 30 days prior to importation; and

(c) Have a pre-entry permit from the state veterinarian.
65.5(5) Swine for slaughter. All swine that are moved directly to a recognized slaughter establishment or to a specifically approved auction market for sale directly to a recognized slaughter establishment for immediate slaughter may be moved without restriction.

21—65.6(163) Goats.

65.6(1) General.

a. Certificate of Veterinary Inspection (CVI). All goats imported into the state, except goats consigned directly to a recognized slaughter establishment and goats consigned to a specifically approved auction market, must be accompanied by a CVI.

b. All sexually intact goats imported into the state that are registered, are used for exhibition, or have resided on the same premises with or been commingled with sheep must be officially identified with either ear tags or tattoos that meet the requirements specified in 9 CFR §79.2 and §79.3 and the Scrapie Eradication Uniform Methods and Rules. All other goats imported into the state must have official individual identification.

c. All goats imported into the state must originate from a herd or area not under quarantine.

65.6(2) Breeding and dairy goats.

a. Brucellosis.

(1) All sexually intact goats six months of age or older, except those for immediate slaughter, must:

1. Originate from a certified brucellosis-free herd (the date of the last test and certified herd number shall be listed on the CVI); or

2. Originate from a herd not known to be infected with, or exposed to, brucellosis and be accompanied by proof of a negative brucellosis test conducted within 30 days prior to importation.

(2) Sexually intact goats less than six months of age must originate from a herd which has been whole-herd tested negative for brucellosis within the last 12 months or must originate from a certified brucellosis-free herd (the date of the last test and certified herd number shall be listed on the CVI).

b. Tuberculosis.

(1) All goats six months of age or older must:

1. Originate from an accredited tuberculosis-free herd (the date of last test and accredited herd number shall be listed on the CVI); or

2. Originate from a herd which has been whole-herd tested negative for tuberculosis within 12 months of importation (the date of herd test shall be listed on the CVI); or

3. Originate from a herd not known to be infected with, or exposed to, tuberculosis and be accompanied by proof of a negative tuberculosis test conducted within 60 days of importation.

(2) Goats less than six months of age must originate from a herd which has been whole-herd tested negative for tuberculosis within the last 12 months or must originate from an accredited tuberculosis-free herd (the date of last test and accredited herd number shall be listed on the CVI).

65.6(3) Scrapie. Sexually intact goats from premises where scrapie has been known to exist within the last 60 months or sexually intact goats under surveillance for scrapie shall not be admitted into Iowa, except by permission of the state veterinarian for direct movement to a recognized slaughter establishment.

21—65.7(163) Sheep.

65.7(1) General.

a. Certificate of Veterinary Inspection (CVI). All sheep imported into the state, except sheep consigned directly to a recognized slaughter establishment for immediate slaughter or sheep consigned to a specifically approved auction market, shall be accompanied by a CVI. For animals requiring identification, the CVI must include the official scrapie flock identification number(s) for the animal(s) listed or the official individual identification for each animal.

b. Identification.

(1) All sheep imported into the state must be officially, individually identified with ear tags that meet the requirements specified in 9 CFR §79.2 and §79.3 and the Scrapie Eradication Uniform Methods and Rules, unless exempted pursuant to 65.7(1)“b”(2).
(2) Exemption to identification requirements. Exemptions to requirements for individual identification of sheep include:
1. Sheep less than 18 months of age consigned directly to a recognized slaughter establishment; and
2. Wethers less than 18 months of age; and
3. Sheep less than 18 months of age consigned directly to an Iowa approved terminal feedlot. The CVI must list the approved terminal feedlot number for the feedlot.

65.7(2) Restrictions and limitations.
   a. Scabies. Sheep from scabies-quarantined areas must meet federal regulations for interstate movement.
   b. Scrapie. Sheep that are known to be scrapie-positive, suspect, high-risk, or exposed, or that originate from a known infected, source, exposed, or noncompliant flock may not be imported into the state unless:
      (1) The flock from which they originate has completed an approved scrapie flock cleanup plan, or
      (2) Prior permission has been granted by the state veterinarian.

21—65.8(163) Equine.
65.8(1) General.
   a. Certificate of Veterinary Inspection (CVI). All equine imported into the state of Iowa shall be accompanied by a CVI.
   b. Equidae which are positive to a brucellosis test or which show evidence of “poll evil” or “fistulous withers” whether draining or not shall not be allowed to enter the state for any purpose.

65.8(2) Testing—equine infectious anemia (EIA). All Equidae imported into the state must be accompanied by proof of a negative EIA serological test conducted within 12 months prior to importation, except foals under 6 months of age accompanied by their dams which meet the EIA test requirements. The name of the testing laboratory, laboratory accession number, and the date of test must appear on the CVI.

21—65.9(163) Cervidae.
65.9(1) General.
   a. Definitions.
      “Cervidae” means all animals belonging to the Cervidae family.
      “Chronic wasting disease” or “CWD” means a transmissible spongiform encephalopathy of cervids.
      “CWD susceptible Cervidae” means all species of Cervidae susceptible to chronic wasting disease, including whitetail deer, blacktail deer, mule deer, red deer, elk, moose, and related species and hybrids of these species.
   b. Certificate of Veterinary Inspection (CVI). All Cervidae imported into the state shall be accompanied by a CVI.
   c. All Cervidae imported into this state, except Cervidae consigned directly to a recognized slaughter establishment, must have a pre-entry permit. The permit number must be requested by the licensed accredited veterinarian signing the CVI and issued by the state veterinarian prior to movement of the Cervidae. The permit number must be recorded on the CVI.

65.9(2) Chronic wasting disease.
   a. Cervidae originating from an area considered to be endemic for chronic wasting disease shall not be allowed entry into Iowa. Cervidae that originate from a herd that has had animal introductions from an area endemic to chronic wasting disease during the preceding five years shall not be allowed entry into Iowa.
   b. CWD susceptible Cervidae shall only be allowed into Iowa from herds which are currently enrolled in and have satisfactorily completed at least five years in an official recognized CWD monitoring program. The CWD herd number, anniversary date, expiration date, and herd status for each individual animal must be listed on the CVI.

The following statement must be accurate and listed on the CVI:
“All Cervidae on this certificate originate from a CWD monitored or certified herd in which these animals have been kept for at least one year or were natural additions. There has been no diagnosis, sign, or epidemiological evidence of CWD in this herd for the past five years.”

c. Cervidae other than CWD susceptible Cervidae shall be allowed into the state only from herds which are currently enrolled in an official recognized CWD monitoring program. The CWD herd number, anniversary date, expiration date, and herd status for each individual animal must be listed on the CVI. The following statement must be accurate and listed on the CVI:

“All Cervidae on this certificate originate from a CWD monitored or certified herd and have not spent any time within the past 36 months in a zoo, animal menagerie or like facility, and have not been on the same premises as a cervid herd which has been classified as a CWD infected herd, exposed herd or trace herd.”

d. Each animal must have official individual identification, and all forms of identification must be listed on the certificate.

65.9(3) Testing.

a. Tuberculosis test. Herd status and Single Cervical Tuberculin (SCT) test (Cervidae) are according to USDA Tuberculosis Eradication in Cervidae Uniform Methods and Rules effective January 22, 1999.

(1) Cervidae six months of age or older imported into this state, except Cervidae imported directly to a recognized slaughter establishment, must:

1. Originate from a herd not under quarantine and be tested negative for tuberculosis (TB) within 90 days of importation by the Single Cervical Tuberculin (SCT) test (Cervidae) or by the Cervid TB Stat-Pak test; or

2. Originate from an accredited herd (Cervidae) or originate from a qualified herd (Cervidae) and be tested negative within 90 days of importation (the test dates and herd number shall be listed on the CVI).

(2) Cervidae less than 6 months of age imported into the state must originate from a herd which has been whole-herd tested negative for tuberculosis within the last 12 months or must originate from an accredited herd (Cervidae).

b. Brucellosis test.

(1) Cervidae six months of age or older imported into the state, except Cervidae imported directly to a recognized slaughter establishment, must:

1. Originate from a herd not under quarantine and be accompanied by proof of a negative brucellosis test conducted within 90 days of importation; or

2. Originate from a certified brucellosis-free cervid herd or a cervid class free status state (brucellosis). The date of the last test and herd number shall be listed on the CVI.

(2) Cervidae less than 6 months of age must originate from a herd which has been tested negative for brucellosis within the last 12 months or must originate from a certified brucellosis-free herd.

21—65.10(163) Dogs and cats.

65.10(1) General.

a. Certificate of Veterinary Inspection (CVI). All dogs and cats imported into the state must be accompanied by a CVI indicating apparent freedom from disease or exposure to infectious or contagious disease, except dogs for exhibition and performing dogs entering for a limited period of time.

b. Dogs or cats originating from rabies-quarantined areas shall not be admitted.

65.10(2) Rabies.

a. Cats. No rabies vaccination is required.

b. Dogs. All dogs four months of age and older must have a current rabies vaccination with a USDA-approved rabies vaccine.

21—65.11(163) Poultry, domestic fowl, and hatching eggs.
65.11(1) Certificate of Veterinary Inspection (CVI). All poultry, domestic fowl, and their hatching eggs imported into the state, except poultry and domestic fowl consigned directly to a recognized slaughter establishment or a specifically approved auction market, must be accompanied by a CVI. For poultry and hatching eggs classified under provisions of the National Poultry Improvement Plan (NPIP), a VS Form 9-3, Report of Sales of Hatching Eggs, Chicks and Poults, may be substituted for the CVI.

65.11(2) Restrictions and limitations. General.
   a. All poultry, domestic fowl, and their hatching eggs being imported into the state and not originating from an AI- or VND-affected area must have a pre-entry permit issued by the Iowa Poultry Association. This permit may be obtained by calling (515)727-4701, extension 100.
   b. Importations from an AI- or VND-affected area.
      (1) Approval. All domestic fowl, live poultry or poultry products from an AI- or VND-affected area may be considered for importation on a case-by-case basis following a risk assessment.
      (2) Documentation. Poultry or poultry products must originate from a flock that is classified as AI clean under provision of the NPIP. The CVI must indicate that the poultry or poultry products originate from an AI- or VND-negative flock and include a description of the birds, the test date, test results, and the name of the testing laboratory. The initial tests required for pre-entry permitting of a flock from an AI-affected area include polymerase chain reaction (PCR) and agar gel precipitin (AGP) or enzyme-linked immunosorbent assay (ELISA). The PCR test is required for subsequent permitting during the originating area’s continuous designation as AI-affected. PCR is the test required of a flock from a VND-affected area.
      (3) Pre-entry permit. All domestic fowl, live poultry or poultry products originating from an AI- or VND-affected area must have a pre-entry permit issued by the state veterinarian. Requests for pre-entry permits should be directed to the Animal Industry Bureau, Department of Agriculture and Land Stewardship, Wallace State Office Building, Des Moines, Iowa 50319, or may be made by telephoning (515)281-4103 during normal business hours.
      (4) Domestic fowl, live poultry or poultry products originating from a quarantined area shall not be allowed entry into the state.

65.11(3) Testing.
   a. Pullorum-typhoid test.
      (1) An official negative test for pullorum-typhoid is required within 30 days of importation for domestic fowl or live poultry or for the flock from which hatching eggs originate unless exempted pursuant to 65.11(3)"a"(2).
      (2) Exemptions to the test requirements. No test is required for the following:
         1. Imported domestic fowl, live poultry or hatching eggs originating from flocks classified under provisions of the NPIP, or an equivalent program as determined by the department, as pullorum-typhoid clean.
         2. Exotic birds or other pet birds.
         3. Poultry consigned directly to a recognized slaughter establishment.
   b. Mycoplasma gallisepticum test—turkeys. Live turkeys or turkey-hatching eggs for importation must originate from a flock that has been tested annually and can be classified as U.S. mycoplasma gallisepticum clean as provided by the NPIP or an equivalent program as determined by the department. Turkeys consigned directly to a recognized slaughter establishment are not affected by this subrule.

21—65.12(163) Swine production health plan (SPHP).

65.12(1) General.
   a. Swine production health plan (SPHP). A swine production health plan is a written agreement developed for a swine production system and designed to maintain the health of the swine and detect signs of communicable disease. The plan must include all of the following:
      (1) Address and contact information for all premises that are part of the swine production system and that receive or send swine in interstate commerce.
(2) Provisions for regular veterinary inspections of all swine maintained on the identified premises, at intervals no greater than 30 days, by the swine production system’s licensed accredited veterinarian(s).

(3) Description of the record-keeping system of the swine production system.

(4) The signature of each official of each swine production system identified in the plan, including the swine production system’s licensed accredited veterinarian(s), the state veterinarian, an APHIS representative, and the state animal health official from each state in which the swine production system has a premises.

(5) Acknowledgment that the managers of all the swine production system’s premises listed in the plan have been notified that any failure of the participants in the swine production system to abide by the provisions of the plan and the applicable provisions of 9 CFR Parts 71 and 85 constitutes a basis for the cancellation of the swine production health plan.

b. Interstate swine movement report. An interstate swine movement report is a paper or electronic document detailing interstate movement of animals within a swine production health system. The interstate swine movement report must include the following information:

(1) The name, location, and premises identification number of the premises from which the swine are to be moved.

(2) The name, location, and premises identification number of the premises to which the swine are to be moved.

(3) The date of movement.

(4) The number, age, and type of swine to be moved.

(5) A description of any individual identification or group identification associated with the swine.

(6) The name of the swine production system’s licensed accredited veterinarian(s).

(7) The health status of the herd from which the swine are to be moved, including any disease of regulatory concern to the state or the United States Department of Agriculture (USDA) Animal Plant Health Inspection Service (APHIS).

(8) An accurate statement that swine on the premises from which the swine are to be moved have been inspected by the swine production system’s licensed accredited veterinarian(s) within 30 days prior to the interstate movement, consistent with the dates specified by the premises’ swine production health plan, and found free from signs of communicable disease.

c. Swine production system. A swine production system is an enterprise that consists of multiple sites of swine production (i.e., sow herds, nursery herds, and growing or finishing herds) that do not include a recognized slaughter facility or livestock market, that are connected by ownership or contractual relationships, and between which swine are moved while remaining under the control of a single owner or a group of contractually connected owners.

d. Swine production system’s licensed accredited veterinarian. A swine production system’s licensed accredited veterinarian is a licensed accredited veterinarian who is named in a swine production health plan for a premises within a swine production system and who performs inspection of such premises and animals and other duties related to the movement of swine in a swine production system. 65.12(2) Identification of swine moving interstate within an SPHP. Swine that are moved into the state within a swine production system to other than a recognized slaughter facility or a specifically authorized livestock market are not required to be individually identified when moved provided that the following requirements are met:

a. The swine may be moved interstate only to another premises identified in a valid swine production health plan for that swine production system.

b. The swine production system must operate under a valid swine production health plan in which both the sending and receiving states have agreed to allow the movement.

c. The swine must have been found free from signs of any communicable disease during the most recent inspection of the premises by the swine production system’s licensed accredited veterinarian(s) within 30 days prior to movement.

d. Prior to the movement of any swine, the producer(s) moving swine must deliver the required interstate swine movement report to the following individuals identified in the swine production health plan:
(1) The swine production system’s licensed accredited veterinarian for the premises from which the swine are to be moved.

(2) The state animal health officials for the state of origin of the swine.

(3) The state veterinarian for the state of destination of the swine.

(4) Individuals designated by the state animal health officials.

e. The receiving premises must not commingle swine received from different premises in a manner that prevents identification of the premises that sent the swine or groups of swine. This requirement may be met by use of permanent premises or individual animal identification, by keeping groups of animals received from one premises physically separate from animals received from other premises, or by any other effective means.

f. For each premises, the swine production system must maintain for three years after their date of creation records that will allow a state animal health official to trace any animal on the premises back to its previous premises and must maintain copies of each swine production health plan signed by the producer, all interstate swine movement reports issued by the producer, and all reports the swine production system’s accredited veterinarian(s) issues documenting the health status of the swine on the premises.

  
g. Each premises must allow state animal health officials access to the premises upon request to inspect animals and review records.

  
h. Every seven calendar days, each swine production system must send the state veterinarian a written summary that is based on the interstate swine movement report data and that shows how many animals were moved in the past seven calendar days, the premises from which they were moved, and the premises to which they were moved.

65.12(3) Cancellation of SPHP. The following procedures apply to cancellation of, or withdrawal from, a swine production health plan:

  a. The state veterinarian may cancel the state’s participation in a swine production health plan by giving written notice to all swine producers, APHIS representatives, accredited veterinarians, and other state animal health officials listed in the plan. Withdrawal shall be effective upon the date specified by the state veterinarian in the notice, but for shipments in transit, withdrawal shall become effective seven days after the date of such notice. Upon withdrawal of the state, the swine production health plan may continue to operate among the other states and parties that are signatory to the plan.

  b. A swine production system may withdraw one or more of its premises from participation in the plan upon giving written notice to the state veterinarian, APHIS administrator, the accredited veterinarian(s), and all swine producers listed in the plan. Withdrawal shall be effective upon the date specified by the swine production system in the written notice, but for shipments in transit, withdrawal shall become effective seven days after the date of such notice.

  c. The state veterinarian shall cancel a swine production health plan after determining that swine movements within the swine production system have occurred that were not in compliance with the swine production health plan or with other requirements of this chapter. Before a swine health production plan is canceled, the state veterinarian shall inform a representative of the swine production system of the reasons for the cancellation. The swine production system may appeal the cancellation in writing in accordance with Iowa Code chapter 17A and Iowa Administrative Code 21—Chapter 2. This cancellation shall continue in effect pending the completion of the proceeding, and any judicial review thereof, unless otherwise ordered by the state veterinarian.

21—65.13(163) Penalties. A person violating a provision of this chapter shall be subject to a civil penalty of at least $100 but not more than $1,000. In the case of a continuing violation, each day of the continuing violation is a separate violation. A person who falsifies a Certificate of Veterinary Inspection shall be subject to a civil penalty of not more than $5,000 for each reference to an animal falsified on the certificate.

These rules are intended to implement Iowa Code chapter 163.

[Filed 12/3/64]

[Filed 4/13/76, Notice 2/9/76—published 5/3/76, effective 6/7/76]
[Filed 9/2/77, Notice 7/27/77—published 9/21/77, effective 10/26/77]
[Filed 11/21/80, Notice 10/15/80—published 12/10/80, effective 1/14/81]
[Filed 8/13/82, Notice 7/7/82—published 9/1/82, effective 10/6/82]
[Filed emergency 10/8/85—published 11/6/85, effective 10/8/85]
[Filed 12/13/85, Notice 11/6/85—published 1/1/86, effective 2/5/86]
[Filed emergency 4/6/87—published 4/22/87, effective 4/6/87]
[Filed emergency 5/15/87—published 6/3/87, effective 7/1/87]
[Filed 10/18/90, Notice 7/25/90—published 11/14/90, effective 11/1/91]
[Filed 8/25/94, Notice 7/20/94—published 9/14/94, effective 10/19/94]
[Filed 2/21/96, Notice 1/17/96—published 3/13/96, effective 4/17/96]
[Filed 5/29/96, Notice 4/24/96—published 6/19/96, effective 7/24/96]
[Filed 11/27/96, Notice 10/23/96—published 12/18/96, effective 1/22/97]
[Filed 11/7/03, Notice 10/1/03—published 11/26/03, effective 12/31/03]
[Filed emergency 7/2/04—published 7/21/04, effective 7/2/04]
[Filed 5/6/05, Notice 3/30/05—published 5/25/05, effective 6/29/05]
[Filed emergency 4/11/08—published 5/7/08, effective 4/11/08]
[Filed 10/2/08, Notice 8/27/08—published 10/22/08, effective 11/26/08]
[Filed Emergency ARC 7723B, IAB 4/22/09, effective 4/2/09]
[Filed ARC 8951B (Notice ARC 8754B, IAB 5/19/10), IAB 7/28/10, effective 9/1/10]
[Filed Emergency After Notice ARC 9151B (Notice ARC 8985B, IAB 8/11/10), IAB 10/20/10, effective 9/20/10]
[Filed ARC 0230C (Notice ARC 0140C, IAB 5/30/12), IAB 7/25/12, effective 8/29/12]
[Filed Emergency ARC 90656C (Notice ARC 0642C, IAB 3/6/13), IAB 3/20/13, effective 3/1/13]
[Filed ARC 1278C (Notice ARC 1179C, IAB 11/13/13), IAB 1/8/14, effective 2/12/14]
[Filed ARC 3993C (Notice ARC 3892C, IAB 7/18/18), IAB 9/12/18, effective 10/17/18]
[Filed ARC 6336C (Notice ARC 6235C, IAB 3/9/22), IAB 6/1/22, effective 7/6/22]

1 Objection to 30 IAC 17.1(3) filed 1/9/81; subrule renumbered 21—65.1(3) IAC 7/27/88; renumbered as 65.3(2) IAB 5/25/05.
OBJECTION

At its January 9, 1981 meeting the administrative rules review committee voted the following objection:

The committee objects to subrule 30 IAC 17.1(3)* on the grounds it is unreasonable. The subrule appears as part of ARC 1630 in III IAB 12 (12/10/80) and requires all livestock vehicles to be cleaned and disinfected before they carry shipments into the state. The committee feels this provision is impossible to enforce because it relates to activities that occur outside of Iowa jurisdiction.

* Renumbered 21—65.1(3) IAC 7/27/88; renumbered as 65.3(2) IAB 5/25/05.
INSURANCE PRODUCERS

CHAPTER 10

INSURANCE PRODUCER LICENSES AND LIMITED LICENSES

191—10.1(522B) Purpose and authority.

10.1(1) The purpose of these rules is to set out the requirements, procedures and fees relating to the qualification, licensure and appointment of insurance producers.

10.1(2) These rules are authorized by Iowa Code section 505.8 and are intended to implement Iowa Code chapters 252J, 272D and 522B.

[ARC 4910C, IAB 2/12/20, effective 3/18/20]

191—10.2(522B) Definitions. In addition to the definitions in 191—1.1(502,505), the following definitions apply:

“Appointment” means a notification filed with the division or its designated vendor that an insurer has established an agency relationship with a producer. A company filing such a request must verify that the producer is licensed for the appropriate line(s) of authority.

“Birth month” means the month in which a producer was born.

“Business entity” means a corporation, association, partnership, limited liability company, limited liability partnership or other legal entity.

“CSRU” means child support recovery unit.

“Home state” means the District of Columbia or any state or territory of the United States in which a producer maintains the producer’s principal place of residence or principal place of business and is licensed to act as a producer.

“Individual” means a private or natural person, as distinguished from a partnership, corporation or association.

“Insurance” means any of the lines of insurance listed in rule 191—10.7(522B).

“License” means the division’s authorization for a person to act as a producer for the authorized lines of insurance.

“License number” means the National Insurance Producer Registry (NIPR) national producer number (NPN) issued to all licensees whose license records exist in the state producer licensing database (SPLD). For purposes of this definition, “state producer licensing database (SPLD)” means the national database of producers maintained by the National Association of Insurance Commissioners (NAIC), its affiliates or subsidiaries.

“National Insurance Producer Registry” or “NIPR” means the nonprofit affiliate of the National Association of Insurance Commissioners (NAIC). The NIPR’s website is www.NIPR.com.

“Negotiate” means the act of conferring directly with or offering advice directly to a purchaser or prospective purchaser of a particular contract of insurance concerning any of the substantive benefits, terms or conditions of the contract provided that the person engaged in that act either sells insurance or obtains insurance for purchasers.

“NIPR Gateway” means the communication network developed and operated by NIPR that links state insurance regulators with the entities they regulate to facilitate the electronic exchange of producer information regarding license applications, license renewals, appointments and terminations.

“Nonresident” means a person whose home state is not Iowa.

“Notification” means a written or electronic communication from a producer to the division.

“Person” means an individual or a business entity.

“Producer” or “insurance producer” means a person required to be licensed in this state to sell, solicit or negotiate insurance.

“Producer renewal notice” means an electronic communication issued by the division to inform a producer about license renewal.

“Resident” means a person whose home state is Iowa.

“Sell” means to exchange a contract of insurance by any means, for money or its equivalent, on behalf of an insurer.
“Solicit” or “solicitation” means attempting to sell insurance or asking or urging a person to apply for a particular kind of insurance from a particular company.

“Termination” means that an insurer has ended its agency relationship with a producer.

“Termination for cause” means that an insurer has ended its agency relationship with a producer for one of the reasons set forth in Iowa Code section 522B.11.

“Uniform application” means the National Association of Insurance Commissioners’ uniform application for resident and nonresident insurance producer licensing, as it appears on the NAIC website.

[ARC 7836B, IAB 6/3/09, effective 7/8/09; ARC 4910C, IAB 2/12/20, effective 3/18/20]

191—10.3(522B) Requirement to hold a license.

10.3(1) No person may sell, solicit or negotiate insurance in Iowa until that person has been issued an Iowa producer license.

10.3(2) A person offering to the public, for a fee or commission, to engage in the business of offering any advice, counsel, opinion or service with respect to the benefits, advantages or disadvantages promised under any policy of insurance must be licensed as a producer.

10.3(3) A person shall not advise an Iowa resident to cancel, not renew, or otherwise change an existing insurance policy unless that person holds an Iowa producer license regarding the line of insurance for which the advice is given. This subrule does not apply to a licensed attorney or certified public accountant who does not sell or solicit insurance.

10.3(4) The license itself does not provide the producer with any authority to represent or commit an insurer.

[ARC 4910C, IAB 2/12/20, effective 3/18/20]

191—10.4(522B) Licensing of resident producers.

10.4(1) A person whose home state is Iowa and who desires to be licensed as a producer must satisfy the following requirements:

a. Be at least 18 years of age;

b. Have not committed any act that is grounds for denial under subrule 10.20(4);

c. Submit a completed uniform application;

d. Pass an examination in the line of authority sought;

e. Pay the appropriate producer license fee; and

f. Submit to a criminal history check pursuant to Iowa Code section 522B.5.

10.4(2) Examinations are conducted by the outside testing service on contract with the division. Applications and fees for examinations and for initial producer licensing will be submitted either to the outside testing service on contract with the division or as directed by the division. Instructions are available on the division’s website.

10.4(3) Reserved.

10.4(4) Examination results are valid for 90 days after the date of the test. Failure to apply for licensure within 90 days after the examination is passed shall void the examination results.

10.4(5) Amendments to producer licenses shall be done either by an outside vendor or by the division, as directed by the division. Any licensed producer desiring to become licensed in an additional line of authority must:

a. Submit a completed uniform application form through the NIPR Gateway or as directed by the division, specifying the line(s) of authority requested to be added. Instructions are available on the division’s website; and

b. For each line of authority requested to be added, pass any required examination.

10.4(6) A producer who holds a personal lines authority can obtain property and casualty lines of authority upon successful completion of the commercial insurance subject examination.

10.4(7) To receive a license for excess and surplus lines, the applicant must have successfully completed the excess and surplus lines examination and also have successfully completed either: (1) the examinations for property and casualty lines of authority; or (2) the examinations for personal lines of authority and the commercial insurance subject examination.
10.4(8) To receive a license for the variable products line of authority, the applicant must:
   a. Hold an active Iowa insurance license with a life insurance line of authority;
   b. Pass the Financial Industry Regulatory Authority (FINRA) examinations necessary to obtain an Iowa securities license; and
   c. File an application through the NIPR Gateway or as directed by the division to amend the license to add the variable products line of authority.

10.4(9) The division may require any documents reasonably necessary to verify the information contained in the application or to verify that the individual making application has the character and competency required to receive a producer license. If an applicant does not provide the additional information requested by the division within 45 days of receipt of the request, the application will expire and the license fee will not be returned.

[ARC 4910C, IAB 2/12/20, effective 3/18/20; ARC 5250C, IAB 11/4/20, effective 12/9/20]

191—10.5(522B) Licensing of nonresident producers.

10.5(1) A producer for whom Iowa is not the home state who desires to sell, solicit or negotiate insurance in Iowa must satisfy the following requirements to obtain an Iowa nonresident producer license:
   a. Be licensed and in good standing in the home state;
   b. Submit a proper request for licensure to the division through the NIPR Gateway;
   c. Pay the appropriate fee; and
   d. Submit to a criminal history check pursuant to Iowa Code section 522B.5A if a state and national criminal history check has not already been completed.

10.5(2) Any licensed nonresident producer desiring to become licensed in an additional line of authority shall submit to the division using the NIPR Gateway a completed application form specifying the line(s) of authority requested to be added.

10.5(3) A license will not be issued to a nonresident producer if the producer’s resident state does not issue licenses to Iowa resident producers applying for nonresident producer licenses in that state or if the producer’s resident state restricts Iowa resident producers’ nonresident activities in that state.

10.5(4) The division may require any documents reasonably necessary to verify the information contained in the application or to verify that the individual making application has the character and competency required to receive a producer license. If an applicant does not provide the additional information requested by the division within 45 days of receipt of the request, the application will expire and the license fee will not be returned.

[ARC 5250C, IAB 11/4/20, effective 12/9/20]

191—10.6(522B) Issuance of license.

10.6(1) In order to be issued a producer license, a person must meet the requirements of Iowa Code sections 522B.4 and 522B.5, or section 522B.7, and rule 191—10.5(522B), unless otherwise denied licensure pursuant to Iowa Code section 522B.11 or rule 191—10.20(522B). The initial term of a producer license is three years and ends after the last day of the applicant’s birth month of the year the license was issued, unless revoked or suspended. A license may be continually renewed pursuant to rule 191—10.8(522B) as long as the proper fees are paid and home state continuing education requirements are met. A renewal term is three years. If not renewed, a producer license automatically terminates on the last day of the month of the initial or renewal term.

10.6(2) An individual producer whose license has expired may seek reinstatement or reissuance as set forth in rule 191—10.9(522B) or 191—10.10(522B), as applicable.

10.6(3) The license shall contain the producer’s name, address, license number, date of issuance, date of expiration, the line(s) of authority held, and any other information the division deems necessary. The license number shall be the same as the producer’s National Insurance Producer Registry (NIPR) national producer number (NPN).

10.6(4) If the division issues or renews a producer license and subsequently determines that payment for the license or renewal was returned to the division by a bank without payment, or that the credit card company does not approve, cancels, or refuses amounts charged to the credit card, the license must be
immediately suspended until the payments are made and any fees or penalties charged by the division are paid, at which time the license may be reinstated. The individual may request a hearing within 30 days of receipt of the division’s notice that the license was suspended. [ARC 4910C, IAB 2/12/20, effective 3/18/20; ARC 5250C, IAB 11/4/20, effective 12/9/20]

191—10.7(522B) License lines of authority. In addition to the lines of authority listed in Iowa Code subsection 522B.6(2), the following lines of authority also are available for issuance in Iowa: crop, surety, and reciprocal (any other line of insurance issued in another state and for which Iowa grants authority to sell, solicit or negotiate in this state). [ARC 4910C, IAB 2/12/20, effective 3/18/20]

191—10.8(522B) License renewal.

10.8(1) Upon request by a licensed producer, the division must electronically transmit a producer renewal notice to the producer’s last-known electronic mail address as it appears in division records. If the division has received notification that the electronic address of record is no longer valid, no renewal notice will be transmitted.

10.8(2) A producer must apply for license renewal during the 90 days prior to the expiration date of the license. Failure to apply to renew a license and pay appropriate fees prior to the expiration date of the license will result in expiration of the license.

10.8(3) A producer may submit an electronic mail address to the division as directed by the division.

10.8(4) Resident producer licenses may be renewed electronically through the NIPR Gateway at www.NIPR.com.

10.8(5) Nonresident producer licenses may only be renewed through the NIPR Gateway, or as otherwise directed by the division. [ARC 7836B, IAB 6/3/09, effective 7/8/09; ARC 4910C, IAB 2/12/20, effective 3/18/20]

191—10.9(522B) License reinstatement.

10.9(1) A resident producer may reinstate an expired license up to 12 months after the license expiration date by proving that during the applicable continuing education (CE) term the producer met the CE requirements found in 191—Chapter 11 and by paying a reinstatement fee and a license renewal fee. A resident producer who fails to apply for license reinstatement within 12 months of the license expiration date must apply for a new license.

10.9(2) A nonresident producer may reinstate an expired license up to 12 months after the expiration date by submitting a request through the NIPR Gateway and by paying a reinstatement fee and a license renewal fee. A nonresident producer who fails to apply for a license reinstatement within 12 months of the license expiration date or fails to update the nonresident producer’s address pursuant to subrule 10.12(3) must apply for license reissuance.

10.9(3) A producer who has surrendered a license that was not in connection with a disciplinary matter and stated an intent to exit the insurance business may file a request to reactivate the license. The request must be received at the division within 90 days of the date the license was placed on inactive status. The request will be granted if the former producer is otherwise eligible to receive the license. If the request is not received within 90 days, the producer must apply for a new license.

10.9(4) A producer whose license was suspended, revoked, forfeited in connection with a disciplinary matter, or forfeited in lieu of compliance is not eligible for reinstatement under this rule and must follow the procedures in rule 191—10.10(522B). [ARC 4910C, IAB 2/12/20, effective 3/18/20; ARC 5250C, IAB 11/4/20, effective 12/9/20]

191—10.10(522B) Reinstatement or reissuance of a license after suspension, revocation or forfeiture in connection with disciplinary matters; and forfeiture in lieu of compliance.

10.10(1) Terminology: The term “reinstatement” as used in this rule means the reinstatement of a suspended license. The term “reissuance” as used in this rule means the issuance of a new license following the revocation of a license, the suspension and subsequent termination of a license, or the forfeiture of a license in connection with a disciplinary matter, including but not limited to proceedings
pursuant to rule 191—10.21(252J,272D). Disciplinary matters include, but are not limited to, being the subject of an investigation, complaint, or pending administrative action in this or any other state. This rule does not apply to the reinstatement of an expired license or the issuance of a new license that is not in connection with a disciplinary matter.

10.10(2) Application required. Any producer whose license has been revoked or suspended by order or who forfeited a license in connection with a disciplinary matter must apply to the commissioner for reinstatement or reissuance in accordance with the terms of the order of revocation or suspension or the order accepting the forfeiture and submit to a criminal history check as required pursuant to Iowa Code section 522B.5A.

a. All proceedings for reinstatement or reissuance must be initiated by the applicant, who shall file with the commissioner an Iowa Insurance Producer Application for Reinstatement or Reissuance After Disciplinary Action. An applicant is not eligible for reinstatement or reissuance until the applicant has satisfied the other prescribed requirements of rule 191—10.4(522B), including the timing requirements of subrule 10.4(4). An applicant may also have to submit a new or renewal producer application through the NIPR Gateway and pay any associated fee.

b. An application for reinstatement or reissuance must allege facts which, if established, will be sufficient to enable the commissioner to determine that the basis of revocation, suspension, or forfeiture of the applicant’s license no longer exists and must disclose whether the producer has engaged in any conduct that is listed as a cause for licensing action under Iowa Code section 507B.4 or 522B.11(1) that was not included in the order for suspension, revocation, or forfeiture.

c. An application for reinstatement or reissuance must allege sufficient facts to enable the commissioner to determine that it will be in the public interest for the application to be granted. The commissioner may determine it is not in the public interest if the producer has engaged in any conduct that is listed as a cause for licensing action under Iowa Code section 507B.4 or 522B.11(1) that was not included in the order for suspension, revocation, or forfeiture.

d. The burden of proof to establish such facts shall be on the applicant.

e. A producer may request reinstatement of a suspended license prior to the end of the suspension term; however, reinstatement will not be effected until the suspension period has ended.

f. Unless otherwise provided by law, if the order of revocation, suspension, or acceptance of forfeiture did not establish terms upon which reinstatement or reissuance may occur, or if the license was forfeited, an initial application for reinstatement or reissuance may not be made until at least one year has elapsed from the date of the order of the suspension (notwithstanding paragraph 10.10(2) “e”), revocation, or acceptance of the forfeiture of a license.

g. The period of suspension shall continue, regardless of any specified suspension end date, until such time as the producer’s license is reinstated by order.

10.10(3) Proceedings. All proceedings upon the application for reinstatement or reissuance, including matters preliminary and ancillary thereto, shall be held in accordance with Iowa Code chapter 17A. Such application shall be docketed in the original case in which the license was suspended, revoked, or forfeited, if a case exists.

10.10(4) Order. An order of reinstatement or reissuance must be a written decision that incorporates findings of fact and conclusions of law. An order granting an application for reinstatement or reissuance may impose such terms and conditions as the commissioner or the commissioner’s designee deems appropriate, which may include one or more of the types of disciplinary sanctions provided by Iowa Code section 522B.11. The producer’s license will be reinstated or reissued on the date of the order, unless the order specifies a different date. The order is a public record and may be disseminated in accordance with Iowa Code chapter 22.

10.10(5) Voluntary forfeiture. A submission of voluntary forfeiture of a license must be made in writing as prescribed by the commissioner. Forfeiture of a license is effective upon the submission unless a contested case proceeding is pending at the time of the submission. If a contested case proceeding is pending, the forfeiture becomes effective when and upon such conditions as required by order of the commissioner. A forfeiture made during the pendency of a contested case proceeding is considered
a disciplinary action and must be published in the same manner as is applicable to any other form of disciplinary order. 

10.10(6) Reinstatement in relation to expiration date. If a producer’s ordered suspension period ends prior to the producer’s license expiration date and the producer applies for reinstatement prior to the license expiration date, the commissioner must reinstate the license as soon as practicable but no earlier than the end of the suspension period if the division determines the license should be reinstated after a complete review.

10.10(7) Suspension beyond expiration date. When a producer’s license is suspended beyond the producer’s license expiration date, whether due to an ordered suspension time period or failure to apply for reinstatement prior to expiration as stated in subrule 10.10(6), the license terminates on the license expiration date and the producer must apply for reissuance pursuant to subrule 10.10(2).

10.10(8) Application denial or additional action. The commissioner is not prohibited from denying an application for reinstatement or reissuance or bringing an additional immediate action if the producer has engaged in any additional violation of Iowa Code section 507B.4 or 522B.11(1) or otherwise failed to meet all of the applicable requirements.

[ARC 4910C, IAB 2/12/20, effective 3/18/20; ARC 5250C, IAB 11/4/20, effective 12/9/20]

191—10.11(522B) Temporary licenses. An Iowa resident may apply for a temporary license pursuant to Iowa Code section 522B.10. The applicant must submit a written request to the division that includes the reason for the request and the length of time for which the temporary license is requested. Temporary licenses will be issued for 90 days, with extensions allowed, but in no event for longer than 180 days, pursuant to Iowa Code section 522B.10.

[ARC 4910C, IAB 2/12/20, effective 3/18/20]

191—10.12(522B) Change in name, address or state of residence.

10.12(1) If a producer’s name is changed, the producer must file notification with the division, as instructed on the division’s website, within 30 days of the name change. The notification must include:

a. The producer’s prior name;

b. The producer’s license number;

c. The producer’s new name; and

d. A copy of a legal document with proof of the name change.

10.12(2) If a resident or nonresident producer’s address is changed, the producer must file notification with the division through the NIPR Gateway at www.NIPR.com, unless the division instructs otherwise, within 30 days of the address change. The notification must include the producer’s:

a. Name;

b. License number;

c. Previous address; and

d. New address. A producer may designate a business address instead of a resident address at the option of the producer.

10.12(3) A nonresident producer who moves from one state to another state or an Iowa resident producer who moves to another state and wishes to retain an Iowa producer license must file a change of address with the division and provide a certification from the new resident state within 30 days of the change of legal residence. No fee or license application is required. If the new resident state is actively participating in the producer database, a letter of certification is not required. A nonresident licensed producer who moves to Iowa and wishes to retain the nonresident’s producer license must file a change of address with the division within 90 days of the change of legal residence.

10.12(4) Issuance of an Iowa nonresident producer license is contingent on proper licensure in the nonresident producer’s home state. Termination of the producer’s resident license will be deemed termination of the Iowa nonresident producer license unless the producer files a change of address within 30 days of the termination of the resident license.

10.12(5) If a producer has provided an email address to the division, the division may send information to the producer through the email address rather than through the mail.

[ARC 4910C, IAB 2/12/20, effective 3/18/20; ARC 5250C, IAB 11/4/20, effective 12/9/20]
191—10.13(522B) Reporting of actions.

10.13(1) A producer must report to the division any actions required to be reported by Iowa Code section 522B.16.

10.13(2) A producer must report to the division all CSRU or centralized collection unit of the department of revenue actions taken under or in connection with Iowa Code chapter 252J or 272D and all court orders entered in such actions.

10.13(3) Failure to file reports required by this rule is a violation of this chapter and will subject producers to penalty pursuant to rule 191—10.20(522B).

[ARC 4910C, IAB 2/12/20, effective 3/18/20]

191—10.14(522B) Commissions and referral fees.

10.14(1) An insurance company shall not pay, and a person shall not accept, any commission, service fee, brokerage or other valuable consideration unless the person performing the service held a valid license for the line of insurance for which the service was rendered at the time the service was performed.

10.14(2) A producer may assign commissions to an entity organized for the purpose of operating that producer’s insurance business if all of the entity’s representatives who personally sell, solicit or negotiate insurance in Iowa are individually licensed as producers under Iowa law.

10.14(3) An insurer or a producer may pay a nominal fee for referrals if the same fee is paid for each referral whether or not the referral results in an insurance transaction.

10.14(4) An insurer or a producer may not charge an additional fee for services that are customarily associated with the sale, solicitation, negotiation and servicing of an insurance policy. This prohibition does not apply to assigned risk and commercial property/casualty policies. Any fees or other charges that are assessed to an insurance consumer must be fully disclosed.

10.14(5) A person who is not engaged in any activities in Iowa that require a producer license in Iowa is not required to maintain an active producer license in order to receive override or hierarchy commissions or to receive renewal commissions earned while the producer was actively engaged in activities that required a producer license.

191—10.15(522B) Appointments.

10.15(1) Insurers are required to file and pay for appointments with the division for each insurer with which the producer has an agency relationship. The determination of whether an insurer and a producer have an agency relationship will be made by the division based on the totality of the circumstances surrounding the business relationship. Appointments are not issued for business entities.

10.15(2) Insurers must file and pay for appointments using the NIPR Gateway.

10.15(3) The notice of appointment must be filed within 30 days of the date the insurer and producer execute an agency contract or the first insurance application is submitted to the insurer.

10.15(4) Appointment fees are set forth in rule 191—10.26(522B).

10.15(5) Rescinded IAB 6/1/22, effective 7/6/22.

10.15(6) When a company loses its identity in a new company by merger, acquisition, or otherwise, the new company must contact the division to arrange for reappointment of the producers to the remaining company.

10.15(7) Insurance companies must file the name, address, and electronic address of a contact person for the company, to whom the billing statements will be sent. Insurance companies must notify the division if there is a change of the person appointed as the contact person or if a change of the address of such contact occurs. If an insurance company fails to notify the division of such a change, the insurance company must pay a $100 fee.

[ARC 7836B, IAB 6/3/09, effective 7/8/09; ARC 4910C, IAB 2/12/20, effective 3/18/20; ARC 6338C, IAB 6/1/22, effective 7/6/22]

191—10.16(522B) Appointment renewal.

10.16(1) On or about December 1 of each year, the division or its designee will deliver reminders to insurance companies that appointment renewals are imminent. Appointments must be renewed electronically via the NIPR Gateway at www.NIPR.com.
10.16(2) On or about January 2 of each year, a list of the producers currently appointed with each insurance company and a billing statement will be provided to each insurance company via the NIPR Gateway. The billing statement must not be altered, amended or used for appointing or terminating producers.
10.16(3) Payment is due on or before March 1.
10.16(4) Failure to pay renewal appointment fees by March 15 will result in termination of a company’s appointments. Appointments that are terminated due to nonpayment of renewal fees may be reappointed using the NIPR Gateway.
10.16(5) Insurance companies must file the name, address, and electronic address of a contact person for the company, to whom the appointment renewals will be sent. Insurance companies must notify the division if a change of the address of such contact occurs. If an insurance company fails to notify the division of such a change of address, the insurance company must pay a $100 fee.

[ARC 7836B, IAB 6/3/09, effective 7/8/09; ARC 4910C, IAB 2/12/20, effective 3/18/20; ARC 6338C, IAB 6/1/22, effective 7/6/22]

191—10.17(522B) Appointment terminations.
10.17(1) When an insurance company terminates its relationship with a producer, the company must notify the division using the NIPR Gateway. The termination must be filed within 30 days of the date the insurer terminated its agency relationship with the producer. The company must also notify the producer that the producer’s appointment has been terminated.
10.17(2) There is no fee for the filing of an appointment termination.
10.17(3) The division may adopt special procedures for the filing of termination requests for a group of affiliated insurance companies that comprise a holding company.
10.17(4) When an insurer terminates an appointment for cause pursuant to Iowa Code section 522B.14, the notification of termination may be filed according to subrule 10.17(1). The supporting documents required by Iowa Code section 522B.14 must be submitted to the division within ten days of the filing of the notification. The documents must include a certification by an officer or authorized representative of the insurer.

[ARC 4910C, IAB 2/12/20, effective 3/18/20]

191—10.18(522B) Licensing of a business entity.
10.18(1) Application. A business entity may apply for an Iowa insurance license. For purposes of this rule, upon approval of an application by the division, the business entity will be classified as a producer and is subject to all standards of conduct and reporting requirements applicable to producers.
10.18(2) Requirements.
   a. To qualify for such a license, the business entity must:
      (1) File a completed NAIC uniform business entity application through the NIPR Gateway or as directed by the division. For purposes of this subrule, “uniform business entity application” means the National Association of Insurance Commissioners’ uniform business entity application for resident and nonresident business entities, as the application appears on the NAIC website;
      (2) Designate one officer, owner, partner, or member of the business entity, which person also is a producer licensed by the division, as the person who will have full responsibility for the conduct of all business transactions of the business entity or of producers affiliated with the business entity;
      (3) For a nonresident business entity, submit an appropriate request through the NIPR Gateway; and
      (4) Pay the license fee.
   b. The designated responsible producer must maintain an active Iowa producer license. If the license of the designated responsible producer terminates or lapses for any reason, the business entity must supply the division with a substitute designated responsible producer within ten days. If the business entity does not provide a substitute, the division must immediately terminate the license, and the entity must submit a new application and pay the appropriate license fee.
10.18(3) License term. A business entity license issued under this rule is effective for three years and one month, including the year of application, beginning on the first day of the month of the business
entity’s formation date and ending with the last day of the month of the business entity’s formation date. By arrangement with the division, a business entity may choose a different month for its license term.

10.18(4) License renewal. Upon request by a business entity, the division must electronically transmit a renewal notice to the electronic mail address of the business entity on file with the division on or before the first day of the month preceding the renewal month. The renewal fee must be received by the division or its designated vendor on or before the license expiration date. All business entities must renew their licenses through the NIPR Gateway or as otherwise directed by the division.

10.18(5) Business address. Business entities licensed under this rule must maintain a current business address with the division. If a business entity’s address is changed, notification from the designated responsible producer must be submitted to the division within 30 days of the address change, stating:
   a. Name of the business entity;
   b. License number;
   c. Previous address; and
   d. New address.

The notification may be sent by electronic mail through the NIPR Gateway at www.NIPR.com, unless the division instructs the producer otherwise.

10.18(6) Business name. A business entity licensed under this rule must keep the division informed of its business name. If a business entity changes the name under which it is operating, notification from the designated responsible producer must be submitted to the division within 30 days of the name change. The notification may be sent through the NIPR Gateway, if available, or as instructed on the division’s website.

[ARC 7836B, IAB 6/3/09, effective 7/8/09; ARC 4780C, IAB 11/20/19, effective 12/25/19; ARC 4910C, IAB 2/12/20, effective 3/18/20]

191—10.19(522B) Use of senior-specific certifications and professional designations in the sale of life insurance and annuities.

10.19(1) Purpose. The purpose of this rule is to set forth standards to protect consumers from misleading and fraudulent marketing practices with respect to the use of senior-specific certifications and professional designations in the solicitation, sale or purchase of, or advice made in connection with, a life insurance or annuity product.

10.19(2) Scope. This rule applies to any solicitation, sale or purchase of, or advice made in connection with, a life insurance or annuity product by a producer.

10.19(3) Authority.
   a. This rule is promulgated under the authority of Iowa Code chapters 507B and 522B.
   b. Nothing in this rule limits the division’s authority to enforce existing provisions of law.

10.19(4) Prohibited uses of senior-specific certifications and professional designations.
   a. It is an unfair and deceptive act or practice in the business of insurance within the meaning of Iowa Code chapter 507B for a producer to use a senior-specific certification or professional designation that indicates or implies in such a way as to mislead a purchaser or prospective purchaser that the producer has special certification or training in advising or servicing seniors in connection with the solicitation, sale or purchase of a life insurance or annuity product or in the provision of advice as to the value of or the advisability of purchasing or selling a life insurance or annuity product, either directly or indirectly through publications or writings, or by issuing or promulgating analyses or reports related to a life insurance or annuity product.
   b. The prohibited use of senior-specific certifications or professional designations includes, but is not limited to, the following:
      (1) Use of a certification or professional designation by an insurance producer who has not actually earned or is otherwise ineligible to use such certification or designation;
      (2) Use of a nonexistent or self-conferred certification or professional designation;
(3) Use of a certification or professional designation that indicates or implies a level of occupational qualifications obtained through education, training or experience that the producer using the certification or designation does not have; and

(4) Use of a certification or professional designation that was obtained from a certifying or designating organization that:
   1. Is primarily engaged in the business of instruction in sales or marketing;
   2. Does not have reasonable standards or procedures for assuring the competency of its certificants or designees;
   3. Does not have reasonable standards or procedures for monitoring and disciplining its certificants or designees for improper or unethical conduct; or
   4. Does not have reasonable continuing education requirements for its certificants or designees in order to maintain the certificate or designation.

c. There is a rebuttable presumption that a certifying or designating organization is not disqualified solely for purposes of subparagraph 10.19(4)“b” (4) when the certification or designation issued from the organization does not primarily apply to sales or marketing and when the organization or the certification or designation in question has been accredited by:
   (1) The American National Standards Institute (ANSI);
   (2) The National Commission for Certifying Agencies; or
   (3) Any organization that is on the U.S. Department of Education’s list entitled “Accrediting Agencies Recognized for Title IV Purposes.”

   d. In determining whether a combination of words or an acronym standing for a combination of words constitutes a certification or professional designation indicating or implying that a person has special certification or training in advising or servicing seniors, factors to be considered shall include:
      (1) Use of one or more words such as “senior,” “retirement,” “elder,” or like words combined with one or more words such as “certified,” “registered,” “chartered,” “adviser,” “specialist,” “consultant,” “planter,” or like words, in the name of the certification or professional designation; and
      (2) The manner in which those words are combined.

c. Financial services regulatory agency.

(1) For purposes of this rule, a job title within an organization that is licensed or registered by a state or federal financial services regulatory agency is not a certification or professional designation, unless it is used in a manner that would confuse or mislead a reasonable consumer, when the job title:
   1. Indicates seniority or standing within the organization; or
   2. Specifies an individual’s area of specialization within the organization.

(2) For purposes of paragraph 10.19(4)“e,” “financial services regulatory agency” includes, but is not limited to, an agency that regulates insurers, insurance producers, broker-dealers, investment advisers, or investment companies as defined under the Investment Company Act of 1940.

f. Effective date. This rule shall become effective January 1, 2009.

[ARC 4910C, IAB 2/12/20, effective 3/18/20]

191—10.20(522B) Violations and penalties.

10.20(1) A producer who sells, solicits or negotiates insurance, directly or indirectly, in violation of this chapter is deemed to be in violation of Iowa Code section 522B.2 and is subject to the penalties provided in Iowa Code section 522B.17.

10.20(2) A person who sells, solicits or negotiates insurance, directly or indirectly, who is not properly licensed as a producer is subject to the penalties provided in Iowa Code chapter 507A and Iowa Code section 522B.17.

10.20(3) Any company or company representative who aids and abets a producer in the above-described violation is deemed to be in violation of Iowa Code section 522B.2 and is subject to the penalties provided in Iowa Code section 522B.17.

10.20(4) The commissioner may place on probation, suspend, revoke, or refuse to issue or renew a producer’s license or may levy a civil penalty, in accordance with Iowa Code section 522B.17 or any
combination of actions, for any action listed in Iowa Code section 522B.11 and any one or more of the following causes:
   a. Submitting to the division or to the outside testing service on contract with the division a check which is returned to the division by a bank without payment, or submitting a payment to the division by credit card which the credit card company does not approve, or canceling or refusing amounts charged to a credit card by the outside testing service on contract with the division where services were received by the producer;
   b. Failing to report any administrative action or criminal prosecution taken against the producer or failure to report the termination of a resident producer license;
   c. Acting as a producer through persons not licensed as producers; or
   d. Taking any action to circumvent the spirit of these rules and the Iowa insurance statutes or any other action that shows noncompliance with the requirements of Iowa Code chapter 522B or these rules.

10.20(5) If a producer fails to provide to the division any notification required either by Iowa Code chapter 522B or by this chapter, including but not limited to notification of a change of address, notification of change of name, or notification of administrative criminal action as required by rules 191—10.12(522B) and 191—10.13(522B), within the required time, the producer must pay a late fee of $100 for each notification unless otherwise ordered pursuant to Iowa Code section 522B.6(7) or 522B.17. A business entity that fails to make a notification to the division as required by rule 191—10.18(522B) within the required time must pay a late fee of $100 for each notification unless otherwise ordered pursuant to Iowa Code section 522B.6(7) or 522B.17.

10.20(6) In the event that the division denies a request to renew a producer license or denies an application for a producer license, the commissioner must provide written notification to the producer or applicant of the denial or failure to renew, including the reason therefor. The producer or applicant may request a hearing within 30 days of receipt of the notice to determine the reasonableness of the division’s action. The hearing must be held within 30 days of the date of the receipt of the written request by the applicant, unless otherwise agreed to by the producer, and be held pursuant to 191—Chapter 3.

10.20(7) The commissioner may suspend, revoke, or refuse to issue the license of a business entity if the commissioner finds, after hearing, that an individual licensee’s violation was known or should have been known by one or more of the partners, officers or managers acting on behalf of the entity and the violation was neither reported to the insurance division nor was corrective action taken.

[ARC 4910C; IAB 2/12/20, effective 3/18/20]

191—10.21(252J,272D) Suspension for failure to pay child support or state debt.

10.21(1) The commissioner must deny the producer’s application for license issuance, renewal, reinstatement, or reissuance; suspend a current license; or revoke a currently suspended license upon receipt of a certificate of noncompliance from the CSRU according to the procedures in Iowa Code chapter 252J or upon receipt of a certificate of noncompliance from the centralized collection unit of the department of revenue according to the procedures in Iowa Code chapter 272D. In addition to the procedures set forth in Iowa Code chapters 252J and 272D, this rule applies.

10.21(2) Upon receipt of a certificate of noncompliance, the commissioner must issue a notice to the producer that the division will, unless the certificate of noncompliance is withdrawn, deny the producer’s application for license issuance, renewal, reinstatement, or reissuance; suspend a current license; or revoke a currently suspended license 30 days after the mailing of the notice. Notice must be sent to the producer’s last-known address by restricted certified mail, return receipt requested, or in accordance with the division’s rules for service.

10.21(3) The notice must contain the following items:
   a. A statement that the commissioner intends to deny the producer’s application for license issuance, renewal, reinstatement, or reissuance; suspend a current license; or revoke a currently suspended license in 30 days unless the certificate of noncompliance is withdrawn.
   b. A statement that the producer must contact the agency that issued the certificate of noncompliance (“the issuing agency”) to request a withdrawal;
c. A statement that the producer does not have a right to a hearing before the division, but that the producer may file an application for a hearing in district court pursuant to Iowa Code section 252J.9 or 272D.9, as applicable;  
d. A statement that the filing of an application with the district court will stay the proceedings of the division; and  
e. A copy of the certificate of noncompliance.  
10.21(4) Producers must keep the commissioner informed of all actions taken by the district court or the issuing agency in connection with the certificate of noncompliance. Producers must provide to the commissioner, within seven days of filing or issuance, copies of all applications filed with the district court pursuant to an application of hearing, of all court orders entered in such actions, and of all withdrawals of certificates of noncompliance.  
10.21(5) In the event an applicant or licensed producer timely files an application for hearing in district court and the division is notified of such a filing, the commissioner’s denial, suspension, or revocation proceedings will be stayed until the division is notified by the district court, the issuing agency, the licensee, or the applicant of the resolution of the application. Upon receipt of a court order lifting the stay or otherwise directing the commissioner to proceed, the commissioner shall continue with the intended action described in the notice.  
10.21(6) If the commissioner does not receive a withdrawal of the certificate of noncompliance from the issuing agency or a notice from a clerk of court, the issuing agency, the licensee, or the applicant that an application for hearing has been filed, the commissioner must deny the producer’s application for license issuance, renewal, reinstatement, or reissuance; suspend a current license; or revoke a currently suspended license 30 days after the notice is issued.  
10.21(7) Upon receipt of a withdrawal of the certificate of noncompliance from the issuing agency, suspension or revocation proceedings must halt and the named producer must be notified that the proceedings have been halted. If the producer’s license has already been suspended, the producer must apply for reinstatement and the license must be reinstated if the producer is otherwise in compliance with division rules. If the producer’s application for licensure was stayed, application processing must resume. All fees required for license renewal, reinstatement, or reissuance must be paid by producers and all continuing education requirements must be met before a producer license will be renewed or reinstated after a license suspension or revocation pursuant to this chapter.  
10.21(8) The commissioner must notify the producer in writing through regular first-class mail, or such other means as the commissioner deems appropriate in the circumstances, within ten days of the effective date of the suspension or revocation of a producer license, and must similarly notify the producer when the producer license is reinstated following the commissioner’s receipt of a withdrawal of the certificate of noncompliance.  
10.21(9) Notwithstanding any statutory confidentiality provision, the division may share information with the CSRU or the centralized collection unit of the department of revenue for the sole purpose of identifying producers subject to enforcement under Iowa Code chapter 252J or 272D.  

[ARC 4910C, IAB 2/12/20, effective 3/18/20]


191—10.23(82GA,SF2428) Suspension for failure to pay state debt. Rescinded ARC 4910C, IAB 2/12/20, effective 3/18/20.

191—10.24(522B) Administration of examinations.  
10.24(1) The division may enter into a contractual relationship with an outside testing service, in compliance with Iowa law, to provide the licensing examinations for all lines of authority which require an examination.  
10.24(2) If contracted, the outside testing service must administer all examinations for license applicants.
10.24(3) Any contract to implement subrule 10.24(1) must require the outside testing service to:
   a. Update, on a continual basis, the licensing examinations;
   b. Ensure that the examinations are job-related;
   c. Adequately inform the applicants of the procedures and requirements for taking the licensing examinations;
   d. Prepare and administer examinations for all lines listed in Iowa Code subsection 522B.6(2) and rule 191—10.7(522B), except variable contracts; and
   e. Conform to division guidelines and Iowa law, and report to the division on at least a quarterly basis.
   [ARC 4910C, IAB 2/12/20, effective 3/18/20]

191—10.25(522B) Forms. An original of each form necessary for the producer’s licensure, appointment and termination may be downloaded from the NAIC website, and the division’s website will provide a link to that site. Exact, readable, high-quality copies may be made therefrom.
   [ARC 4910C, IAB 2/12/20, effective 3/18/20]

191—10.26(522B) Fees.
10.26(1) Fees may be paid by check, money order, or credit card.
10.26(2) The fee for an examination may be set by the outside testing service under contract with the division and must be approved by the division.
10.26(3) The fee for issuance or renewal of a producer license is $50 for three years.
10.26(4) The fee for issuance or renewal of a business entity license is $50 for three years.
10.26(5) The fee for reinstatement or reissuance of a producer license is $100. In addition, applicable issuance or renewal fees will be assessed.
10.26(6) The fee for an appointment or the renewal of an appointment is $5 for each producer appointed to a domestic company. The fee for appointment or renewal of each producer appointed to a foreign company is the fee charged by the state of domicile.
10.26(7) The division may charge a reasonable fee for the compilation and production of producer licensing records.
10.26(8) The fee for a criminal history check as required pursuant to Iowa Code section 522B.5 is $50.
   [ARC 4910C, IAB 2/12/20, effective 3/18/20; ARC 5250C, IAB 11/4/20, effective 12/9/20]

191—10.27 to 10.50 Reserved.

191—10.51(522A,522E) Limited licenses.
10.51(1) Limited licenses for vehicle rental companies and counter employees.
   a. Purpose. The purpose of this subrule is to govern the qualifications of and procedures for the licensing of vehicle rental companies and counter employees and to set out the requirements, procedures and fees relating to the qualification and licensure of vehicle rental companies and counter employees.
   b. Definitions. For purposes of this subrule, in addition to the definitions in rule 191—1.1(502,505), the definitions of Iowa Code chapter 522A apply.
   c. Requirement to hold a license.
      (1) A rental company that desires to offer or sell insurance set forth in Iowa Code section 522A.3 in connection with the rental of a vehicle must file a vehicle rental limited license application with the division and, at the discretion of the division, receive a vehicle rental limited license.
      (2) A counter employee who desires to offer or sell insurance products must file a vehicle rental counter employee limited license application with the division and, at the discretion of the division, receive a vehicle rental counter employee limited license.
   d. Limited license application process for vehicle rental company.
      (1) To obtain a limited license, a vehicle rental company must file a completed vehicle rental limited license application with the division and pay a fee of $50 for a license. The vehicle rental limited license application form is available on the division’s website.
(2) If the vehicle rental limited license application is approved, the division must issue a vehicle rental limited license. The vehicle rental limited license term is from the date of approval through the third December 31 after the vehicle rental limited license is issued.

e. **Limited license application process for counter employees.**

(1) An individual may not obtain a vehicle rental counter employee limited license unless that individual is employed by a vehicle rental limited licensee.

(2) To obtain a vehicle rental counter employee limited license, an individual must successfully complete an examination and submit to the division a completed vehicle rental counter employee limited license application, pursuant to Iowa Code section 522A.3. The vehicle rental counter employee limited license application form is available on the division’s website.

(3) If the application is approved, the division must issue a vehicle rental counter employee limited license. Vehicle rental counter employee limited license applications will be deemed approved if not disapproved by the division within 30 days of receipt by the division. The vehicle rental counter employee limited license term is from the date of approval through the third December 31 after the license is issued.

(4) The vehicle rental counter employee limited license will automatically terminate:
   1. When the counter employee ceases employment with a vehicle rental limited licensee; or
   2. At the end of the term of the vehicle rental counter employee limited license term if the license is not renewed pursuant to this subrule.

g. **Duties of vehicle rental limited licensees.**

(1) Pursuant to Iowa Code section 522A.3, a vehicle rental limited licensee is responsible for the training, examination and payment of license fees for all individuals it employs for whom the licensee desires to obtain vehicle rental counter employee limited licenses.

(2) A vehicle rental limited licensee must obtain and administer an examination for all vehicle rental counter employee limited license candidates. The content of the examination and the manner of its administration must be approved by the division.

(3) The vehicle rental limited licensee must develop a system for the security of examination content.

(4) The vehicle rental limited licensee must administer the vehicle rental counter employee limited license examination under controlled conditions, approved by the division, which ensure that each candidate completes the examination without outside assistance or interference.

(5) The vehicle rental limited licensee must notify the division of the termination of employment of any of its vehicle rental employee limited licensees. The vehicle rental limited licensee must file reports of terminations within 30 days of termination of employment.

h. **License renewal.**

(1) All vehicle rental limited licenses and vehicle rental counter employee limited licenses must be issued with an expiration date of the December 31 at the end of the license terms and must be renewed before the end of the license terms.

(2) Each year, the division must mail to the vehicle rental limited licensee’s latest electronic mail or mailing address appearing in the division’s records a renewal form for use in renewing the vehicle rental limited license and all of the vehicle rental counter employee limited licenses that will expire that year.

(3) The vehicle rental limited licensee must complete the renewal form for its license if applicable and for all of the vehicle rental counter employee limited licenses that will expire that year and must return the completed renewal form and applicable fee to the division on or before December 31 of the renewal year or all licenses listed on the renewal form will expire.

(4) The fee for renewal of a vehicle rental limited license is $50, and the fee to renew each vehicle rental counter employee limited license is $50.

i. **Limitation on fees.** A vehicle rental limited licensee is not required to pay license and renewal fees of more than $1,000 in aggregate in any calendar year.

j. **Change in name or address.**
(1) Vehicle rental limited licensees must file written notification with the division of a change in name or address within 30 days of the change. This requirement applies to any change in any locations at which the vehicle rental limited licensee is doing business.

(2) Vehicle rental limited licensees must file written notification with the division of changes in names or addresses of vehicle rental counter employee limited licensees. If the change of name is by a court order, a copy of the order shall be included with the notification. The limited licensee must file reports of name and address changes within 30 days of the change.

j. Violations and penalties.

(1) A rental company or counter employee who sells insurance in violation of this rule is in violation of Iowa Code chapter 522A and is subject to the penalties provided in Iowa Code section 522A.3.

(2) A vehicle rental limited licensee or vehicle rental counter employee limited licensee who commits an unfair or deceptive trade practice in violation of Iowa Code chapter 507B, or in violation of administrative rules which implement that chapter, is subject to the penalties provided for in Iowa Code chapter 507B.

10.51(2) Limited licenses for persons who sell portable electronics insurance.

a. Purpose. The purpose of this subrule is to govern the qualifications of and procedures for the licensing of persons offering or selling any form of portable electronics insurance in this state, pursuant to Iowa Code chapter 522E.

b. Definitions. For purposes of this subrule, in addition to the definitions in rule 191—1.1(502,505), the definitions of Iowa Code chapter 522E apply.

c. Requirement to hold a portable electronics insurance limited license. A person that desires to offer or sell any form of portable electronics insurance in this state must:

(1) Be licensed as an insurance producer pursuant to Iowa Code chapter 522B;

(2) Submit an application to the division and, at the discretion of the division, receive a portable electronics insurance limited license pursuant to Iowa Code sections 522E.2, 522E.3, and 522E.4 and this subrule; or

(3) Be an endorsee in compliance with Iowa Code sections 522E.6 and 522E.7 and this subrule.

d. Application process for portable electronics insurance limited license.

(1) To obtain a portable electronics insurance limited license, a portable electronics vendor must submit to the division a completed portable electronics insurance limited license application and the appropriate fee, as required by Iowa Code section 522E.3.

(2) If the application is approved, the division must issue a portable electronics insurance limited license. The portable electronics insurance limited license term is from the date of approval through the third December 31 after the portable electronics insurance limited license was issued.

e. Portable electronics insurance limited license renewal.

(1) All portable electronics insurance limited licenses must be issued for a license period as defined in Iowa Code section 522E.1 and must be renewed triennially.

(2) Not less than 60 days before the end of the license period, the division must mail a renewal form to the portable electronics insurance limited licensee at the last-known electronic mail or mailing address appearing in the division’s records.

(3) The portable electronics insurance limited licensee must complete and return to the division the completed renewal form and the applicable fee, as required by Iowa Code section 522E.5, on or before the expiration date of the portable electronics insurance limited license, or the licensee’s portable electronics insurance limited license will expire and the authority of all endorsee(s) to sell under the portable electronics insurance limited license also will expire.

f. Change in name or address. A portable electronics insurance limited licensee must file written notification with the division of a change in name or address within 30 days of the change. This requirement applies to any change in any location at which the portable electronics insurance limited licensee is doing business.
g. **Violations and penalties.** A portable electronics vendor or endorsee that sells insurance in violation of this rule is in violation of Iowa Code chapter 522E and is subject to the penalties in Iowa Code chapter 522E.

[ARC 2260C, IAB 11/25/15, effective 1/1/16; ARC 4910C, IAB 2/12/20, effective 3/18/20; ARC 6338C, IAB 6/1/22, effective 7/6/22]

These rules are intended to implement Iowa Code chapters 252J, 272D, 522A, 522B, and 522E.

[Filed November 21, 1963]

Appeared as 9.1, 1973 IDR

[Filed 1/13/84, Notice 11/23/84—published 2/1/84, effective 3/7/84]
[Filed 9/21/84, Notice 7/18/84—published 10/10/84, effective 11/15/84]
[Filed 4/8/85, Notice 1/30/85—published 4/24/85, effective 5/31/85]
[Filed 8/7/86, Notice 7/2/86—published 8/27/86, effective 10/1/86]
[Editorially transferred from [510] to [191], IAC Supp. 10/22/86; see IAB 7/30/86]

[Filed emergency 6/24/88—published 7/13/88, effective 7/1/88]
[Filed 10/25/91, Notice 9/18/91—published 11/13/91, effective 12/18/91]
[Filed 11/19/93, Notice 10/13/93—published 12/8/93, effective 1/12/94]
[Filed 10/21/94, Notice 9/14/94—published 11/9/94, effective 12/14/94]
[Filed 2/2/96, Notice 12/6/95—published 2/28/96, effective 4/3/96]
[Filed 10/30/97, Notice 9/10/97—published 11/19/97, effective 1/1/98]
[Filed 1/20/00, Notice 12/1/99—published 2/9/00, effective 3/15/00]
[Filed 10/26/01, Notice 9/19/01—published 11/14/01, effective 1/1/02]
[Filed 4/21/05, Notice 3/2/05—published 5/11/05, effective 6/15/05]
[Filed 10/5/06, Notice 8/30/06—published 10/25/06, effective 11/29/06]
[Filed 10/5/07, Notice 8/29/07—published 10/24/07, effective 11/28/07]
[Filed 10/30/08, Notice 9/24/08—published 11/19/08, effective 1/1/09]
[Filed ARC 7836B (Notice ARC 7711B, IAB 4/8/09), IAB 6/3/09, effective 7/8/09]
[Editorial change: IAC Supplement 11/18/09]
[Filed ARC 2260C (Notice ARC 2174C, IAB 9/30/15), IAB 11/25/15, effective 1/1/16]
[Filed ARC 4780C (Notice ARC 4660C, IAB 9/25/19), IAB 11/20/19, effective 12/25/19]
[Filed ARC 4910C (Notice ARC 4821C, IAB 12/18/19), IAB 2/12/20, effective 3/18/20]
[Filed ARC 5250C (Notice ARC 5129C, IAB 8/12/20), IAB 11/4/20, effective 12/9/20]
[Filed ARC 6338C (Notice ARC 6285C, IAB 4/6/22), IAB 6/1/22, effective 7/6/22]

0 Two or more ARCs
CHAPTER 35
ACCIDENT AND HEALTH INSURANCE

BLANKET ACCIDENT AND SICKNESS INSURANCE
[Prior to 10/22/86, Insurance Department[510]]

191—35.1(509) Purpose. The purpose of this regulation is to establish guidelines for insurers to make special risk coverage available to particular groups that will be exposed to specific hazards for a certain period of time.

191—35.2(509) Scope. These rules shall apply to all insurance companies holding a certificate of authority to transact the business of insurance under the provisions of Iowa Code chapters 508 and 515.

191—35.3(509) Definitions.

35.3(1) Blanket accident and sickness insurance is hereby declared to be that form of accident, sickness or accident and sickness insurance designed to insure against specified hazards incident to or defined by reference to a particular activity or activities and covering groups of persons as enumerated in the following subparagraphs:

a. Under a policy issued to an employer, who shall be deemed the policyholder covering any group of employees defined by reference to specific hazards incident to an activity or activities of the policyholder.

b. Under a policy issued to a college, high school, junior high school, grade school, school district, school jurisdictional unit or other institution of learning; or to the head, principal, governing board of any such educational unit who or which shall be deemed the policyholder covering students, teachers or employees.

c. Under a policy issued to any religious, charitable or educational organization, or branch thereof, which shall be deemed the policyholder covering any group of members or participants defined by reference to specified hazards incident to an activity or activities sponsored or supervised by such policyholder.

d. Under a policy issued to a sports team, youth camp, recreational organization or sponsor thereof, which shall be deemed the policyholder, covering members, campers, participants, employees, officials or supervisors.

e. Under a policy issued to any volunteer fire department, first aid, civil defense or other such volunteer organizations, which shall be deemed the policyholder, covering any group of members or participants defined by reference to specified hazards incident to an activity or activities or operations sponsored or supervised by such policyholder.

f. Under a policy issued to a newspaper or other publisher, which shall be deemed the policyholder, covering its carriers.

g. Under a policy issued to an association, other than a labor union, trade association or industrial association, which shall have a constitution and bylaws and which has been organized and is maintained in good faith for purposes other than that of obtaining insurance, which shall be deemed the policyholder, covering any group of members or participants defined by reference to specified hazards incident to an activity or activities or operations sponsored or supervised by such policyholder.

h. Under a policy issued to cover any other risk or class of risks which, in the discretion of the commissioner, may be properly eligible for blanket accident and sickness insurance. The discretion of the commissioner may be exercised on an individual risk basis or class of risks, or both.

35.3(2) Brochure shall mean an instrument, booklet or pamphlet setting forth a statement as to the insurance protection provided, to whom the insurance benefits are payable, sufficient information on the procedure an insured shall follow in filing a claim and such other provisions as are in the opinion of the commissioner of insurance necessary to inform the holder thereof as to rights under the policy.

35.3(3) For purposes of Iowa Code section 514C.22 relating to biologically based mental illness coverage in a group policy, contract or plan providing for third-party payment of health, medical, and surgical coverage benefits issued by a carrier, “biologically based mental illness” shall mean
the following mental disorders as they are defined under the following diagnostic classes within the American Psychiatric Association’s Diagnostic and Statistical Manual of Mental Disorders, edition DSM-IV-TR:

a. Schizophrenia. Diagnostic codes 295.xx and 293.xx, including all specific subtypes of schizophrenia listed under those two diagnostic codes and using an appropriate extension. Schizophrenia also includes diagnostic codes 295.40, 295.70, 297.1, 298.8, 297.3 and 298.9.

b. Bipolar disorders. Diagnostic code 296.xx including all specific subtypes of bipolar disorders listed under that diagnostic code and using an appropriate extension. Bipolar disorders also includes diagnostic codes 286.89, 301.13, 296.80, 293.83 and 296.90.

c. Major depressive disorders. Diagnostic codes 296.2x and 296.3x including all specific subtypes of major depressive disorders listed under those two diagnostic codes and using an appropriate extension.


e. Obsessive-compulsive disorders. Diagnostic code 300.3.

f. Pervasive development disorders. Diagnostic codes 299.00, 299.80 and 299.10.

g. Autistic disorders. Diagnostic code 299.00.

[ARC 3682C, IAB 3/14/18, effective 4/18/18]

191—35.4(509) Required provisions. No blanket policy as herein defined shall be issued or delivered in this state unless a copy of the policy and brochure if required, has been approved by the commissioner of insurance in accordance with the provisions set forth in rule 191—35.7(509). All policies of blanket accident or sickness insurance or combination thereof issued in this state shall contain in substance the following provisions:

35.4(1) A provision that the policy including endorsements and a copy of the application, if any, of the policyholder and the persons insured shall constitute the entire contract between the parties, and that any statement made by the policyholder or by a person insured shall be in the absence of fraud, be deemed a representation and not a warranty. No such statement shall be used in defense of a claim under the policy, unless it is contained in a written application. If a copy of such application is not delivered to the person insured the insurer shall be precluded from introducing such application as evidence in any action involving any statements contained therein.

35.4(2) A provision that written notice of sickness or of injury must be given to the insurer within 20 days of the date when such sickness or injury occurred. Failure to give notice within such time shall not invalidate nor reduce any claim if it shall be shown not to have been reasonably possible to give such notice and that notice was given as soon as was reasonably possible.

35.4(3) A provision that the insurer will furnish either to the claimant or to the policyholder for delivery to the claimant such forms as are usually furnished by it for filing proof of loss. If such forms are not furnished before the expiration of 15 days after giving such notice, the claimant shall be deemed to have complied with the requirements of the policy as to proof of loss upon submitting within the time fixed in the policy for filing proof of loss, written proof covering the occurrence, the character and the extent of the loss for which claim is made.

35.4(4) A provision that in the case of claim for loss of time for disability, written proof of such loss must be furnished to the insurer within 90 days after the commencement of the period for which the insurer is liable, and that subsequent written proofs of the continuance of such disability must be furnished to the insurer at such intervals as the insurer may reasonably require, and that in the case of claim for any other loss, written proof of such loss must be furnished to the insurer within 90 days after the date of such loss. Failure to furnish such proof within such time shall not invalidate nor reduce any claim if it shall be shown not to have been reasonably possible to furnish such proof and that such proof was furnished as soon as was reasonably possible.

35.4(5) A provision that all benefits payable under the policy other than benefits for loss of time will be payable immediately upon receipt of due written proof of such loss, and that, subject to due proof of loss, all accrued benefits payable under the policy for loss of time will be paid not less frequently than monthly during the continuance of the period for which the insurer is liable, and that any balance remaining unpaid at the termination of such period will be paid immediately upon receipt of such proof.
35.4(6) A provision that the insurer at its own expense, shall have the right and opportunity to examine the person of the insured when and so often as it may reasonably require during the pendency of claim under the policy and also the right and opportunity to make an autopsy where it is not prohibited by law.

35.4(7) A provision that no action at law or in equity shall be brought to recover under the policy prior to the expiration of 60 days after written proof of loss has been furnished in accordance with the requirements of the policy and that no such action shall be brought after the expiration of three years after the time written proof of loss is required to be furnished.

191—35.5(509) Application and certificates not required. An individual application need not be required from a person covered under a blanket accident and sickness policy, nor shall it be necessary for the insurer to furnish each person a certificate; however, a brochure as herein defined shall be issued to the policyholder for delivery to each person insured as defined in 35.3(1) "b" and "g."

191—35.6(509) Facility of payment. All benefits under any blanket accident and sickness policy shall be payable to the person insured, to a designated beneficiary or beneficiaries, or to their estate, except that if the person insured be a minor or otherwise not competent to give a valid release, such benefits may be made payable to their parent, guardian or other person actually supporting the insured, designated beneficiary, or beneficiaries. The policy may also provide that all or a portion of any indemnities provided by any such policy on account of hospital, nursing, medical or surgical services may with the consent of the insured be paid directly to the hospital or person rendering such services, but the policy may not require that the services be rendered by a particular hospital or person. Payment so made shall discharge the obligation of the insurer with respect to the amount of insurance so paid.

These rules are intended to implement Iowa Code section 509.5.

191—35.7(509) General filing requirements.

35.7(1) Insurance companies required to file rates or forms with the division shall submit required rate and form filings pursuant to rule 191—20.1(505,509,514A,515,515A,515F).

35.7(2) Each filing must be submitted to the division of insurance not less than 60 days prior to the effective date of the filing. Any deficiencies or discrepancies in the filing will delay final approval. In case of disapproval, the company will be notified by the division.

This rule is intended to implement Iowa Code section 509.6.

191—35.8(509) Electronic delivery of accident and health group insurance certificates.

35.8(1) Purpose. The purpose of this rule is to authorize the electronic delivery of accident and health group insurance certificates in an efficient manner by insurers and group policyholders, while guaranteeing that individual plan members still receive the important information contained in such group insurance certificates, as required by Iowa Code section 509.3(1) "b," and as allowed by the uniform electronic transactions Act, Iowa Code chapter 554D.

35.8(2) Scope. This rule shall apply to all insurance companies holding a certificate of authority to transact the business of insurance under the provisions of Iowa Code chapters 508 and 515.

35.8(3) Electronic delivery—insurance companies. The insurer will be deemed to comply with the requirements of Iowa Code section 509.3(1) "b" if the group insurance certificate is delivered to the group policyholder electronically and if:

a. The insurer takes appropriate and necessary measures to ensure that the system for furnishing group insurance certificates results in actual receipt of transmitted information by group policyholders, which may be done by:

(1) Using return-receipt electronic mail features;
(2) Periodic reviews or surveys to confirm receipt of the transmitted information; or
(3) Any other method approved by the insurance commissioner.
b. The electronic documents contain the same content and appear in reasonably the same format as the certificates previously approved by the insurance commissioner.

c. Each group policyholder is provided notice, through electronic means or in writing, apprising the group policyholder of the fact that the certificate will be furnished electronically, of the significance of the certificate and the group policyholder’s obligations under this rule, and of the group policyholder’s right to request and receive a paper copy of the document for each participant.

d. Upon request of any group policyholder, the insurer furnishes paper copies of the group insurance certificate that was delivered to the group policyholder electronically, so that the group policyholder may provide them to participants that have requested paper copies.

35.8(4) Electronic delivery—group policyholders. The group policyholder will be deemed to comply with the requirements of Iowa Code section 509.3(1) “b” if the group insurance certificate is delivered to the individual plan member electronically and if:

a. The group policyholder takes appropriate and necessary measures to ensure that the system for furnishing group insurance certificates results in actual receipt of transmitted information by participants, which may be done by:

(1) Using return-receipt electronic mail features;
(2) Periodic reviews or surveys to confirm receipt of the transmitted information; or
(3) Any other method approved by the insurance commissioner.

b. The electronic documents contain the same content and appear in reasonably the same format as the certificates previously approved by the insurance commissioner.

c. Each participant is provided notice, through electronic means or in writing, apprising the participant of the fact that the certificate will be furnished electronically, of the significance of the certificate, and of the participant’s right to request and receive, free of charge, a paper copy of the document.

d. Upon request of any participant, the group policyholder furnishes, free of charge, a paper copy of the group insurance certificate that was delivered to the participant electronically.

This rule is intended to implement Iowa Code chapter 509.

[ARC 6121C, IAB 12/29/21, effective 2/2/22]

GENERAL ACCIDENT AND HEALTH INSURANCE REQUIREMENTS

191—35.9(509B,513B,514D) Notice of cancellation, nonrenewal or termination of accident and health insurance.

35.9(1) Purpose and definitions.

a. Purpose. The purpose of this rule is to clarify the authorized methods of delivery for notices of cancellation, nonrenewal or termination by an insurer, issuer, employer, group policyholder, or carrier, so as to implement the various policyholder protections intended by Iowa Code sections 509B.5, 513B.5, 514D.3, 515.125 and 515.129A and chapter 505B.

b. Definitions. As used in Iowa Code section 505B.1 and this rule:

“Commissioner” means the Iowa insurance commissioner or insurance division.

“Notice of cancellation, nonrenewal or termination” means:

1. Notice of termination of an insurance policy at the end of a term or before the termination date;
2. Notice of a decision or intention not to renew a policy; and
3. For purposes of notices required by Iowa Code sections 509B.5, 513B.5, 514D.3, 515.125 and 515.129A and chapter 505B, “notice of cancellation, nonrenewal or termination” includes but is not limited to the following:

- An employer’s or group policyholder’s notification to employees or members of the termination or substantial modification of the continuation of an employer group accident or health policy pursuant to Iowa Code section 509B.5;
- A carrier’s advance notice to all affected small employers, participants, and beneficiaries of its decision to discontinue offering a particular type of small group health insurance plan pursuant to Iowa Code section 513B.5(1) “e”(2);
• An insurance company’s notice of termination of an individual accident and sickness policy, pursuant to rules promulgated pursuant to Iowa Code section 514D.3;
• An insurance company’s notice of forfeiture, suspension, cancellation, or intention not to renew, pursuant to Iowa Code section 515.125; or
• An insurance company’s notice of cancellation of personal lines policies or contracts pursuant to Iowa Code section 515.129A.

35.9(2) Scope. This rule shall apply to all insurance companies holding a certificate of authority to transact the business of insurance under the provisions of Iowa Code chapters 508, 512B, 515, and 520.

35.9(3) Delivery. For any notice of cancellation, nonrenewal or termination by an insurer, employer, group policyholder, or carrier to be effective, an insurer, employer, group policyholder, or carrier must, within the time frame established by law, deliver the notice to the person to whom notice is required to be provided either in person or by mail through the U.S. Postal Service to the last-known address of the person to whom notice is required to be provided. The use of U.S. Postal Service Intelligent Mail® fulfills any requirement in the Iowa Code sections cited in this subrule for certified mail or certificate of mailing as proof of mailing.

35.9(4) Electronic transmissions. Notwithstanding the requirements of subrule 35.9(3), if an insurer, issuer, employer, group policyholder, or carrier receives, pursuant to 191—subrule 4.21(4), approval from the commissioner of a manner of electronic delivery of a notice of cancellation, nonrenewal or termination of a policy, the approved manner shall satisfy the notice requirements of Iowa Code sections 509B.5, 513B.5, 514D.3, 515.125 and 515.129A and chapter 505B.

This rule is intended to implement Iowa Code chapters 505B, 509B, 513B, 514D, and 515.

[ARC 1999C, IAB 5/27/15, effective 7/1/15; ARC 2415C, IAB 2/17/16, effective 3/23/16; ARC 3682C, IAB 3/14/18, effective 4/18/18; ARC 6338C, IAB 6/1/22, effective 7/6/22]

191—35.10 to 35.19 Reserved.

191—35.20(509A) Life and health self-funded plans.

35.20(1) Scope. This rule shall apply to life and health self-funded plans for political subdivisions of the state, school corporations, and all other public bodies of the state. This rule shall not apply to life and health self-funded plans for the state of Iowa.

35.20(2) Iowa Code chapter 28E agreements—certificate of registration. Public entities seeking to pool risk through a joint exercise of power under Iowa Code chapter 28E shall apply for and obtain a certificate of registration from the commissioner. This subrule shall not apply to single-employer public entities with self-insured plans.

a. An application for a certificate of registration shall contain the following:
   (1) A copy of the proposed agreement entered into pursuant to Iowa Code chapter 28E, to be executed by all plan participants;
   (2) A copy of the articles of incorporation, bylaws, agreements, or other documents or instruments describing the rights and obligations of employers, employees and beneficiaries;
   (3) A copy of all contracts with insurance companies, consultants and third-party administrators;
   (4) A business plan, including a copy of all contracts or other instruments which the 28E agreement proposes to make with or sell to its members, a copy of its plan description and the printed matter to be used in the solicitation of members; and
   (5) A current list of all participating public entities.

b. Iowa Code chapter 28E agreements shall contain the following provisions:
   (1) If the plan is in a deficit position, a participant cannot terminate from the plan without the prior written consent of the commissioner;
   (2) If a participant in the plan terminates, the terminating participant shall be assessed its proportionate share of the plan’s deficit, if any;
   (3) Deficit assessments shall be mandatory for all plan participants within a time frame acceptable to the commissioner;
   (4) Plan participants have no individual interest in the accumulated surplus of a plan; and
(5) Upon termination of the plan, surplus remaining after the payment of all liabilities shall be distributed proportionately to plan participants that were active members of the plan on the termination date.

c. Reporting requirements. In addition to the requirements of subrule 35.20(3), all public entities pooling risk shall submit:

(1) Quarterly financial statement. A plan shall file with the commissioner of insurance within 60 days of the end of each quarter a report which has been verified by at least two of its principal officers and which covers the preceding calendar quarter. The report shall be on a form prescribed by the commissioner. The commissioner of insurance may request additional reports and information from a plan as often as is deemed necessary.

(2) Amendments. A plan shall submit copies of any proposed amendment to the documents submitted in accordance with subrule 35.20(2), paragraph “a,” 30 days in advance of the amendment’s proposed effective date.

(3) Other documents. A plan shall submit any other documents deemed necessary by the commissioner.

35.20(3) Minimum plan standards for both pooled and single-employer public entities. Self-funded life plans subject to this rule shall meet the requirements of Iowa Code sections 509.1, 509.2, 509.4, and 509.15 and rules thereunder. Self-funded health plans subject to this rule shall meet the requirements of Iowa Code sections 509.1 and 509.3 and rules thereunder. In order to ensure that a self-funded life or health plan is able to cover all reasonably anticipated expenses and to avoid liability for the public body, a self-funded life or health plan shall provide that:

a. An annual report showing the starting and ending balance of the fund, deposits of monthly accrual rates and other assets of the fund, and the amount and nature of all disbursements from the fund shall be prepared and submitted to the governing body of the public body. An annual report shall be made to show a separate accounting to reflect all required reserves.

b. Monthly accrual rates shall be established at a satisfactory level to provide funds to cover all claims, reserves, and expenses to operate the plan. Accrual rates shall be reevaluated annually. Accrual rates shall be funded solely through public body contributions or through a combination of employer and employee contributions.

c. A plan fund shall be established exclusively for the deposit of monthly accrual rates and other assets pertaining to the plan. After a self-funded life or health plan is established and as long as any claims may be made against the plan fund, all contributions shall be deposited as collected in the plan fund. The plan fund shall be disbursed only for plan expenses.

d. The following reserves shall be established in the plan fund:

(1) A reserve for claims that have been incurred by participants under the plan, but have not yet been presented for payment. The appropriate amount of this reserve shall be on an actuarially sound basis as determined by an independent actuary, an insurance company, or a nonprofit health service corporation authorized pursuant to Iowa Code chapter 514.

(2) A claims fluctuation reserve for setting aside funds that become available during a month when claims are less than projected for that month. Funds shall be maintained and available for a month in which claims exceed those projected for that month. For public entities that require a certificate of registration under subrule 35.20(2), the claims fluctuation reserve shall equal or exceed a minimum of two months of paid claims.

e. The public body shall obtain a fidelity bond as a guaranty of faithful operation of the self-funded plan by the public body, its officers, agents, and employees.

f. Disbursements from the plan fund shall be made only for the following specified plan expenses:

(1) Payment of claims.

(2) Cost of aggregate excess loss coverage.

(3) Cost of specific excess loss coverage.

(4) Bonding expenses.

(5) Payment of service fees applicable to plan design, payment of claims, materials explaining plan benefits, actuarial assistance, legal assistance, and accounting assistance.
(6) Other expenses directly related to the operation of the plan.

g. Aggregate excess loss coverage shall be obtained which will limit a public body’s total claim liability for each year to not more than 125 percent of the level of claims liability as projected by an independent actuary or insurance company. A public body shall fund this potential additional liability of 25 percent either by allocating necessary funds from the operating fund of the general fund or by setting up an additional reserve in the operating fund. Specific excess loss coverage may also be obtained if a public body wishes to limit its total annual liability on claims for any one claimant.

h. The commissioner may retain an independent actuary, at the commissioner’s discretion, to review the adequacy of a plan’s reserves. The cost of such review shall be paid by the plan. Examples that illustrate when the commissioner may retain an independent actuary include, but are not limited to, negative trends in the plan’s financial statements, an increase in consumer complaints about the plan’s failing to timely pay claims and material changes to the plan’s operations.

35.20(4) Plan shortfalls. If the resources of any self-funded plan subject to this rule are not adequate to fully cover all claims under that plan, then the public body sponsoring that plan shall make up the shortfall from other resources.

35.20(5) Confidentiality. Information held by the plan administrator of a self-funded plan shall be kept confidential. An employee or agent of the plan administrator shall not use or disclose any information to any person, except to the extent necessary to administer claims or as otherwise authorized by law.

35.20(6) A health self-funded plan subject to this rule shall not prohibit a participating provider from or penalize a participating provider for discussing treatment options with covered persons, irrespective of a self-funded plan’s position on the treatment options, or from advocating on behalf of covered persons within the utilization review or grievance processes established by the self-funded plan or a person contracting with the self-funded plan.

The self-funded plan shall not penalize a provider because the provider, in good faith, reports to state or federal authorities any act or practice by the self-funded plan that, in the opinion of the provider, jeopardizes patient health or welfare.

35.20(7) Benefits shall be made available by the health self-funded plan for inpatient and outpatient emergency services. Since self-funded plans may not contract with every emergency care provider in an area, self-funded plans shall make every effort to inform members of participating providers.

The term “emergency services” means, with respect to an individual enrolled with an organization, covered inpatient and outpatient services that are furnished by a provider who is qualified to furnish the services that are needed to evaluate or stabilize an emergency medical condition.

The term “emergency medical condition” means a medical condition manifesting itself by symptoms of sufficient severity, including but not limited to severe pain, that an ordinarily prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in one of the following:

1. Placing the health of the individual or, with respect to a pregnant woman, the health of the woman and her unborn child in serious jeopardy;
2. Serious impairment to bodily function; or
3. Serious dysfunction of any bodily organ or part.

Reimbursement to a provider of “emergency services” shall not be denied by any health maintenance organization without that organization’s review of the patient’s medical history, presenting symptoms, and admitting or initial diagnosis as well as final diagnosis, submitted by the provider, in determining whether, by definition, emergency services could reasonably have been expected to be provided. Reimbursement for emergency services shall not be denied solely on the grounds that a noncontracted provider performed services. If reimbursement for emergency services is denied, the enrollee may file a complaint with the self-funded plan. Upon denial of reimbursement for emergency services, the self-funded plan shall notify the enrollee and the provider that they may register a complaint with the commissioner of insurance.
35.20(8) A health self-funded plan subject to this rule shall allow a female member direct access to obstetrical or gynecological services from network and participating providers. The plan shall also allow a pediatrician to be the primary care provider for a child through the age of 18.

This rule is intended to implement Iowa Code chapter 509A.

[ARC 6121C, IAB 12/29/21, effective 2/2/22]

191—35.21(509) Review of certificates issued under group policies.

35.21(1) Nondiscretionary groups. A certificate of coverage delivered in this state under a group life or accident and health insurance policy issued to a group substantially as described in Iowa Code section 509.1, subsections (1) to (7), shall not be reviewed by the commissioner if the policy is issued outside of this state.

35.21(2) Discretionary groups. A certificate of coverage delivered in this state under a group life or accident and health insurance policy issued to a group not substantially as described in Iowa Code section 509.1, subsections (1) to (7), shall not be reviewed by the commissioner if the policy is issued outside of this state and if the policy is issued or offered in a state which has reviewed and approved the policy under a statute substantially similar to Iowa Code section 509.1(8).

These rules are intended to implement Iowa Code sections 509.1, 509.6, and 509A.14.

LARGE GROUP HEALTH INSURANCE COVERAGE

191—35.22(509) Purpose. This division of Chapter 35 implements the requirements of Pub.L. 104-191, the Health Insurance Portability and Accountability Act of 1996 and Iowa Code section 509.3 for large group health insurance coverage.

191—35.23(509) Definitions.

“Affiliation period” means a period of time that must expire before health insurance coverage provided by an HMO becomes effective, and during which the HMO is not required to provide benefits.

“Beneficiary” has the meaning given the term under Section 3(8) of the Employee Retirement Income Security Act of 1974 (ERISA), which states, “a person designated by a participant, or by the terms of an employee benefit plan, who is or may become entitled to a benefit” under the plan.

“Bona fide association” means, with respect to group health insurance coverage offered in Iowa, an association that meets the following conditions:

1. Has been actively in existence for at least five years.
2. Has been formed and maintained in good faith for purposes other than obtaining insurance.
3. Does not condition membership in the association on any health status-related factor relating to an individual including an employee of an employer or a dependent of any employee.
4. Makes health insurance coverage offered through the association available to all members regardless of any health status-related factor relating to the members or individuals eligible for coverage through a member.
5. Does not make health insurance coverage offered through the association available other than in connection with a member of the association.

“Carrier” means an entity subject to the insurance laws and regulations of this state, or subject to the jurisdiction of the commissioner, that contracts or offers to contract to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services, including an insurance company offering sickness and accident plans, a health maintenance organization, a nonprofit health service corporation, or any other entity providing a plan of health insurance, health benefits or health services.

“COBRA” means Title X of the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended.

“Commissioner” means the commissioner of insurance.

“Continuation coverage” means coverage under a COBRA continuation provision or a similar state program. Coverage provided by a plan that is subject to a COBRA continuation provision or similar state program, but that does not satisfy all the requirements of that provision or program, will be deemed to be continuation coverage if it allows an individual to elect to continue coverage for a period of at
least 18 months. Continuation coverage does not include coverage under a conversion policy required to be offered to an individual upon exhaustion of continuation coverage, nor does it include continuation coverage under the Federal Employees Health Benefits Program.

“Creditable coverage” means health benefits or coverage provided to an individual under any of the following:

1. A group health plan.
2. Health insurance coverage.
3. Part A or Part B Medicare pursuant to Title XVIII of the federal Social Security Act.
4. Medicaid pursuant to Title XIX of the federal Social Security Act, other than coverage consisting solely of benefits under Section 1928 of that Act.
5. 10 U.S.C. ch. 55.
6. A health or medical care program provided through the Indian Health Service or a tribal organization.
9. A public health plan as defined under federal regulations.
10. A health benefit plan under Section 5(e) of the Peace Corps Act, 22 U.S.C. 2504(e).

“Director” means the director of public health appointed pursuant to Iowa Code section 135.2.

“Division” means the division of insurance.

“Eligible employee” means an individual who is eligible to enroll in group health insurance coverage offered to a group health plan maintained by an employer, in accordance with the terms of the group health plan.

“Employee” means any individual employed by an employer.

“Enrollment date” means the first day of coverage or, if there is a waiting period, the first day of the waiting period.

“Exhaustion of continuation coverage” means that an individual’s continuation coverage ceases for any reason other than either failure of the individual to pay premiums on a timely basis, or for cause such as making a fraudulent claim or an intentional misrepresentation of a material fact in connection with the plan. An individual is considered to have exhausted continuation coverage if:

1. Coverage ceases due to the failure of the employer or other responsible entity to remit premiums on a timely basis, or
2. When the individual no longer resides, lives, or works in a service area of an HMO or similar program, whether or not within the choice of the individual, and there is no other continuation coverage available to the individual.

“Group health plan” means an employee welfare benefit plan as defined in Section 3(1) of the federal Employee Retirement Income Security Act of 1974, to the extent that the plan provides medical care including items and services paid for as medical care to employees or their dependents as defined under the terms of the plan directly or through insurance, reimbursement, or otherwise.

1. For purposes of this rule, “medical care” means amounts paid for any of the following:
   - The diagnosis, cure, mitigation, treatment, or prevention of disease, or amounts paid for the purpose of affecting a structure or function of the body.
   - Transportation primarily for and essential to medical care referred to in this definition.
   - Insurance covering medical care referred to in this definition.
2. For purposes of this division, a plan, fund, or program established or maintained by a partnership which, but for this paragraph, would not be an employee welfare benefit plan, shall be treated as an employee welfare benefit plan which is a group health plan to the extent that the plan, fund, or program provides medical care, including items and services paid for as medical care, for present or former partners in the partnership or to the dependents of such partners, as defined under the terms of the plan, fund, or program, either directly or through insurance, reimbursement, or otherwise.
3. With respect to a group health plan, the term “employer” includes a partnership with respect to a partner.
4. With respect to a group health plan the term “participant” includes the following:
   - With respect to a group health plan maintained by a partnership, an individual who is a partner in the partnership.
   - With respect to a group health plan maintained by a self-employed individual, under which one or more of the self-employed individual’s employees are participants, the self-employed individual, if that individual is, or may become, eligible to receive benefits under the plan or the individual’s dependents may be eligible to receive benefits under the plan.

   “Health insurance coverage” or “health insurance plan” means benefits consisting of health care provided directly, through insurance or reimbursement, or otherwise and including items and services paid for as health care under a hospital or health service policy or certificate, hospital or health service plan contract, or health maintenance organization contract offered by a carrier.

1. “Health insurance coverage” does not include any of the following:
   - Coverage for accident only, or disability income insurance.
   - Coverage issued as a supplement to liability insurance.
   - Liability insurance, including general liability insurance and automobile liability insurance.
   - Workers’ compensation or similar insurance.
   - Automobile medical payment insurance.
   - Credit-only insurance.
   - Coverage for on-site medical clinic care.
   - Other similar insurance coverage, specified in federal regulations, under which benefits for medical care are secondary or incidental to other insurance benefits.
   - Flexible spending accounts.

2. “Health insurance coverage” does not include benefits provided under a separate policy as follows:
   - Limited scope dental or vision benefits.
   - Benefits for long-term care, nursing home care, home health care, or community-based care.
   - Short-term limited-duration insurance.
   - Any other similar, limited benefits as provided by rule of the commissioner.
   - Stop loss insurance coverage.

3. “Health insurance coverage” does not include benefits offered as independent noncoordinated benefits as follows:
   - Coverage only for a specified disease or illness;
   - Hospital indemnity or other fixed indemnity insurance.

4. “Health insurance coverage” does not include Medicare supplemental health insurance as defined under Section 1882(g)(1) of the federal Social Security Act, coverage supplemental to the coverage provided under 10 U.S.C. ch. 55, and similar supplemental coverage provided under insurance coverage.

5. “Group health insurance coverage” means health insurance coverage offered in connection with a group health plan.

   “Health maintenance organization” or “HMO” means a federally qualified health maintenance organization as defined in Section 1301(a) of the Public Health Services Act or an organization licensed under Iowa Code section 514B.5.

   “Large employer” means an employer employing two or more employees and which does not meet the definition of small employer under Iowa Code section 513B.2(16).

   “Late enrollee” means an individual, other than one who enrolls during a special enrollment period, who enrolls under a health benefit plan or health insurance coverage in connection with which it is issued, other than during the first period in which the individual is eligible to enroll under terms of the health benefit plan or health insurance coverage.

   “Network plan” means health insurance coverage of a health insurance issuer under which the financing and delivery of medical care including items and services paid for as medical care are provided, in whole or in part, through a defined set of providers under contract with the carrier.
“Plan year” means the year that is designated as the plan year in the plan document of a group health plan, except that if the plan document does not designate a plan year or if there is no plan document, the plan year is:

1. The deductible/limit year used under the plan.
2. If the plan does not impose deductibles or limits on a yearly basis, the plan year is the policy year.
3. If the plan does not impose deductibles or limits on a yearly basis, and either the plan is not insured or the insurance policy is not renewed on an annual basis, the plan year is the employer’s taxable year.

“Preexisting condition exclusion” means, with respect to health insurance coverage, a limitation or exclusion of benefits relating to a condition based on the fact that the condition was present before the date of enrollment for such coverage, whether or not any medical advice, diagnosis, care, or treatment was recommended or received before such date. A preexisting condition exclusion includes any exclusion applicable to an individual as a result of information that is obtained relating to an individual’s health status before the individual’s first day of coverage, such as a condition identified as a result of a preenrollment questionnaire or physical examination given to the individual, or review of medical records relating to the preenrollment period.

“Short-term limited-duration insurance” means health coverage provided pursuant to a contract with an issuer that has an expiration date specified in the contract that is less than 12 months after the original effective date of the contract and, taking into account renewals or extensions, has a duration of no longer than 36 months in total.

“Significant break in coverage” means a period of 63 consecutive days during all of which the individual does not have any creditable coverage, except that neither a waiting period nor an affiliation period is taken into account in determining a significant break in coverage.

“Special enrollment period” means a period other than the first period in which an eligible employee or a dependent is eligible to enroll under the terms of group health insurance coverage in connection with which it is issued, without regard to other enrollment periods defined under the health insurance coverage.

“Waiting period” means, with respect to group health insurance coverage and an eligible employee or a dependent who is potentially eligible for coverage under the plan, the period that must pass with respect to the individual is eligible to be covered for benefits under the terms of the plan.

[ARC 3682C, IAB 3/14/18, effective 4/18/18; ARC 4332C, IAB 3/13/19, effective 2/20/19]

191—35.24(509) Eligibility to enroll.

35.24(1) A carrier offering group health insurance coverage shall not establish rules for eligibility, including continued eligibility, of an individual to enroll under the terms of the coverage based on any of the following health status-related factors in relation to the individual or a dependent of the individual:

a. Health status.

b. Medical condition, including both physical and mental conditions.

c. Claims experience.

d. Receipt of health care.

e. Medical history.

f. Genetic information.

g. Evidence of insurability, including conditions arising out of acts of domestic violence.

h. Disability.

35.24(2) Subrule 35.24(1) does not require group health insurance coverage to provide particular benefits other than those provided under the terms of the coverage, and does not prevent a coverage from establishing limitations or restrictions on the amount, level, extent, or nature of the benefits or coverage for similarly situated individuals enrolled in the coverage.

35.24(3) Rules for eligibility to enroll under group health insurance coverage include rules defining any applicable waiting or affiliation periods for such enrollment.
35.24(4) A carrier offering health insurance coverage shall not require an individual, as a condition of enrollment or continued enrollment under the coverage, to pay a premium or contribution which is greater than a premium or contribution for a similarly situated individual enrolled in the coverage on the basis of a health status-related factor in relation to the individual or to a dependent of an individual enrolled under the coverage. This subrule shall not be construed to do either of the following:
   a. Restrict the amount that an employer may be charged for health insurance coverage.
   b. Prevent a carrier offering group health insurance coverage from establishing premium discounts or rebates or modifying otherwise applicable copayments or deductibles in return for adherence to programs of health promotion and disease prevention.

35.24(5) A carrier shall not modify a health insurance coverage with respect to an employer or any eligible employee or dependent through riders, endorsements or other means, to restrict or exclude coverage or benefits for specific diseases, medical conditions, or services otherwise covered by the health insurance coverage.

[ARC 3682C, IAB 3/14/18, effective 4/18/18]

191—35.25(509) Special enrollments.

35.25(1) A carrier shall permit individuals to enroll for coverage under terms of a health benefit plan, without regard to other enrollment dates permitted under the group health insurance coverage, if an eligible employee requests enrollment or, if the group health insurance coverage makes coverage available to dependents, on behalf of a dependent who is eligible but not enrolled under the group health insurance coverage, during the special enrollment period, which shall be 30 days following an event described in subrule 35.25(2) or 35.25(3) with respect to the individual for whom enrollment is requested. A carrier may impose enrollment requirements that are otherwise applicable under terms of the group health insurance coverage to individuals requesting immediate enrollment.

35.25(2) An individual, who previously had other coverage for medical care and for whom an eligible employee declined coverage under the group health insurance coverage, may be enrolled during a special enrollment period if the individual has lost the other coverage for medical care and:
   a. If required by the group health insurance coverage, the eligible employee stated in writing when declining the coverage, after being given a notice of the requirement form, and the consequences of failure to submit a written statement that coverage was declined because the individual had coverage for medical care under another group health insurance coverage, group health plan, or otherwise; and
   b. When enrollment was declined for the individual:
      (1) The individual had coverage under a COBRA continuation provision and the coverage has been exhausted; or
      (2) The individual had coverage other than under a COBRA continuation provision and the coverage has been terminated due to loss of eligibility for the coverage, including loss of coverage as a result of legal separation, divorce, death, termination of employment, reduction in the number of hours of employment and any loss of eligibility after a period that is measured by reference to any of the foregoing, or termination of employer contributions toward the other coverage.
   c. For purposes of subparagraph 35.25(2) "b "(2):
      (1) Loss of eligibility for the coverages does not include loss of eligibility due to the eligible employee’s or dependent’s failure to make timely premium payments or termination of coverage for cause such as making a fraudulent claim or intentional misrepresentation of material fact in connection with the group health insurance coverage; and
      (2) Employer contributions include contributions by any current or former employer of the individual or another person that was contributing to coverage for the individual.
      (3) Exhaustion of COBRA continuation coverage means that an individual’s COBRA continuation coverage ceases for any reason other than either failure of the individual to pay premiums on a timely basis, or for cause, such as making a fraudulent claim or an intentional misrepresentation of a material fact in connection with the plan. An individual is considered to have exhausted COBRA continuation coverage if the coverage ceases.
35.25(3) If the eligible employee has previously declined enrollment under the group health insurance coverage but acquires a dependent through marriage, birth, adoption or placement for adoption, the eligible employee or dependent may be enrolled during the special enrollment period with respect to the individual.

35.25(4) Enrollment of the eligible employee or dependent is effective not later than the first day of the calendar month or, for a newborn or adopted child, on the date of birth, adoption, or placement for adoption.

[ARC 3682C, IAB 3/14/18, effective 4/18/18]

191—35.26(509) Group health insurance coverage policy requirements.

35.26(1) Group health insurance coverage subject to the rules in this division is renewable with respect to all eligible employees or their dependents at the option of the employer, except for one or more of the following reasons:

a. The health insurance coverage sponsor fails to pay or to make timely payments of premiums or contributions pursuant to the terms of the health insurance coverage.

b. The health insurance coverage sponsors, performs an act or practice constituting fraud or makes an intentional misrepresentation of a material fact under the terms of the coverage.

c. Noncompliance with the carrier’s minimum participation requirements or employer contribution requirements.

d. For a network plan, no enrollees connected to the plan live, reside, or work in the service area of the issuer.

e. A carrier may choose to discontinue offering and cease to renew a particular type of health insurance coverage in the large group market if the carrier does all of the following:

(1) Provides advance notice of its decision to discontinue the plan to the commissioner or director a minimum of three days prior to the notice for affected employers, participants, and beneficiaries.

(2) Provides notice of its decision not to renew a plan to all affected employers, participants, and beneficiaries no less than 90 days prior to nonrenewal of a plan.

(3) Offers to each plan sponsor of the discontinued coverage the option to purchase any other coverage currently offered by the carrier to other employers in this state.

(4) Acts uniformly, in opting to discontinue the coverage and in offering the option under subparagraph 35.26(1)"e"(3), without regard to the claims experience of the sponsors under the discontinued coverage or to a health status-related factor relating to any participants or beneficiaries covered or new participants or beneficiaries who may become eligible for the coverage.

f. A decision by the carrier to discontinue offering and cease to renew all of its health insurance delivered or issued for delivery to employers in this state shall do all of the following:

(1) Provide advance notice of its decision to discontinue such coverage to the commissioner or director. Notice to the commissioner or director, at a minimum, shall be no less than three days prior to the notice provided for in subparagraph 35.26(1)"f"(2) to affected employers, participants, and beneficiaries.

(2) Provide notice of its decision not to renew such coverage to all affected employers, participants, and beneficiaries no less than 180 days prior to the nonrenewal of the coverage.

(3) Discontinue all health insurance coverage issued or delivered for issuance to employers in this state and cease renewal of such coverage.

g. The membership of an employer in a bona fide association, which is the basis for the coverage which is provided through such association, ceases, but only if the termination of coverage under this subrule occurs uniformly without regard to any health status-related factor relating to any covered individual.

h. The commissioner or director finds that the continuation of the coverage is not in the best interests of the policyholders or certificate holders, or would impair the carrier’s ability to meet its contractual obligations.

i. At the time of coverage renewal, a carrier may modify the health insurance coverage for a product offered under group health insurance coverage in the group market, if such modification is
consistent with the laws of this state and is effective on a uniform basis among group health insurance coverage that product.

35.26(2) A carrier that elects not to renew health insurance coverage under 35.26(1) “f” shall not write any new business in the group market in this state for a period of five years after the date of notice to the commissioner or director.

35.26(3) This rule applies only to a carrier doing business in one established geographic service area of the state and the carrier’s operations in that service area.

35.26(4) Preexisting condition exclusions.

a. A carrier, with respect to a participant or beneficiary, may impose a preexisting condition exclusion only as follows:

(1) The exclusion relates to a condition, whether physical or mental, regardless of the cause of the condition, for which medical advice, diagnosis, care, or treatment was recommended or received within the six-month period ending on the enrollment date. However, genetic information shall not be treated as a condition under this subparagraph in the absence of a diagnosis of the condition related to such information.

(2) The exclusion extends for a period of not more than 12 months, or 18 months in the case of a late enrollee, after the enrollment date.

(3) The period of any such preexisting condition exclusion is reduced by the aggregate of the periods of creditable coverage applicable to the participant or beneficiary as of the enrollment date.

b. A carrier offering group health insurance coverage shall not impose any preexisting condition exclusion as follows:

(1) In the case of a child who is adopted or placed for adoption before attaining 18 years of age and who, as of the last day of the 30-day period beginning on the date of the adoption or placement for adoption, is covered under creditable coverage. This subparagraph shall not apply to coverage before the date of such adoption or placement for adoption.

(2) In the case of an individual who, as of the last day of the 30-day period beginning with the date of birth, is covered under creditable coverage.

(3) Relating to pregnancy as a preexisting condition.

c. A carrier shall waive any waiting period applicable to a preexisting condition exclusion or limitation period with respect to particular services under health insurance coverage for the period of time an individual was covered by creditable coverage, provided that the creditable coverage was continuous to a date not more than 63 days prior to the effective date of the new coverage. Any period that an individual is in a waiting period for any coverage under group health insurance coverage, or is in an affiliation period, shall not be taken into account in determining the period of continuous coverage. A health maintenance organization that does not use preexisting condition limitations in any of its health insurance coverage may impose an affiliation period. For purposes of this paragraph, “affiliation period” means a period of time not to exceed 60 days for new entrants and not to exceed 90 days for late enrollees during which no premium shall be collected and coverage issued is not effective, so long as the affiliation period is applied uniformly, without regard to any health status-related factors.

d. A group health plan or carrier offering group health insurance under the plan may not impose a preexisting condition exclusion with respect to a participant or dependent of the participant before notifying the participant under rule 191—35.29(509).

[ARC 3682C, IAB 3/14/18, effective 4/18/18]

191—35.27(509) Methods of counting creditable coverage. For purposes of reducing any preexisting condition exclusion period, a group health plan or carrier offering group health insurance coverage shall determine the amount of an individual’s creditable coverage by using the standard method described in subrule 35.27(1) except that the plan or carrier may use the alternative method under subrule 35.27(2) with respect to any or all of the categories of benefits described under subrule 35.27(4).

35.27(1) Under the standard method, a group health plan or health insurance carrier offering group health insurance coverage shall determine the amount of creditable coverage without regard to the specific benefits included in the coverage.
a. For purposes of reducing the preexisting condition exclusion period, a group health plan or health insurance carrier offering group health insurance coverage shall determine the amount of creditable coverage by counting all the days that the individual has under one or more types of creditable coverage. If on a particular day, an individual has creditable coverage from more than one source, all the creditable coverage on that day is counted as one day. Further, any days in a waiting period for a plan or policy are not creditable coverage under the plan or policy.

b. Days of creditable coverage that occur before a significant break in coverage are not required to be counted.

c. Notwithstanding any other provisions of subrule 35.27(2) for purposes of reducing a preexisting condition exclusion period, a group health plan or a health insurance carrier offering group health insurance coverage may determine the amount of creditable coverage in any other manner that is at least as favorable to the individual as the method set forth in subrule 35.27(2).

35.27(2) Under the alternative method, a group health plan or a health insurance carrier offering group health insurance coverage shall determine the amount of creditable coverage based on coverage within any category of benefits described in subrule 35.27(4) and not based on coverage. The plan may apply a different preexisting condition exclusion period with respect to each category and may apply a different preexisting condition exclusion period for benefits that are not within any category. The creditable coverage determined for a category of benefits applies only for purposes of reducing the preexisting condition exclusion period with respect to that category. An individual’s creditable coverage for benefits that are not within any category for which the alternative method is being used is determined under the standard method of subrule 35.27(1).

35.27(3) A plan or carrier using the alternative method is required to apply it uniformly to all participants and beneficiaries in the plan or policy. The use of the alternative method must be set forth in the plan.

35.27(4) The alternative method for counting creditable coverage may be used for coverage for any of the following categories of benefits:

a. Mental health.


c. Prescription drugs.

d. Dental care.

e. Vision care.

35.27(5) If the alternative method is used, the plan is required to:

a. State prominently that the plan is using the alternative method of counting creditable coverage in disclosure statements concerning the plan, and state this to each enrollee at the time of enrollment under the plan;

b. Include in these statements a description of the effect of using the alternative method, including an identification of the category’s uses; and

c. Count creditable coverage within a category if any level of benefits is provided within the category.

[ARC 3682C, IAB 3/14/18, effective 4/18/18]

191—35.28(509) Certificates of creditable coverage.

35.28(1) Group health plans or carriers shall issue certificates of creditable coverage to persons losing coverage. A group health plan or carrier required to provide a certificate under this rule for an individual is deemed to have satisfied the certification requirements for that individual if another party provides the certificate, but only to the extent that information relating to the individual’s creditable coverage and waiting or affiliation period is provided by the other party. Certificates shall be issued within a reasonable amount of time following termination to employees and dependents:

a. Automatically upon the termination of an individual’s group coverage;

b. Automatically upon the termination of COBRA coverage;

c. Upon request within 24 months after coverage ends.
35.28(2) Certificates in writing. Certificates of coverage must be in writing unless all of the following conditions are met:
   a. The individual requesting the certificate is not entitled to receive a certificate;
   b. The individual requests that the certificate be sent to another plan or carrier;
   c. The plan or carrier receiving the certificate agrees to accept the information through means other than a written certificate;
   d. The plan or carrier receiving the certificate receives the certificate within a reasonable amount of time.

35.28(3) Required information. The certificate shall include the following information:
   a. The date the certificate is issued;
   b. The name of the group plan providing coverage;
   c. The name of the employee or dependent to whom the certificate applies, other relevant identifying information, and the name of the employee if the certificate is for a dependent;
   d. The plan administrator’s name, address and telephone number;
   e. A telephone number to call for further information if different from above;
   f. Either a statement that the person has at least 18 months’ creditable coverage without a significant break of coverage or the date any waiting period and creditable coverage began;
   g. The date creditable coverage ended or an indication that the coverage is in force.

35.28(4) Family information. Information for families may be combined on one certificate. Any differences in creditable coverages shall be clearly delineated.

35.28(5) Dependent coverage transition rule. A group health plan or carrier that does not maintain dependent data is deemed to have satisfied the requirement to issue dependent certificates by naming the employee and specifying that the coverage on the certificate is for dependent coverage.

35.28(6) Delivering certificates. The certificate shall be given to the individual, plan or carrier requesting the certificate. The certificates may be sent by first-class mail. When a dependent’s last-known address differs from the employee’s last-known address, a separate certificate shall be provided to the dependent at the dependent’s last-known address. Separate certificates may be mailed together to the same location.

35.28(7) A group health plan or carrier shall establish a procedure for individuals to request and receive certificates.

35.28(8) A certificate is not required to be furnished until the group health plan or carrier knows or should have known that the dependent’s coverage terminated.

35.28(9) Demonstrating creditable coverage. An individual has the right to demonstrate creditable coverage, waiting periods, and affiliation periods when the accuracy of the certificate is contested or a certificate is unavailable. A group health plan or carrier shall consider information obtained by it or presented on behalf of an individual to determine whether the individual has creditable coverage.

[ARC 3682C, IAB 3/14/18, effective 4/18/18]

191—35.29(509) Notification requirements.

35.29(1) A group health plan or carrier shall provide written notice to the employee and dependents that includes the following:
   a. The existence of any preexisting condition exclusions.
   b. A determination that the group health plan or carrier intends to impose a preexisting condition exclusion and:
      (1) The basis for the decision to do so;
      (2) The length of time to which the exclusion will apply;
      (3) The right of the employee or dependent to appeal a decision to impose a preexisting condition exclusion;
      (4) The right of the person to demonstrate creditable coverage including the right of the person to request a certificate from a prior group health plan or carrier and a statement that the current group health plan or carrier will assist in obtaining the certificate.
c. That the group health plan, carrier, or ODS will use the alternative method of counting creditable coverage.

d. Special enrollment rights when an employee declines coverage for the employee or dependents.

35.29(2) A group health plan or carrier shall provide written notice to the employee and dependents of a modification of a prior creditable coverage decision when the group health plan or carrier subsequently determines either no or less creditable coverage existed provided that the group health plan or carrier acts according to its initial determination until the final determination is made.

[ARC 3682C, IAB 3/14/18, effective 4/18/18]

191—35.30 Reserved.

191—35.31(509) Disclosure requirements. All carriers shall include in contracts and evidence of coverage forms a statement disclosing the existence of any prescription drug formularies. Upon request, all carriers offering health insurance coverage that includes a prescription drug formulary shall inform enrollees of the coverage, and prospective enrollees of the coverage during any open enrollment period, whether a prescription drug specified in the request is included in such formulary.

All carriers shall also disclose the existence of any contractual arrangements providing rebates received by them for prescription drugs or durable medical equipment. Durable medical equipment means equipment that can stand repeated use and is primarily and customarily used to serve a medical purpose and is generally not useful to a person who is not sick or injured or used by other family members and is appropriate for home use for the purpose of improving bodily functions or preventing further deterioration of the medical condition caused by sickness or injury.

[ARC 3682C, IAB 3/14/18, effective 4/18/18]

191—35.32(514C) Treatment options.

35.32(1) A carrier shall not prohibit a participating provider from or penalize a participating provider for discussing treatment options with covered persons, irrespective of the carrier’s position on the treatment options, or from advocating on behalf of covered persons within the utilization review or grievance processes established by the carrier or a person contracting with the carrier.

35.32(2) A carrier shall not penalize a provider because the provider, in good faith, reports to state or federal authorities any act or practice by the carrier that, in the opinion of the provider, jeopardizes patient health or welfare.

191—35.33(514C) Emergency services. Benefits shall be available by the carrier for inpatient and outpatient emergency services. Since carriers may not contract with every emergency care provider in an area, carriers shall make every effort to inform members of participating providers.

35.33(1) The term “emergency services” means, with respect to an individual enrolled with an organization, covered inpatient and outpatient services that are furnished by a provider who is qualified to furnish the services that are needed to evaluate or stabilize an emergency medical condition.

35.33(2) The term “emergency medical condition” means a medical condition manifesting itself by symptoms of sufficient severity, including but not limited to severe pain, that an ordinarily prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in one of the following:

a. Placing the health of the individual or, with respect to a pregnant woman, the health of the woman and her unborn child in serious jeopardy;

b. Serious impairment to bodily function; or

c. Serious dysfunction of any bodily organ or part.

35.33(3) Reimbursement to a provider of “emergency services” shall not be denied by any carrier without that organization’s review of the patient’s medical history, presenting symptoms, and admitting or initial as well as final diagnosis, submitted by the provider, in determining whether, by definition, emergency services could reasonably have been expected to be provided. Reimbursement for emergency services shall not be denied solely on the grounds that services were performed by a noncontracted provider. If reimbursement for emergency services is denied, the enrollee may file a complaint with the
carrier. Upon denial of reimbursement for emergency services, the carrier shall notify the enrollee and the provider that they may register a complaint with the commissioner of insurance.

191—35.34(514C) Provider access. A carrier subject to this chapter shall allow a female enrollee direct access to obstetrical and gynecological services from network or participating providers. The carrier shall also allow a pediatrician to be the primary care provider for a child through the age of 18. [ARC 6121C; IAB 12/29/21, effective 2/2/22]

   These rules are intended to implement Iowa Code chapters 509 and 514C.

191—35.35(509) Reconstructive surgery.

  35.35(1) A carrier that provides medical and surgical benefits with respect to a mastectomy shall provide the following coverage in the event an enrollee receives benefits in connection with a mastectomy and elects breast reconstruction:

  a. Reconstruction of the breast on which the mastectomy has been performed;

  b. Surgery and reconstruction of the other breast to produce a symmetrical appearance; and

  c. Prostheses and coverage of physical complications at all stages of a mastectomy including lymphedemas.

  35.35(2) The benefits under this rule shall be provided in a manner determined in consultation with the attending physician and the enrollee. The coverage may be subject to annual deductibles and coinsurance provisions that are consistent with other benefits under the plan or coverage.

  35.35(3) Written notice of the availability of coverage in this rule shall be provided to the enrollee upon enrollment and then annually.

  35.35(4) A carrier shall not deny an enrollee eligibility or continued eligibility to enroll or renew coverage under the terms of the health insurance solely for the purpose of avoiding the requirements of this rule. A carrier shall not penalize, reduce or limit the reimbursement of an attending provider or induce the provider to provide care in a manner inconsistent with this rule.

   This rule is intended to implement Public Law 105-277. [ARC 3682C; IAB 3/14/18, effective 4/18/18]

CONSUMER GUIDE

191—35.36(514K) Purpose. These rules implement Iowa Code section 514K.1(2) which requires the commissioner and the director of public health to annually publish a consumer guide. These rules apply to all carriers providing health insurance coverage in the individual, small employer group and large group markets that utilize a preferred provider arrangement and to all health maintenance organizations. [ARC 6121C, IAB 12/29/21, effective 2/2/22]

191—35.37(514K) Information filing requirements.

  35.37(1) Each health maintenance organization shall annually file with the division no later than July 1 the following information by plan as requested by the division:

  a. Health plan employer data information set (HEDIS).

  b. Network composition.

  c. Other information determined to be beneficial to consumers including but not limited to consumer survey information.

  35.37(2) Each preferred provider organization health network shall annually file with the division no later than July 1 the following information by plan as requested by the division:

  a. Reportable information as defined by a nationally recognized accreditation organization for preferred provider organization health networks.

  b. Network composition.

  c. Other information determined to be beneficial to consumers including but not limited to consumer survey information.
35.37(3) Each health maintenance organization and insurer using a preferred provider organization health network shall transmit the requested information by electronic mail in a format prescribed by the division.

[ARC 6121C, IAB 12/29/21, effective 2/2/22]

191—35.38(514K) Limitation of information published. The division may establish limits on the data to be collected and published in the event the division believes the information is not statistically relevant and would not be beneficial to consumers.

[ARC 6121C, IAB 12/29/21, effective 2/2/22]

These rules are intended to implement Iowa Code section 514K.1(2).

191—35.39(514C) Contraceptive coverage.

35.39(1) A carrier that provides benefits for outpatient prescription drugs or devices shall provide benefits for prescription contraceptive drugs or prescription contraceptive devices which prevent conception and are approved by the United States Food and Drug Administration or generic equivalents approved as substitutable by the United States Food and Drug Administration.

35.39(2) A carrier is not required to provide benefits for over-the-counter contraceptive drugs or contraceptive devices that do not require a prescription for purchase.

35.39(3) A contraceptive drug or contraceptive device does not include surgical services intended for sterilization, including, but not limited to, tubal ligation or vasectomy.

35.39(4) A carrier shall be required to provide benefits for services related to outpatient contraceptive services for the purpose of preventing conception if the policy or contract provides benefits for other outpatient services provided by a health care professional.

35.39(5) If a carrier does not provide benefits for a routine physical examination, the carrier is not required to provide benefits for a routine physical examination provided in the course of prescribing a contraceptive drug or contraceptive device.

This rule is intended to implement Iowa Code chapter 514C.

[ARC 3682C, IAB 3/14/18, effective 4/18/18]

191—35.40(514C) Autism spectrum disorders coverage.

35.40(1) Purpose. This rule implements Iowa Code section 514C.28, relating to autism spectrum disorders coverage in a group plan established pursuant to Iowa Code chapter 509A for employees of the state that provides for third-party payment or prepayment of health, medical, and surgical coverage benefits.

35.40(2) Definitions. For purposes of this rule, the definitions found in Iowa Code section 514C.28(2) shall apply. In addition, the following definitions shall apply:

“Autism spectrum disorders” means the following neurological disorders as defined under the following diagnostic classes within the American Psychiatric Association’s Diagnostic and Statistical Manual of Mental Disorders, edition DSM-5:

1. Autistic disorders. Diagnostic code 299.00.
5. Pervasive Developmental Disorder NOS. Diagnostic code 299.80.

“Commissioner” means the commissioner of insurance.

“Group plan” or “group health plan” means a group health plan established for the employees of the state of Iowa under Iowa Code chapter 509A.

35.40(3) Services. A group plan is not required to provide coverage for any of the following:

a. Acupuncture.
b. Animal-based therapy including hippotherapy.
c. Auditory integration training.
d. Chelation therapy.
e. Child care.
f. Cranial sacral therapy.
g. Custodial or respite care.
h. Hyperbaric oxygen therapy.
i. Special diets or supplements.

35.40(4) Parents or legal guardians of children diagnosed with autism spectrum disorders. A group
plan shall not be required to pay for treatment rendered by parents or legal guardians who are otherwise
qualified providers, supervising providers, therapists, professionals or paraprofessionals for treatment
rendered to their own children.

35.40(5) Locations for services.
   a. A group plan shall provide coverage for treatments, therapies and services to an insured
diagnosed with autism spectrum disorders by an autism service provider in locations including the
provider’s office or clinic or in a setting conducive to the acquisition of the target skill. Treatments
may be provided in schools when the treatments, therapies, and services are related to the goals of the
treatment plan and do not duplicate services provided by a school.
   b. A group health plan is not required to provide coverage for therapy, treatment or services when
the therapy, treatment or services are provided to an insured who is residing in a residential treatment
center or inpatient treatment or day treatment facility.

35.40(6) Verification of qualified provider: A group health plan is required to verify the licensure,
certification and all training or other credentials of a qualified provider or health professional. A group
health plan shall not deny payment or reimbursement for the necessary diagnosis or treatment provided
by a certified behavior analyst or a health professional licensed under Iowa Code chapter 147.

35.40(7) Annual publication CPI adjustment. The commissioner shall publish on or before
April 1 of each year beginning April 1, 2014, an adjustment to the required maximum benefit equal to the
percentage change in the United States Department of Labor Consumer Price Index for all urban
consumers in the preceding year. The adjusted maximum benefit published each April shall be used by
group health plans in order to comply with this rule and shall be effective January 1 for group plans
issued or renewed on or after January 1 of the following calendar year.

35.40(8) Notice to insureds. A group plan shall provide written notice to the insured regarding claims
submitted and processed for the treatment of autism spectrum disorders and shall include the total amount
expended to date for the current policy year. The notice may be included with the explanation of benefits
form or in a separate communication provided on a periodic basis during the course of treatment.

This rule is intended to implement Iowa Code section 514C.28.

[ARC 9500B, IAB 5/4/11, effective 6/8/11; ARC 6121C, IAB 12/29/21, effective 2/2/22]

[Filed 11/16/65]
[Filed 11/18/85, Notice 10/9/85—published 12/4/85, effective 1/8/86]
[Filed 7/11/86, Notice 6/4/86—published 7/30/86, effective 9/3/86][1]
[Editorially transferred from [510] to [191] IAC Supp. 10/22/86; see IAB 7/30/86]
[Filed 9/18/87, Notice 8/12/87—published 10/7/87, effective 11/11/87]
[Filed emergency 6/26/97—published 7/16/97, effective 7/1/97]
[Filed 10/10/97, Notice 7/16/97—published 11/5/97, effective 12/10/97]
[Filed emergency 10/16/98—published 11/4/98, effective 10/16/98]
[Filed emergency 6/25/99—published 7/14/99, effective 7/1/99]
[Filed 4/10/00, Notice 1/12/00—published 5/3/00, effective 6/7/00]
[Filed 5/10/00, Notice 4/5/00—published 5/31/00, effective 7/5/00]
[Filed 8/17/00, Notice 7/12/00—published 9/6/00, effective 10/11/00]
[Filed emergency 10/26/01—published 11/14/01, effective 10/26/01]
[Filed 3/29/02, Notice 2/6/02—published 4/17/02, effective 5/22/02]
[Filed 7/18/03, Notice 6/11/03—published 8/6/03, effective 9/10/03]
[Filed 12/15/04, Notice 11/10/04—published 1/5/05, effective 2/9/05]
[Filed 11/16/05, Notice 10/12/05—published 12/7/05, effective 1/11/06]
[Filed 10/5/06, Notice 8/30/06—published 10/25/06, effective 11/29/06]
[Filed 3/9/07, Notice 1/31/07—published 3/28/07, effective 5/2/07]
[Filed ARC 9500B (Notice ARC 9340B, IAB 1/26/11), IAB 5/4/11, effective 6/8/11]
[Filed ARC 1999C (Notice ARC 1943C, IAB 4/1/15), IAB 5/27/15, effective 7/1/15]
[Filed ARC 2415C (Notice ARC 2078C, IAB 8/5/15), IAB 2/17/16, effective 3/23/16]
[Filed ARC 3682C (Notice ARC 3571C, IAB 1/17/18), IAB 3/14/18, effective 4/18/18]
[Filed Emergency After Notice ARC 4332C (Notice ARC 4242C, IAB 1/16/19), IAB 3/13/19, effective 2/20/19]
[Filed ARC 6121C (Notice ARC 6002C, IAB 10/20/21), IAB 12/29/21, effective 2/2/22]
[Filed ARC 6338C (Notice ARC 6285C, IAB 4/6/22), IAB 6/1/22, effective 7/6/22]
CHAPTER 76
EXTERNAL REVIEW

191—76.1(514J) Purpose. This chapter is intended to implement Iowa Code chapter 514J and the federal Patient Protection and Affordable Care Act, Pub. L. No. 111-148 as amended by the federal Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, which amends the Public Health Service Act and adopts, in part, 42 U.S.C. Section 300gg-19. These rules address issues which are unique to the external review process in this state and provide a uniform process for covered persons of health carriers providing health insurance coverage or the covered persons’ authorized representatives to request and receive an external review of adverse determinations and final adverse determinations as defined in Iowa Code sections 514J.102(1) and 514J.102(18) and as referenced in Iowa Code section 514J.109(1). Health carriers defined in Iowa Code section 514J.102(23), and included in paragraph 76.2(2)”c” are subject to these rules.

191—76.2(514J) Applicable law and definitions.

76.2(1) The rules contained in this chapter shall apply to any health benefit plan as defined in Iowa Code section 514J.102 other than those excluded under Iowa Code section 514J.103(2), for any plan that is offered or issued by a health carrier as defined in Iowa Code section 514J.102, if the plan was issued in Iowa, and if the external review request is filed with the commissioner on or after July 1, 2011.

76.2(2) For purposes of this chapter, the definitions in Iowa Code chapter 514J shall apply. In addition:

a. For purposes of applying the exemption in Iowa Code section 514J.103(2) “b,” “Medicare supplement policy of insurance” shall mean the same as “Medicare supplement policy” as defined in rule 191—37.3(514D).

b. For purposes of this chapter, the definition of “adverse determination” in Iowa Code section 514J.102 shall include experimental or investigational treatment adverse determinations, as set forth in Iowa Code section 514J.109.

c. For purposes of this chapter, the definition of “health carrier” may include an employer self-funded plan if the employer chooses to opt in to comply with these rules.

191—76.3(514J) Disclosure requirements. The description of external review procedures required by Iowa Code section 514J.116 shall be in the form of Appendix A or substantially similar language approved by the commissioner.

191—76.4(514J) External review request.

76.4(1) Except for requests for expedited review, the covered person or the covered person’s authorized representative shall submit a written request for external review (completed Appendix B) to the commissioner by personal delivery, by mail, by fax or by electronic transmission, including a copy of the health carrier’s written notice containing the final adverse determination, within the time periods specified in Iowa Code section 514J.107(1) or 514J.109(1), as applicable. The request form and notice shall be submitted to the commissioner at Iowa Insurance Division, 1963 Bell Avenue, Suite 100, Des Moines, Iowa 50315; fax (515)654-6500; or email iid.marketregulation@iid.iowa.gov.

76.4(2) Requests for expedited review may be made orally to initiate the process, and the commissioner may require submission of additional documentation such as physician certifications and medical information releases as is deemed practicable under the time constraints.

76.4(3) There is no charge or fee for submitting a request for external review.
191—76.5(514J) Communication between covered person, health carrier, independent review organization and the commissioner.

76.5(1) Notices or other communications required by Iowa Code chapter 514J between the commissioner, the health carrier and the independent review organization shall be by email or facsimile, unless otherwise specified, and shall be documented to prove transmission and receipt of the communication.

76.5(2) Notices or other communications required by Iowa Code chapter 514J from the commissioner, the health carrier or the independent review organization to the covered person shall be by email, facsimile or overnight mail, and shall be documented to prove transmission and receipt of the communication.

76.5(3) The covered person or covered person’s representative may provide notifications and communications to the health carrier, independent review organization and the commissioner as required by Iowa Code chapter 514J by email, facsimile or overnight mail, but also may do so by first-class mail or personal delivery.

76.5(4) Any time periods or deadlines specified in Iowa Code chapter 514J shall commence upon receipt of the notice or communication and cease upon the transmission of the subsequent notice or communication.

191—76.6(514J) Assignment of independent review organization by the commissioner.

76.6(1) The assignment by the commissioner of an independent review organization pursuant to Iowa Code chapter 514J shall be by rotation among approved independent review organizations.

76.6(2) Upon assignment by the commissioner of an independent review organization, in addition to providing notice to the health carrier and the covered person or covered person’s representative as required by Iowa Code chapter 514J, the commissioner shall provide notice of the assignment to the independent review organization.

76.6(3) Within two business days of receipt by the independent review organization of notice from the commissioner pursuant to subrule 76.6(2), the independent review organization shall make a determination of its ability to perform the external review and advise the commissioner if the independent review organization is unable to perform the review due to conflict of interest or due to lack of expertise or qualification for the particular subject matter of the review.

191—76.7(514J) Decision notification. The independent review organization shall immediately provide a copy of a draft of the decision to the commissioner for review. The commissioner shall review the draft of the decision to verify that the independent review organization has included in its draft of the decision the requirements set forth in Iowa Code section 514J.107, 514J.108, or 514J.109. The commissioner shall make any suggestions for changes to make the draft of the decision comply with the requirements. The independent review organization shall make such required changes within two business days. Once the commissioner determines that the decision meets the requirements of Iowa Code section 514J.107, 514J.108, or 514J.109, as applicable, the independent review organization shall immediately send the decision to the commissioner, the health carrier, and the covered person or covered person’s authorized representative. The decision approved by the commissioner shall be delivered by telephone, fax or electronic transmission to the health carrier, the commissioner and the covered person or covered person’s authorized representative, and a hard copy of the decision also shall be delivered by mail to the covered person or covered person’s authorized representative.

191—76.8(514J) Health carrier information.

76.8(1) Each health carrier shall provide to the commissioner the name, title, telephone number, fax number and email address of the individual who shall be the health carrier’s contact person for
external review procedures. The carrier’s contact person or an appointed alternate shall be available to the commissioner during the Iowa insurance division’s normal business hours, 8 a.m. to 4:30 p.m., Monday through Friday, central time, excluding state holidays. Any change in personnel or contact information shall be immediately sent to the commissioner.

76.8(2) Each health carrier shall make available to the commissioner upon request within five business days a detailed description of the process the health carrier has in place to ensure compliance with the requirements found in this chapter and in Iowa Code chapter 514J. The description shall include:

a. An explanation of how the carrier determines when a person has qualified for external review and should receive a notice from the carrier, and

b. A copy of the notice sent to persons who fall within the scope of the law.

76.8(3) Each health carrier shall provide to the commissioner, upon request, information set forth in Iowa Code section 514J.114(2) “b,” in a format substantially similar to Appendix D, or as approved by the commissioner.

[ARC 9637B, IAB 7/27/11, effective 7/8/11; ARC 9979B, IAB 1/25/12, effective 2/29/12; ARC 2601C, IAB 6/22/16, effective 7/27/16; ARC 6121C, IAB 12/29/21, effective 2/2/22]

191—76.9(514J) Certification of independent review organization.

76.9(1) In addition to the minimum qualifications set forth in Iowa Code section 514J.112, the following minimum standards are required for certification as an independent review organization:

a. The applicant shall provide a description of the procedures employed to comply with Iowa Code section 514J.112(1)”a.”

b. The applicant shall provide the number of reviewers retained by the independent review organization and a description of the areas of expertise available from such reviewers and the types of cases such reviewers are qualified to review.

c. The applicant shall provide the names and résumés of all directors, officers, and executives of the independent review organization.

d. The applicant shall provide a description of the fees to be charged to the carrier by the independent review organization for external reviews.

e. The applicant shall provide the name of the medical director or health professional director responsible for the supervision and oversight of the independent review procedure.

76.9(2) The independent review organization shall develop written policies and procedures to ensure adherence to the requirements of this chapter and Iowa Code chapter 514J by any contractor, subcontractor, subvendor, agent or employee affiliated with the certified independent review organization.

76.9(3) In addition to the toll-free telephone service required by Iowa Code section 514J.112(1) “b,” the independent review organization shall establish a facsimile and electronic mail service to receive information relating to external reviews pursuant to this chapter and Iowa Code chapter 514J.

76.9(4) The independent review organization shall provide the commissioner within ten business days of request such data, information, and reports as the commissioner determines necessary to evaluate the external review process established under Iowa Code chapter 514J or a report in the format of Appendix C to comply with Iowa Code section 514J.114(1).

76.9(5) Applications shall be submitted to the Commissioner of Insurance, 1963 Bell Avenue, Suite 100, Des Moines, Iowa 50315; or as designated by the commissioner. Applications must be submitted in full to be considered. The form for initially approving and for reapproving independent review organizations required by Iowa Code section 514J.111(4) shall be in the form of Appendix E. If the commissioner designates an entity to review applications, the designee may charge a fee, as permitted by Iowa Code section 514J.111(5) and as approved by the commissioner. All applicants will be notified of the certification decision.

76.9(6) A list of certified independent review organizations shall be maintained by the commissioner and shall be available through the website of the Iowa insurance division, iid.iowa.gov.

[ARC 9637B, IAB 7/27/11, effective 7/8/11; ARC 9979B, IAB 1/25/12, effective 2/29/12; ARC 2601C, IAB 6/22/16, effective 7/27/16; Editorial change: IAC Supplement 9/23/20; ARC 6121C, IAB 12/29/21, effective 2/2/22]
191—76.10(514J) Fees charged by independent review organizations.

76.10(1) Fees charged by independent review organizations shall be reasonable.

76.10(2) A health carrier objecting to the fee charged by an independent review organization shall file a written notice with the commissioner and the independent review organization indicating the health carrier’s objections to the fee and the reasons and any documentation for the objections.

76.10(3) Five days after receipt of the notice, the independent review organization may submit to the commissioner written documentation supporting the fee.

76.10(4) If the parties do not come to an agreement within 30 days of the initial notice, the commissioner or the commissioner’s designee shall conduct a review of the fee and submissions and issue a written decision within 60 days. Factors to consider in determining whether a fee is unreasonable may include the following:

a. The time and labor required to perform the independent review;

b. The novelty and difficulty of the issues;

c. The skill requisite to perform the independent review properly;

d. The customary fee;

e. The experience, reputation and ability of the independent review organization and those performing the independent review.

76.10(5) A party may appeal the commissioner’s decision pursuant to 191—Chapter 3.

[ARC 9979B, IAB 1/25/12, effective 2/29/12]

191—76.11(514J) Penalties.

76.11(1) Independent review organizations. The commissioner may withdraw the approval of an independent review organization for any of the following reasons:

a. Failure to maintain the minimum standards set forth in Iowa Code sections 514J.111 and 514J.112 or in subrule 76.9(1).

b. Failure to comply with any of the requirements in subrules 76.9(2) through 76.9(5) or rule 191—76.10(514J).

c. Failure to meet any time requirements for conducting a standard, an experimental or investigational, or an expedited external review.

d. Failure to comply with any other requirements set forth in this chapter or in Iowa Code chapter 514J.

76.11(2) Health carriers.

a. Failure to comply with any of the provisions of this chapter is a violation of Iowa Code chapter 507B.

b. The commissioner may require a health carrier to provide additional time for a covered person to request an external review or submit documentation if the health carrier failed to comply with any part of Iowa Code chapter 514J or of this chapter.

c. The commissioner may order restitution or take other corrective action pursuant to Iowa Code section 505.8(10).

[ARC 9979B, IAB 1/25/12, effective 2/29/12; ARC 2601C, IAB 6/22/16, effective 7/27/16]

These rules are intended to implement Iowa Code chapter 514J.
Appendix A

NOTICE OF APPEAL RIGHTS

You have a right to appeal any decision we make that denies payment on your claim or your request for coverage of a health care service or treatment.

You may request additional explanation when your claim or request for coverage of a health care service or treatment is denied or the health care service or treatment you received was not fully covered. Contact us when you:

- Do not understand the reason for denial;
- Do not understand why the health care service or treatment was not fully covered;
- Do not understand why a request for coverage of a health care service or treatment was denied;
- Cannot find the applicable provision in your Benefit Plan Document;
- Want a copy (free of charge) of the guidelines, criteria or clinical rationale that we used to make our decision; or
- Disagree with the denial or the amount not covered and you want to appeal.

If your claim was denied due to missing or incomplete information, you or your health care provider may resubmit the claim to us with the necessary information to complete the claim.

Internal Appeal: All appeals to us for claim denials (or any decision that does not cover expenses you believe should have been covered) must be sent to [insert address of the health carrier contact person where appeals should be sent] within 180 days of the date you receive our denial. We will provide a full and fair review of your claim by individuals associated with us, but who were not involved in making the initial denial of your claim. You may provide us with additional information that relates to your claim, and you may request copies of information that we have that pertains to your claim. We will notify you of our decision in writing within 30 days of receiving your appeal. If you do not receive our decision within 30 days of receiving your appeal, you may be entitled to file a request for external review.

External Review: We have denied your request for the provision of or payment for a health care service or course of treatment. If our decision involved making a judgment as to the medical necessity, appropriateness, health care setting, level of care or effectiveness of the health care service or treatment you requested, you may have a right to have our decision reviewed by health care professionals who have no association with us. Requests for external review may be submitted to the Commissioner of Insurance.
You may obtain an external review if:

- Our decision involved the admission, availability of care, continued stay, or other health care service that is a covered benefit; and

- We denied, reduced or terminated the requested service or treatment or payment for the service or treatment because we determined it did not meet our requirements for medical necessity, health care setting, level of care or effectiveness of the health care service or treatment you requested.

- You have a medical condition that would seriously jeopardize your life or health or would jeopardize your ability to regain maximum function. In this situation, you may file a request for an **expedited external review** of our denial.

- The final adverse determination concerns an admission, availability of care, continued stay, or a health care service for which you received emergency services, but you have not been discharged from a facility. In this situation, you or your authorized representative may request an **expedited external review**.

- Our denial to provide or pay for health care service or course of treatment is based on a determination that the service or treatment is experimental or investigational. In addition, if your treating health care professional certifies in writing that the recommended or requested health care service or treatment that is the subject of the recommendation or request would be significantly less effective if not promptly initiated, then you or your authorized representative may request an **expedited external review**.

You can obtain a copy of the External Review Request Form from: the Iowa Insurance Division, 1963 Bell Avenue, Suite 100, Des Moines, Iowa 50315; telephone 877-955-1212 or 515-654-6600; facsimile 515-654-6500; website iid.iowa.gov.

Within **four months** after receipt of our notice containing the final adverse determination and this Notice of Appeal Rights, you should submit a request for external review to the Iowa Insurance Division, 1963 Bell Avenue, Suite 100, Des Moines, Iowa 50315; telephone 877-955-1212 or 515-654-6600; facsimile 515-654-6500; email iid.marketregulation@iid.iowa.gov.

For standard external review, a decision will be made within **45 days** after the independent review organization receives your request.

For details, please review your Benefit Plan Document, contact us, or contact the Iowa Insurance Division.

[ARC 2601C, IAB 6/22/16, effective 7/27/16; Editorial change: IAC Supplement 9/23/20; ARC 6121C, IAB 12/29/21, effective 2/2/22]
Appendix B

EXTERNAL REVIEW REQUEST FORM

SECTION 1. ELIGIBILITY FOR EXTERNAL REVIEW

This External Review Request Form must be filed with the Iowa Insurance Division within four months after your health carrier denied, reduced or terminated the requested health care service or treatment or payment for the service or treatment. You or your authorized representative may request an external review under any of the following circumstances:

1. Your health carrier has made a determination that an admission, availability of care, continued stay, or other health care service that is a covered benefit does not meet the health carrier’s requirements for medical necessity, appropriateness, health care setting, level of care or effectiveness, and the requested service or payment for the service is therefore denied, reduced, or terminated. **Please follow the directions in Sections 1 and 2, then submit completed Sections 3 and 4, Section 5 if applicable, and Section 7 if you are requesting an expedited review.**

2. Your health carrier has made a denial of coverage based on a determination that the health care service or treatment recommended or requested is experimental or investigational. **Please follow the directions in Sections 1 and 2, then submit completed Sections 3 and 4, Section 5 if applicable, Section 6, and Section 7 if you are requesting an expedited review.**

3. The final adverse determination concerns an admission, availability of care, continued stay, or a health care service for which you received emergency services, but you have not been discharged from a facility. **Please follow the directions in Sections 1 and 2, then submit completed Sections 3 and 4, Section 5 if applicable, and Section 7.**

If coverage was denied for a service or treatment specifically listed in your health insurance policy as excluded from coverage (other than what is listed in paragraphs 1 and 2 above), you will not be eligible for external review.

You also will need to have completed any internal appeals with your health carrier before you can request an external review, unless:

1. You already did request an internal appeal with your health carrier and have not received a decision and it has been 30 days since you requested the appeal; or

2. Your health carrier has waived the requirement that you complete an internal appeal before requesting an external review; or

3. You need an expedited review because time is a factor in your treatment.
SECTION 2. WHAT TO SEND AND WHERE TO SEND IT

YOU MUST SUBMIT ITEMS 1 AND 2 BELOW:

1. This External Review Request Form, signed and dated, with the sections completed for your particular situation as described in Section 1. If you would like help completing your external review request for submission, contact the Market Regulation Bureau of the Iowa Insurance Division by calling 515-654-6600, or by email at iid.marketregulation@iid.iowa.gov.

2. One of the following:
   a. The letter from the covered person’s health carrier or utilization review company that states that the decision is final and that the covered person or the covered person’s authorized representative has exhausted all internal appeal procedures;
   b. The letter from the covered person’s health carrier or utilization review company that states it has waived the requirement to exhaust all of the health carrier’s internal appeal procedures;
   c. A copy of the covered person’s or the covered person’s authorized representative’s request for internal appeal and a statement that no decision from the health carrier has been received for 30 days; or
   d. A completed request for expedited review, Section 7 of this form.

WHERE TO SEND IT:

If you are requesting a standard external review, send all paperwork to the Iowa Insurance Division, 1963 Bell Avenue, Suite 100, Des Moines, Iowa 50315; facsimile 515-654-6500; email iid.marketregulation@iid.iowa.gov. If you have questions, telephone 877-955-1212 or 515-654-6600.

If you are requesting an expedited external review, call the Iowa Insurance Division (telephone 877-955-1212 or 515-654-6600) before sending your paperwork, and you will receive instructions on the quickest way to submit the application and supporting information.
SECTION 3. INFORMATION REQUIRED FOR ALL EXTERNAL REVIEW REQUESTS

APPLICANT NAME

The applicant is a:

☐ Covered Person/Patient

☐ Provider (the covered person/patient must complete Section 4)

☐ Authorized Representative (submit completed Sections 4 and 5)

COVERED PERSON/PATIENT INFORMATION

Covered Person’s/Patient’s Name:
Address:
Telephone Number:
   Daytime:
   Evening:
Email Address:
Fax Number:

INSURANCE INFORMATION

Name of Insurer or HMO:
Covered Person’s Insurance ID Number and/or Policy Number:
Insurance Claim/Reference Number:
Insurer/HMO Mailing Address:
Insurer/HMO Telephone Number:
Insurer/HMO Email Address:
Insurer/HMO Fax Number:

EMPLOYER INFORMATION

Employer’s Name:

Is the health coverage that you have through your employer a self-funded plan? (Y/N)_______.

Some self-funded plans may voluntarily provide external review, but may have different procedures. You should check with your employer.

HEALTH CARE PROVIDER INFORMATION

Treating Physician/Health Care Provider:
   Address:
   Contact Person:
   Telephone Number:
   Email Address:
   Fax Number:
Patient Medical Record Number:
REASON FOR HEALTH CARRIER’S DENIAL

(Please check one.)

☐ The health care service or treatment was denied due to medical necessity, appropriateness, health care setting, level of care or effectiveness.

☐ The health care service or treatment is experimental or investigational (submit completed Section 6).

☐ Other: ____________________________________________________________.

SUMMARY OF EXTERNAL REVIEW REQUEST

Enter a brief description of the claim and the request for health care service or treatment that was denied and attach a copy of the denial from your health carrier.

HEALTH CARE SERVICE OR TREATMENT DECISION IN DISPUTE

Describe in your own words the health care service or treatment decision in dispute and why you are appealing this denial. Indicate clearly the services being denied and the specific dates for the services being denied. Explain why you disagree. Attach additional pages if necessary and include available pertinent medical records, any information you received from your health carrier concerning the denial, any pertinent peer literature or clinical studies, and any additional information from your physician or health care provider that you want the independent review organization to consider.

SECTION 4. SIGNATURE AND RELEASE OF MEDICAL RECORDS

To appeal your health carrier’s denial, you must sign and date this external review request form and consent to the release of medical records.

I, __________________________, hereby request an external review. I attest that the information provided in this application is true and accurate to the best of my knowledge. I authorize my insurance company and my health care providers to release all relevant medical or treatment records to the independent review organization. I understand that the independent review organization will use this information to make a determination on my external review and that the information will be kept confidential and will not be released to anyone else. This release is valid for one year.

________________________________________________________________________

Signature of covered person/patient or legal representative (parent, guardian, conservator or other – please specify)

Date:

SECTION 5. APPOINTMENT OF AUTHORIZED REPRESENTATIVE

(Fill out this section only if someone else will be representing you in this request for external review.)

You can represent yourself, or you may ask another person, including your treating health care provider, to act as your authorized representative. You may revoke this authorization at any time.
I hereby authorize ___________________________ to pursue my external review request on my behalf.

____________________________________
Signature of covered person/patient or legal representative (parent, guardian, conservator or other – please specify)

Date:

Address of Authorized Representative:
Authorized Representative’s Telephone Number:
   Daytime:
   Evening:
Fax Number:
Email Address:

SECTION 6. REQUEST FOR EXTERNAL REVIEW OF DENIALS BASED ON THE REASON THAT THE TREATMENT WAS EXPERIMENTAL OR INVESTIGATIONAL

PHYSICIAN CERTIFICATION: EXPERIMENTAL OR INVESTIGATIONAL DENIALS

(To Be Completed by Treating Physician)

I hereby certify that I am the treating physician for __________________________ (covered person’s/patient’s name) and that I have requested the authorization for a drug, device, procedure or therapy denied for coverage due to the insurance carrier’s determination that the proposed therapy is experimental and/or investigational. I understand that in order for the covered person/patient to obtain the right to an external review of this denial, as treating physician I must certify that the covered person’s/patient’s medical condition meets certain requirements:

In my medical opinion as the insured’s treating physician, I hereby certify to the following:

(NOTE: Requirements 1 through 3 below must all apply for the covered person/patient to qualify for an external review.)

1. The covered person/patient has a condition that qualifies under one or more of the following descriptions.

   (Please check all descriptions that apply.)

   □ Standard health care services or treatments have not been effective in improving the covered person’s/patient’s condition.

   □ Standard health care services or treatments are not medically appropriate for the covered person/patient.

   □ There is no available standard health care service or treatment covered by the health carrier that is more beneficial than the requested or recommended health care service or treatment.
2. The physician is a licensed, board-certified, or board-eligible physician qualified to practice in the area of medicine appropriate to treat the covered person’s condition.

3. Scientifically valid studies using accepted protocols demonstrate that the health care service or treatment recommended or that is the subject of the adverse determination or final adverse determination is likely to be more beneficial to the covered person/patient than any available standard health care services or treatments.

**Explain:**

Please provide a description of the recommended or requested health care service or treatment that is the subject of the denial. (Attach additional information as necessary.)

Physician’s Signature_______________________________________ Date: _______________

Physician’s Name (Please print.)____________________________________________________

### SECTION 7. REQUEST FOR EXPEDITED EXTERNAL REVIEW

**CERTIFICATION OF TREATING HEALTH CARE PROVIDER FOR EXPEDITED EXTERNAL REVIEW REQUEST**

*(To Be Completed by Treating Health Care Provider)*

**NOTE TO THE TREATING HEALTH CARE PROVIDER:**

The standard external review process can take up to 60 days from the date the patient’s request for external review is received by the Iowa Insurance Division.

The independent review organization should complete an expedited external review within 72 hours.

This form is for the purpose of providing the certification necessary to trigger expedited review.

**CERTIFICATION**

I hereby certify that I am a treating health care provider for the patient, ____________________ ; and that one of the following is true: (Please check all that apply.)

- □ Adherence to the time frame for conducting a standard external review of the patient’s appeal would, in my professional judgment, seriously jeopardize the life or health of the patient or would jeopardize the patient’s ability to regain maximum function.

- □ The recommended or requested health care service or treatment that is the subject of the external review request would be significantly less effective if not promptly initiated.

- □ The final adverse determination concerns an admission, availability of care, continued stay, or a health care service for which the patient received emergency services, but has not been discharged from a facility.
For this reason, the patient’s appeal of the denial by the patient’s health carrier of the requested health care service or course of treatment should be processed on an expedited basis.

Treating Health Care Provider’s Signature ____________________________ Date ______________ 

Treating Health Care Provider’s Name (Please print.) ________________________________

Provider’s Mailing Address: 
Telephone Number: 
Email Address: 
Fax Number: 

Licensure and Area of Clinical Specialty:

[ARC 2601C, IAB 6/22/16, effective 7/27/16; ARC 4780C, IAB 11/20/19, effective 12/25/19; Editorial change: IAC Supplement 9/23/20; ARC 6121C, IAB 12/29/21, effective 2/2/22; ARC 6338C, IAB 6/1/22, effective 7/6/22]
Appendix C

IOWA INSURANCE DIVISION

INDEPENDENT REVIEW ORGANIZATION EXTERNAL REVIEW ANNUAL REPORT FORM

(Attach information to this form if necessary.)

External Review Annual Summary for 20__

Each independent review organization (IRO) shall submit upon request of the Commissioner an annual report with information for each health carrier in the aggregate for Iowa on external reviews performed and by type of health benefit plan.

1. IRO name:
   Filing date:

2. IRO address:

3. IRO Web site:

4. Name, email address, telephone number and fax number of the person completing this form:

5. Name, title, email address, telephone number and fax number of the person responsible for regulatory compliance and quality of external reviews:

6. Total number of requests for external review received from the Iowa Insurance Division during the reporting period:

7. Number of standard external reviews:

8. Average number of days the IRO required to reach a final decision in standard reviews:

9. Number of expedited reviews completed to a final decision:

10. Average number of days the IRO required to reach a final decision in expedited reviews:

11. Number of medical necessity reviews decided in favor of the health carrier:

   Briefly list procedures denied:

12. Number of medical necessity reviews decided in favor of the covered person/patient:

   Briefly list procedures approved:
13. Number of experimental/investigational reviews decided in favor of the health carrier:
   Briefly list procedures denied:

14. Number of experimental/investigational reviews decided in favor of the covered person/patient:
   Briefly list procedures approved:

15. Number of reviews terminated as the result of a reconsideration by the health carrier:

16. Number of reviews terminated by the covered person/patient prior to issuance by the IRO of external review decision:

17. Number of reviews declined due to possible conflict with:
   Health carrier:
   Covered person/patient:
   Health care provider:
   Describe possible conflicts of interest:

18. Number of reviews declined due to other reasons not reflected in #17 above:

[ARC 6121C, IAB 12/29/21, effective 2/2/22]
Appendix D

IOWA INSURANCE DIVISION

HEALTH CARRIER EXTERNAL REVIEW ANNUAL REPORT FORM

(Attach information to this form if necessary.)

External Review Annual Summary for 20__

Each health carrier shall submit upon request of the Commissioner an annual report with information in the aggregate for Iowa and by type of health benefit plan.

1. Health carrier name:

2. Health carrier address:

3. Health carrier Web site:

4. Name, email address, telephone number and fax number of the person completing this form:

5. Name, title, email address, telephone number and fax number of the person responsible for regulatory compliance:

6. Total number of external review requests of the health carrier’s adverse determinations and final adverse determinations received from the Iowa Insurance Division during the reporting period:

7. From the total number of external review requests provided in Question 6, the number of requests determined eligible for an external review:

8. Total number of external review requests resolved and, of those resolved, the number resolved upholding the adverse determination or final adverse determination of the health carrier and the number resolved reversing the adverse determination or final adverse determination of the health carrier:

9. Total number of external review requests that were terminated as the result of a reconsideration by the health carrier of its adverse determination or final adverse determination after the receipt of additional information from the covered person or the covered person’s authorized representative:

[ARC 6121C, IAB 12/29/21, effective 2/2/22]
Appendix E

INDEPENDENT REVIEW ORGANIZATION APPLICATION

1. BASIC INFORMATION:
   Name:
   Street Address:
   City, State, ZIP:
   Telephone (a toll-free telephone service to receive information related to external reviews 24 hours a day, 7 days a week, that is capable of accepting, recording, or providing appropriate instruction to incoming telephone callers outside normal business hours):
   Fax Number:
   Email Address:
   Director, Officer, or Executive Officer responsible for supervision and oversight of review procedures:
      Telephone:
      Fax Number:
      Email Address:
   Contact person to receive contacts, notices, and information from the Division:
      Telephone:
      Fax Number:
      Email Address:

2. Names and titles of all directors, officers, and executives:

3. Identify independent review accreditation by nationally recognized private accrediting entity:

4. Identify all clinical reviewers to be assigned by your IRO by name, general certification, and specialty or subspecialty certification:

   A clinical reviewer shall be a physician or other appropriate health care professional who is an expert in the treatment of the covered person’s medical condition, is knowledgeable about the recommended or requested health care service or treatment through actual clinical experience treating patients with the same or similar medical condition, holds a nonrestricted license in a state of the United States and, for physicians, a current certification by a recognized American medical specialty board in the area or areas appropriate to the subject of the external review, and has no history of disciplinary actions or sanctions.

5. I, ________________ (authorized signatory), agree to the following undertakings and have provided attachments as required:

   a. To provide notices and conduct reviews within the specified time frames.

   b. To ensure the selection of qualified and impartial clinical reviewers and suitable matching of reviewers to specific cases.
c. To ensure the confidentiality of medical and treatment records and clinical review criteria.

d. To establish and maintain written procedures to ensure the IRO is unbiased.

Specifically, the IRO shall not own or control, be a subsidiary of, or in any way be owned or controlled by, or exercise control with, a health benefit plan, a national, state, or local trade association of health benefit plans, or a national, state, or local trade association of health care providers. Further, neither the independent review organization nor any clinical reviewer assigned by the independent organization to conduct an external review shall have a material professional, familial, or financial conflict of interest with the health carrier, the covered person or covered person’s representative, any officer, director, or management employee of the health carrier, the health care professional, the health care professional’s medical group or independent practice association recommending the health care service or treatment that is the subject of the external review, the facility at which the recommended health care service or treatment would be provided, the developer or manufacturer of the principal drug, device, procedure, or other therapy being recommended for the covered person whose health care service or treatment is the subject of the external review.

e. To maintain required records and provide access to those records by the commissioner upon request.

6. Set forth a description of fees to be charged by the independent review organization for external reviews.

[ARC 6121C, IAB 12/29/21, effective 2/2/22]
[Filed 4/10/00, Notice 1/12/00—published 5/3/00, effective 6/7/00]
[Filed 11/21/01, Notice 10/17/01—published 12/12/01, effective 1/16/02]
[Filed Emergency ARC 9637B, IAB 7/27/11, effective 7/8/11]
[Filed ARC 9979B (Notice ARC 9854B, IAB 11/16/11), IAB 1/25/12, effective 2/29/12]
[Filed ARC 2601C (Notice ARC 2430C, IAB 3/2/16), IAB 6/22/16, effective 7/27/16]
[Filed ARC 4780C (Notice ARC 4660C, IAB 9/25/19), IAB 11/20/19, effective 12/25/19]
[Editorial change: IAC Supplement 9/23/20]
[Filed ARC 6121C (Notice ARC 6002C, IAB 10/20/21), IAB 12/29/21, effective 2/2/22]
[Filed ARC 6338C (Notice ARC 6285C, IAB 4/6/22), IAB 6/1/22, effective 7/6/22]
CHAPTER 17
OPEN ENROLLMENT

281—17.1(282) Intent and purpose. It is the intent of Iowa Code section 282.18 to maximize parental choice in providing a wide range of educational opportunities which are not available for pupils because of where they live. It is the purpose of this chapter to give guidance and direction to parents/guardians, public school district administrators and boards in making quality decisions regarding school district choice for the education of pupils.

281—17.2(282) Definitions. For the purpose of this chapter the indicated terms are defined as follows:

“Alternative receiving district” means a district to which a parent/guardian petitions for the open enrollment of a pupil from a receiving district. An alternative receiving district could be the district of residence of the parents/guardians.

“Attendance center” means a public school building that contains classrooms used for instructional purposes for elementary, middle, or secondary school students.

“Court-ordered desegregation plan” means a decree, judgment, or order entered by a court in response to a case or controversy alleging the district engaged in unlawful segregation. A desegregation plan is not “court-ordered” merely because a school district seeks approval of a voluntarily developed desegregation plan.

“Department” means the department of education.

“Director” means the director of the department of education or the director’s designee.

“Open enrollment” is the procedure allowing a parent/guardian to enroll one or more pupils in a public school district other than the district of residence at no tuition cost.

“Receiving district” is the public school district in which a parent/guardian desires to have the pupil enrolled or the district accepting the application for enrollment of a pupil under the provisions of Iowa Code section 282.18.

“Resident district” is the district of residence for school purposes of the parent/guardian and the district in which an open enrollment pupil shall be counted for the purpose of generating state aid regardless of the district in which the pupil is enrolled.

“Sending district” is synonymous with the term resident district.

“Sibling” means a child residing primarily in the same household as the child for whom an open enrollment request is filed and who is related by adoption, blood or marriage to the child for whom an open enrollment request is filed. “Sibling” also includes a foster child who is placed in the same household as the child for whom an open enrollment request is filed.

[ARC 5869C, IAB 8/25/21, effective 9/29/21]

281—17.3(282) Application process. The following procedure shall be used by parents/guardians and school districts in processing open enrollment applications.

17.3(1) Parent/guardian responsibilities. On or before March 1 of the school year preceding the school year for which open enrollment is requested, a parent/guardian shall formally notify both the district of residence and the receiving district of the request for open enrollment. The request for open enrollment shall be made on forms provided by the department of education. Failure by the parent to send the form to the resident district and receiving district by the deadline may cause the application to be considered untimely. The parent/guardian is required to indicate on the form if the request is for a pupil requiring special education, as provided by Iowa Code chapter 256B. The forms for open enrollment application are available from each public school district and area education agency and from the state department of education.

17.3(2) School district responsibilities.

a. The board of the resident district shall take no action on an open enrollment request except for a request made under rule 281—17.5(282) or 281—17.14(282).

b. The board of the receiving district shall act on an open enrollment request no later than June 1 of the school year preceding the school year for which the request is made.
(1) The receiving district superintendent shall provide notification of either approval or denial of the request to the parent/guardian and to the resident district within five days of board action.

(2) As an alternative procedure, the receiving board may by policy authorize the superintendent to approve, but not deny, applications filed on or before March 1. The board of directors of a receiving school district may adopt a policy granting the superintendent of the school district authority to approve open enrollment applications submitted after the March 1 deadline, but the board of the receiving district shall take action to approve the request if good cause exists. The board shall have the discretion to determine the scope of the authorization. The authorization may be for regular applications filed on or before March 1, good cause applications, and kindergarten applications filed on or before September 1, or any combination that the board determines. The same timelines for approval, forwarding, and notification shall apply.

c. The parent/guardian may withdraw an open enrollment request any time prior to the first day of school in the resident district. After the first day of school, an open enrollment request can only be changed during the term of the approval by the procedures of subrules 17.8(4), 17.8(5), 17.8(6), and 17.8(7).

d. The board of the receiving district shall comply with the provisions of rule 281—17.11(282) if the application for open enrollment is for a pupil requiring special education as provided by Iowa Code chapter 256B.

e. Notification to parents.
   (1) By September 30 of each school year, all districts shall notify parents of the following:
      1. Open enrollment deadlines;
      2. Transportation assistance;
      3. That within 30 days of a denial of an open enrollment request by a district board of education, the parent/guardian may file an appeal with the state board of education only if the open enrollment request was based on repeated acts of harassment or a serious health condition of the pupil that the district cannot adequately address; and that all other denials must be appealed to the district court in the county in which the primary business office of the district is located; and
      4. Possible loss of athletic eligibility for open enrollment pupils.

   (2) This notification may be published in a school newsletter, a newspaper of general circulation, a website, or a parent handbook provided to all patrons of the district. This information shall also be provided to any parent/guardian of a pupil who enrolls in the district during the school year.

17.3(3) Exception to process when resident district is under court-ordered desegregation. If the resident district has a court-ordered desegregation plan, the request for open enrollment shall be filed solely with the district of residence on or before March 1 of the school year preceding the school year for which open enrollment is requested. The superintendent of the resident district may deny a request under this subrule unless the request is made on behalf of a student whose sibling already actively participates in open enrollment to the same receiving district to which open enrollment is sought for this student. A denial by the superintendent may be appealed to the board of the district in which the request was denied. A decision of the local board to uphold the denial may only be appealed to the district court in the county in which is located the primary business office of the district that upheld the denial of the open enrollment request.

[ARC 2746C, IAB 10/12/16, effective 11/16/16; ARC 5869C, IAB 8/25/21, effective 9/29/21]

281—17.4(282) Filing after the March 1 deadline—good cause. A parent/guardian may apply for open enrollment after the filing deadline of March 1 of the school year preceding the school year for which open enrollment is requested and before the date specified in Iowa Code section 257.6, subsection 1, of that calendar year if good cause exists for the failure to meet the deadline. Good cause is a change in the status of the pupil’s residence or a change in the status of the pupil’s resident district taking place after March 1, or the closing or loss of accreditation of a nonpublic school of attendance after March 1 resulting in the desire of the parent/guardian to obtain open enrollment for the following school year. If good cause can be established, the parent/guardian shall be permitted to apply for open enrollment in the same manner as if the deadline had been met pursuant to rule 17.3(282).
Consideration of an open enrollment request filed under the provision of good cause does not preclude the authority, as appropriate, for the resident or receiving district to administer board policy related to insufficient classroom space or the requirements of a desegregation plan or order in acting to approve or deny the request. (See subrules 17.6(2) and 17.6(3).)

17.4(1) Good cause related to change in the pupil’s residence shall include:

a. A change in the family residence due to the family’s moving from the district of residence any time after March 1 of the school year preceding the school year for which open enrollment is requested.

b. A change in the child’s residence from the residence of one parent or guardian to the residence of a different parent or guardian.

c. A change in the state of residence allowing a parent/guardian moving into an Iowa school district from out of state to obtain open enrollment to a different district from their new district of residence.

d. A change in the marital status of the pupil’s parents.

e. A guardianship or custody proceeding.

f. Placement of the child in foster care.

g. Adoption.

h. Participation in a foreign exchange program.

i. Initial placement of a prekindergarten student in a special education program requiring specially designed instruction.

j. Participation in a substance abuse or mental health treatment program.

17.4(2) Good cause related to change in status of the pupil’s resident district or nonpublic school of attendance shall include:

a. Reorganization action.

(1) Failure of the area education board to vote in favor of a reorganization proposal,

(2) Failure of the area education board to act on objections to exclude territory from a reorganization proposal,

(3) Failure of a reorganization election,

(4) Rescinded IAB 3/8/00, effective 4/12/00.

b. Dissolution action.

(1) Failure of a dissolution commission to make a recommendation to the board of directors,

(2) Failure of the board to take positive action on objections filed by residents of the district to a dissolution proposal,

(3) Failure of contiguous districts to accept a dissolution proposal,

(4) Failure of an election on a dissolution proposal.

c. Whole grade sharing action.

(1) Failure of the board to pursue negotiations for a whole grade sharing proposal for which it has given public notice by board action of its intent to pursue,

(2) Failure of the board to approve a request by a parent/guardian to send an affected pupil to a contiguous district rather than to the district party to the agreement,

(3) Failure of the board to extend or renew a whole grade sharing agreement,

(4) Unilateral rejection by one board of a whole grade sharing agreement prior to expiration of the term of the agreement.

d. Loss of accreditation.

(1) Removal of accreditation by the state board after March 1.

(2) Surrender of accreditation after March 1.

(3) Permanent closure of a nonpublic school after March 1.

e. Other actions.

(1) Revocation of a charter school contract after March 1 as provided in Iowa Code section 256F.8.

(2) The child’s assigned attendance center in the district of residence is identified as in significant need for improvement. “Significant need for improvement” means a school attendance center designated by the department of education under the priority category under the Iowa school performance profiles for two or more of the immediately preceding school years or identified for comprehensive support
and improvement under the federal Every Student Succeeds Act, Pub. L. No. 114-95, or an equivalent objective federal standard, for two or more of the immediately preceding school years.

On open enrollment requests for good cause related to a change in status of the pupil’s school district of residence, action by a parent/guardian must be taken to file notification within 45 days of the last board action or within 30 days of the certification of an election, whichever circumstance is applicable.

17.4(3) Good cause shall not include:
   a. Actions of a board of education in the designation of attendance centers within a school corporation and in the assignment of pupils to such centers as provided by Iowa Code section 279.11.
   b. Actions of a board of education in making its own rules of government for the internal organization and operation of the school corporation as provided by Iowa Code section 279.8.

17.4(4) Rescinded IAB 8/21/02, effective 9/25/02.

17.4(5) Timelines for board action on applications filed after March 1 for good cause. The board of the receiving district shall act on the request within 30 days of its receipt. The same timelines for approval, forwarding, and notification shall apply.

The receiving district superintendent shall provide notification of either approval or denial of the request to the parent/guardian and to the resident district within five days of board action.

17.4(6) If the resident district believes that the board of the receiving district approved a late-filed open enrollment request that does not meet the definition of “good cause” under Iowa Code section 282.18(4) “b,” the resident district may appeal to the director.
   a. Upon affirmative vote of a majority of its board to do so, the resident district shall file a written appeal to the director within 30 days of receipt by the resident district of notification by the board of the receiving district of the approval by the receiving district of a late-filed open enrollment request. The written appeal shall state the name and grade level of the affected student, the name of the receiving district, the date of approval by the board of the receiving district, the date the resident district was notified of the approval, and a brief statement explaining why the resident district board believes there is no good cause for the request to have been filed and approved after March 1. The appeal shall be signed by the president of the board of the resident district and shall have attached to it a copy of the disputed open enrollment request and the minutes of the board meeting at which the resident district board voted to appeal. An appeal is timely filed if it is postmarked or delivered personally or via facsimile transmission or electronic mail to the director within the 30-day time period.
   b. The director shall, upon receipt of an appeal, first attempt to mediate the dispute. If mediation is unsuccessful, the director shall schedule a telephonic hearing for the purpose of hearing testimony from both boards.
   c. If a hearing is necessary, the boards may stipulate to any or all facts to be considered by the director. At the sole discretion of the director, an in-person hearing may be scheduled. The director shall issue a written decision within ten days of the hearing, upholding or reversing the decision of the board of the receiving district.
   d. Within five days of the issuance of the decision of the director, the aggrieved board may appeal the decision to the state board of education under the procedures in Iowa Code chapter 290.

[ARC 5869C, IAB 8/25/21, effective 9/29/21]

281—17.5(282) Filing after the March 1 deadline—harassment, failure to respond to academic needs, or serious health condition. A parent/guardian may apply for open enrollment after the filing deadline of March 1 of the school year preceding the school year for which open enrollment is requested if the parent’s/guardian’s child is the victim of repeated acts of harassment that the resident district cannot adequately address, if there is a consistent failure of the resident district to reasonably respond to a student’s failure to meet basic academic standards after notice provided by a parent or guardian, or if the child has a serious health condition that the resident district cannot adequately address. If any of these conditions exists, the parent/guardian shall be permitted to apply for open enrollment by sending notification to both the resident and receiving districts.

17.5(1) Board action. The board of the resident district shall act on the request within 30 days of its receipt. If the request is denied, the parent/guardian shall be notified by the district superintendent within
3 days following board action. If the request is approved, the district superintendent shall forward the approved application form to the receiving district within 5 days following board action and shall notify the parent/guardian within 3 days of this action. The board of the receiving district shall act to approve or deny an open enrollment request within 30 days following receipt of the notice of approval from the resident district. The receiving district superintendent shall provide notification of either approval or denial of the request to the parent/guardian and to the resident district within 15 days of board action.

17.5(2) Appeal. A denial by either board of a request made under this rule involving repeated acts of harassment of the student or serious health condition of the student that the resident district cannot adequately address may be appealed by a parent/guardian to the state board of education pursuant to Iowa Code section 290.1. The state board shall exercise broad discretion to achieve just and equitable results that are in the best interest of the affected child or children.

17.5(3) Criteria for determining whether a resident district consistently failed to reasonably respond to a student’s failure to meet basic academic standards. School officials, upon having data to evidence a student’s failure to meet basic academic standards and having received notice from a student’s parent/guardian, must have failed to respond to the student’s failure.

a. Basic academic standards include Iowa academic standards for English language arts, mathematics, science, and social studies.

b. Evidence of a student’s failure to meet basic academic standards may include one or more of the following:

   (1) Failure to meet grade-level benchmarks on universal screening assessments.
   (2) Failure to achieve proficiency on standards-based outcome assessments.
   (3) Receiving a grade of D or F (or equivalent) for a course.

c. A district’s consistent failure to respond may include one or more of the following, measured over a minimum period of 12 weeks:

   (1) Failure to provide evidence-based interventions or strategies targeted to the student’s needs.
   (2) Failure to monitor student growth.
   (3) Failure to make changes to the student’s improvement plan if the student does not show progress.

[ARC 5869C, IAB 8/25/21, effective 9/29/21; ARC 6332C, IAB 6/1/22, effective 7/6/22]

281—17.6(282) Restrictions to open enrollment requests. A district board may exercise the following restrictions related to open enrollment requests.

17.6(1) Enrollment loss caps. Rescinded IAB 12/8/93, effective 1/12/94.

17.6(2) Court-ordered desegregation plans. In districts with court-ordered desegregation plans where there is a requirement to maintain minority and nonminority student ratios according to the plan, the superintendent of the district may deny a request for open enrollment if it is found that the enrollment or release of a pupil will adversely affect the district’s court-ordered desegregation plan. Open enrollment requests that would facilitate the court-ordered desegregation plan shall be given priority over other open enrollment requests received by the district. A parent/guardian whose request for open enrollment is denied by the superintendent of the district on the basis of its adverse effect on the district’s court-ordered desegregation plan may appeal that decision to the district board.

17.6(3) Policy on insufficient classroom space. No receiving district shall be required to accept an open enrollment request if it has insufficient classroom space to accommodate the pupil(s). Each district board shall adopt a policy which defines the term “insufficient classroom space” for that district. This policy shall establish a basis for the district to make determinations on the acceptance or denial, as a receiving district, of an open enrollment request. This policy may include, but shall not be limited to, one or more of the following: nature of the educational program, grade level, available instructional staff, instructional method, physical space, pupil-teacher ratio, equipment and materials, facilities either being planned or under construction, facilities planned to be closed, finances available, sharing agreement in force or planned, bargaining agreement in force, special education class size or caseload established pursuant to rule 281—41.408(256B,273,34CFR300), or board-adopted district educational goals and objectives. This policy shall be reviewed annually by the district board.
17.6(4) Designation of attendance center. The right of a parent/guardian to request open enrollment is to a district other than the district of residence, not to an attendance center within the nonresident district. In accepting an open enrollment pupil, the receiving district board has the same authority it has in regard to its resident pupils as provided by Iowa Code section 279.11, to “determine the particular school which each child shall attend.” In the application process, however, the parent or guardian may request an attendance center of preference.

[ARC 5651C, IAB 6/2/21, effective 7/7/21; ARC 5869C, IAB 8/25/21, effective 9/29/21]

281—17.7(282) Open enrollment for kindergarten or certain prekindergarten programs. While the regular time frame in requesting open enrollment is that an application should be made no later than March 1 of the school year preceding the school year for which the enrollment is requested, a parent/guardian requesting to enroll a kindergarten pupil in a district other than the district of residence or a parent/guardian of a prekindergarten student enrolled in a special education program and included in the resident school district’s basic enrollment under Iowa Code section 257.6(1)”a”(1) may make such application on or before September 1 of that school year. In considering an application for a kindergarten pupil, the resident and the receiving district are not precluded from administering board-adopted policies related to insufficient classroom space, the requirements of rule 281—17.11(282), or the requirements of a desegregation order.

As an alternative procedure, the receiving board may by policy authorize the superintendent to approve, but not deny, applications filed on or before September 1 under this rule. The timelines established in rule 281—17.4(282) shall apply to applications for a pupil under this rule.

[ARC 5869C, IAB 8/25/21, effective 9/29/21]

281—17.8(282) Requirements applicable to parents/guardians and students.

17.8(1) Expelled or suspended students. A pupil who has been suspended or expelled by action of the administration or board of the resident district shall not be permitted to enroll if an open enrollment request is filed until the pupil is reinstated for school attendance in the resident district. Once reinstated, the application for open enrollment shall be considered in the same manner as any other open enrollment request. If a pupil for whom an open enrollment request has been filed is subsequently expelled by action of the resident district board, the pupil may be denied enrollment by the receiving district board until the pupil is reinstated for school attendance by the resident district. The provisions of this subrule shall also apply to a pupil who has been suspended or expelled in a receiving district and is requesting open enrollment to an alternative receiving district or is seeking to return to the resident district as outlined in subrule 17.8(4).

17.8(2) Restrictions on participation in interscholastic athletic contests and competitions. Subject to rule 281—17.15(282), a pupil who changes school districts under open enrollment in any of the grades 9 through 12 shall not be eligible to participate in varsity interscholastic athletic contests and competitions during the first 90 school days of enrollment. This restriction also shall apply to enrollments resulting from an approved petition filed by a parent/guardian to open enroll to an alternative receiving district and when the pupil returns to the district of residence using the process outlined in subrule 17.8(4). This 90-school-day restriction does not prohibit the pupil from practicing with an athletic team during the 90 school days of ineligibility. If a pupil is declared ineligible for interscholastic athletic contests and athletic competitions in the pupil’s district of residence due to the pupil’s academic performance, upon participating in open enrollment, in addition to any other period of ineligibility under this rule, the pupil shall be ineligible in the receiving district for the remaining period of ineligibility declared by the district of residence. This 90-school-day restriction is not applicable to a pupil who:

a. Participates in an athletic activity in the receiving district that is not available in the district of residence.

b. Participates in an athletic activity for which the resident district and the receiving district have a “cooperative student participation agreement” in place as provided by rule 281—36.20(280).

c. Has paid tuition for one or more years to the receiving school district prior to making application and being approved for open enrollment.
d. Has attended the receiving district for one or more years, prior to making application and being approved for open enrollment, under a sharing or mutual agreement between the resident district and the receiving district.

e. Has been participating in open enrollment and whose parents/guardians move out of their district of residence but exercise the option of maintaining the open enrollment agreement as provided in subrule 17.8(6) except that the period of 90 school days of ineligibility shall apply to a pupil who open enrolls to another school district. If the pupil has established athletic eligibility under open enrollment, it is continued despite the parent’s or guardian’s change in residence.

f. Obtains open enrollment as provided in subrule 17.8(7) except that the period of 90 school days of ineligibility shall apply to a pupil who open enrolls to another school district.

g. Obtains open enrollment due to the dissolution and merger of the former district of residence under Iowa Code subsection 256.11(12).

h. Obtains open enrollment due to the pupil’s district of residence entering into a whole-grade sharing agreement on or after July 1, 1990, including the grade in which the pupil would be enrolled at the start of the whole-grade sharing agreement.

i. Participates in open enrollment and the parent/guardian is an active member of the armed forces and resides in permanent housing on government property provided by a branch of the armed services.

j. Open enrolls from a district of residence that has determined that the pupil was previously subject to a founded incident of harassment or bullying as defined in Iowa Code section 280.28 while attending school in the district of residence.

k. Participates in open enrollment because of circumstances that meet the definition of “good cause” under rule 281—17.4(282).

l. Resides in a district in which the board of directors or superintendent issues or implements a decision that results in the discontinuance or suspension of varsity interscholastic sports activities in the district.

m. Participates in open enrollment and the board of directors of the district of residence and the board of directors of the receiving district both agree to waive the ineligibility period.

n. Open enrolls for the school year beginning July 1, 2021, if the pupil’s district of residence had a voluntary diversity plan in effect on January 1, 2021, and applicable to the school year beginning July 1, 2021.


17.8(4) Petition for attendance in an alternative receiving district. Once the pupil of a parent/guardian has been accepted for open enrollment, attendance in an alternative receiving district under open enrollment can be initiated by filing a petition for change with the receiving district. The petition shall be filed by the parent/guardian with the receiving district on or before March 1 of the year preceding the school year for which the change is requested. The timelines and notification requirements for such a request shall be the same as outlined in subrule 17.3(2). If the request is approved, the alternative district shall send notice of this action to the parent/guardian, to the original receiving district, and to the resident district of the pupil. Petitions for change shall be effectuated at the start of the next school year.

As an alternative procedure, the receiving and alternative receiving district boards by mutual agreement may effectuate the change in enrollment of an open enrollment pupil at any time following receipt of a written request for such change which is approved by the two boards. The parent/guardian and the resident district board shall be notified of the approval and the date for change in open enrollment within 15 days of the mutual agreement action of the receiving and alternative receiving boards.

A pupil in good standing may return to the district of residence at any time following written notice from the parent/guardian to both the resident district and the receiving district.

17.8(5) Renewal of an open enrollment agreement. An open enrollment agreement shall remain in place unless canceled by the parent/guardian or terminated as outlined in the provisions of subrule 17.8(10).

17.8(6) Change in residence when participating in open enrollment. If the parent/guardian of a pupil who is participating in open enrollment changes the school district of residence during the term of the
agreement, the parent/guardian shall have the option to leave the pupil in the receiving district under open enrollment, to open enroll to another school district, or to enroll the pupil in the new district of residence, thus terminating the open enrollment agreement. If the choice is to leave the pupil under open enrollment or to open enroll to another school district, the district of residence, as determined on the date specified in Iowa Code section 257.6(1), shall be responsible for payment of the cost per pupil plus any applicable weightings or special education costs for the balance of the school year. The new district of residence shall be responsible for these payments during succeeding years of the agreement.

If the pupil is to remain under open enrollment or to open enroll to another school district, the parent/guardian shall write a letter, delivered by mail or by hand on or before the date specified in Iowa Code section 257.6(1), to notify the original resident district, the new resident district, and the receiving district of this decision.

Timely requests under this rule shall not be denied. If the request is for a high school pupil, the pupil shall not be subject to the initial 90-school-day ineligibility period of subrule 17.8(2).

17.8(7) Change in residence when not participating in open enrollment. If a parent/guardian moves out of the school district of residence, and the pupil is not currently under open enrollment, the parent/guardian has the option for the pupil to remain in the original district of residence as an open enrollment pupil with no interruption in the education program or to open enroll to another school district. This option is not available to the parent/guardian of a student who is entering kindergarten for the first time. The parent/guardian exercising this option shall file an open enrollment request form with the new district of residence for processing and record purposes. This request shall be made on or before the date specified in Iowa Code section 257.6(1). Timely requests under this subrule shall not be denied. If the request is for a high school pupil, the pupil shall not be subject to the initial 90-school-day ineligibility period of subrule 17.8(2). If the move is on or after the date specified in Iowa Code section 257.6(1), the new district of residence is not required to pay per-pupil costs or applicable weighting or special education costs to the receiving district until the first full year of the open enrollment.

a. This subrule applies in the following circumstances: a change in family residence, a change in a child’s residence from the residence of one parent or guardian to the residence of a different parent or guardian, a change in the state in which the family residence is located, a change in a child’s parents’ marital status, a guardianship proceeding, placement in foster care, adoption, participation in a foreign exchange program, or participation in a substance abuse or mental health treatment program.

b. This rule applies to the following children:

(1) A child who is enrolled in any grade from kindergarten through grade 12.

(2) A prekindergarten student who is enrolled in a special education program at the time of the request and is not currently using any provision of open enrollment.

17.8(8) Pupil governance. An open enrollment pupil, and where applicable the pupil’s parent/guardian, shall be governed by the rules and policies established by the board of directors of the receiving district. Any complaint or appeal by the parent/guardian concerning the educational system, its process, or administration in the receiving district shall be initially directed to the board of directors of that district in compliance with the policy of that district.

17.8(9) Appeal procedure. A parent/guardian may appeal the decision of the board of directors of a school district (resident or receiving) only on an application for open enrollment under Iowa Code section 282.18(5) and rule 281—17.5(282). This appeal is to the state board of education and shall comply with the provisions of Iowa Code section 290.1. The appeal shall be filed within 30 days of the decision of the district board and shall be in the form of an affidavit signed by the parent/guardian. It shall state in a plain and concise manner what the parent/guardian feels to be the basis for appeal.

17.8(10) Open enrollment termination. Open enrollment ends when:

a. The pupil graduates, moves into the receiving district, moves into a third district and does not elect to continue attending in the receiving district, moves out of state, elects to attend a nonpublic school instead of the receiving district, or any other circumstance not excepted below that results in the pupil no longer attending the receiving district.
Exceptions: This rule shall not apply if the pupil is placed temporarily in foster care, a juvenile detention center, mental health or substance abuse treatment facility, or other similar placement. In such cases, the open enrollment status will automatically be reinstated when the pupil returns.

b. The pupil drops out of school. In this instance, if the pupil desires to return to the resident district during the term of the original open enrollment, notice must be given as outlined in the provisions of subrule 17.8(4).

[ARC 2746C; IAB 10/12/16, effective 11/16/16; ARC 4296C, IAB 2/13/19, effective 3/20/19; ARC 5869C, IAB 8/25/21, effective 9/29/21]

281—17.9(282) Transportation.

17.9(1) Parent responsibilities. The parent/guardian of a pupil who has been accepted for open enrollment shall be responsible to transport the pupil without reimbursement, except as provided in subrule 17.9(2), to and from a point on a regular school bus route of the receiving district. This point shall be a designated stop on the bus route of the receiving district. If this point—designated stop—is within the distances established by Iowa Code section 285.1 from the school designated for attendance by the receiving district, that district may, but is not required to, provide transportation for an open enrollment pupil. A receiving district may send buses into a resident district solely for the purpose of transporting an open enrollment pupil if the boards of both the sending and receiving districts agree to this arrangement. Bus routes that are outside the boundary of the receiving district that have been authorized by an area education agency board of directors, as provided by Iowa Code subsection 285.9(3), may be used to transport open enrollment pupils if boards of directors of the resident and receiving districts have both taken action to approve such an arrangement. Bus routes that have been established by the receiving district for the purpose of transporting nonpublic school or special education pupils that operate in the resident district of an open enrollment pupil shall not be utilized for the transportation of such pupil for the portion of the route that is within the resident district unless the boards of directors of the resident and receiving districts have both taken action to approve such an arrangement. Bus routes transporting pupils for the purpose of whole-grade sharing shall not be used to transport open enrollment pupils for the portion of the route that is within the resident district unless the boards of directors of the resident and receiving districts have both taken action to approve such an arrangement.

17.9(2) Qualifications and provisions for transportation assistance. Open enrollment pupils that meet the economic eligibility requirements established by the department of education shall receive transportation assistance from their resident district under the following conditions. The resident district is not required to provide any transportation assistance for a pupil involved in open enrollment with a district that is not contiguous with the pupil’s resident district. The resident district shall provide transportation for the pupil to a point that is a designated stop on a regular bus route of a contiguous receiving district, or as an alternative, the resident district shall pay the parent/guardian for providing this transportation. In either situation the resident district is not obligated to expend more than the average cost per pupil transported amount established for that district for the previous school year. If the resident district provides the transportation, it shall determine that it is able to perform this function at a cost not in excess of the average cost per pupil transported for the resident district as established the previous year. It shall not assess any additional cost to the parent/guardian for providing transportation. If the district chooses to reimburse the parent/guardian for providing transportation, to determine the amount to be reimbursed, the district shall use the provisions of Iowa Code subsection 285.1(3). This reimbursement shall not exceed the average cost per pupil transported for the resident district as established the previous year. The resident district may withhold from the amount it is required to pay to a receiving district for an open enrollment pupil the actual amount or the average cost per pupil transported amount it pays for transportation assistance, whichever is the lesser amount.

17.9(3) Economic eligibility requirements for transportation. A parent/guardian shall be eligible for transportation assistance from the resident district if the household income of the parent/guardian is 200 percent or less of the federal poverty level as defined by the most recently revised poverty income guidelines published by the United States Department of Health and Human Services. Since the federal
poverty income guidelines are adjusted each year, the department of education shall provide revised eligibility guidelines to school districts each year. 

[ARC 5869C, IAB 8/25/21, effective 9/29/21]

281—17.10(282) Method of finance. Open enrollment options shall be made available for pupils at no instructional cost to their parents/guardians. Open enrollment pupils shall be considered enrolled resident pupils in the resident district and shall be included in the certified enrollment count of that district for the purposes of generating school foundation aid.

17.10(1) Full-time pupils. Unless otherwise agreed to in the mediation under paragraph 17.4(6) “b,” for full-time pupils, the resident district shall pay each year to the receiving district an amount equal to the sum of the state cost per pupil for the previous year; plus any moneys received for the pupil as a result of non-English speaking weighting provided by Iowa Code section 280.4; plus either the teacher leadership supplement state cost per pupil for the previous year as provided in Iowa Code section 257.9(11) or the teacher leadership supplement foundation aid allocation for fiscal year 2017 as provided in Iowa Code section 284.13(1) “e,” whichever the district received, if both the district of residence and the receiving district received either of the supplements. If the pupil participating in open enrollment is also an eligible pupil under Iowa Code section 261E.6 (postsecondary enrollment options program), the receiving district shall pay the tuition reimbursement amount to an eligible postsecondary institution as provided in Iowa Code section 261E.7.

17.10(2) Dual enrolled pupils. Unless otherwise agreed to in the mediation under paragraph 17.4(6) “b,” for pupils who receive competent private instruction and are dual enrolled, the resident district shall pay each year to the receiving district an amount equal to .1 times the state cost per pupil for the previous year plus any moneys received for the pupil as a result of non-English speaking weighting provided by Iowa Code section 280.4. However, a pupil dual enrolled in grades nine through twelve shall be counted by the receiving district in the same manner as a shared-time pupil under Iowa Code section 257.6(1) “c.”

17.10(3) Home school assistance program pupils. Unless otherwise agreed to in the mediation under paragraph 17.4(6) “b,” for pupils who receive competent private instruction and are registered for a home school assistance program, the resident district shall pay each year to the receiving district an amount equal to .3 times the state cost per pupil under Iowa Code chapter 257 for the previous year plus any moneys received for the pupil as a result of non-English speaking weighting provided by Iowa Code section 280.4.

17.10(4) Transportation assistance. The resident district may deduct any transportation assistance funds for which the pupil is eligible as provided by subrule 17.9(2).

17.10(5) Method of payment. These moneys shall be paid to the receiving district by the first resident district according to the timeline in Iowa Code section 282.20(3) (on or before February 15 and July 15 of each year). Payments shall be made to the receiving district in a timely manner. The district cost per pupil for nonspecial education students shall be the cost calculated each year for the school year preceding the school year for which the open enrollment takes place. Costs for special education students shall be as outlined in rule 281—17.11(282).

17.10(6) Partial-year situations. In the event that the pupil who is under open enrollment withdraws from school, moves into the district of attendance, moves out of state, moves to another district in the state of Iowa and elects to attend that district, graduates at midyear, is allowed to return to the district of residence during the school year, or other similar set of circumstances that result in the pupil no longer attending in the receiving district, payment of cost per pupil will be prorated.

17.10(7) Late changes of open enrollment. The resident district and the receiving district boards by mutual agreement may effectuate the change in enrollment of an open enrollment pupil at any time following receipt of a petition for such change which is approved by the two boards. A change due to good cause is a late change in enrollment. If any change in enrollment is made on or after the date specified in Iowa Code section 257.6, subsection 1, the resident district is not required to pay per-pupil costs or applicable weighting or special education costs to the receiving district until the first full year of the open enrollment.
Supplemental weighting. A student under open enrollment is eligible to be counted for supplementary weighting pursuant to 281—subrule 97.2(5) for qualifying concurrent enrollment classes in which the student is enrolled, including concurrent enrollment classes provided via the ICN, or supplementary weighting for project lead the way (PLTW) enrollment through sharing with a community college pursuant to 281—subrule 97.2(6). An open enrolled student who is under competent private instruction (CPI) shall be weighted in the student’s receiving district, and no tuition shall be billed to the resident district. An open enrolled student who is not under CPI shall be weighted in the resident district, and the funding shall be sent to the receiving district in addition to open enrollment tuition.

1. If the open enrolled student is present in the resident district on October 1 of the school year, the resident district shall count the student, excluding a student under CPI, for supplementary weighting.

2. The concurrent enrollment course must qualify for supplementary weighting in the receiving district pursuant to 281—subrule 97.2(5), and the PLTW course must qualify for supplementary weighting in the receiving district pursuant to 281—subrule 97.2(6).

3. The resident district shall forward the weighting generated for the concurrent or PLTW enrollment for that student using the district cost per pupil of the school year. The amount generated is calculated as the supplementary weighting full-time-equivalency for that one student for each qualified concurrent or PLTW enrollment course multiplied by the current school year’s district cost per pupil in the resident district.

4. The receiving district shall pay the community college the tuition negotiated for the course. The tuition negotiated may cost the receiving district a different amount than that received from the resident district. No additional amount may be charged to the resident district, the student, or the parent, guardian, or legal custodian.

5. If the student was not present in the resident district on October 1 of the school year and is a late transfer, the receiving district bears all the tuition cost and shall not bill the resident district in the first year pursuant to subrule 17.10(7).

Open enrollment pursuant to rule 281—17.15(282). If a pupil participates in cocurricular or extracurricular activities in accordance with subrule 17.15(2), the district of residence may deduct up to $200 per activity, for up to two activities, from the amount calculated in this rule. For a cocurricular activity, one semester shall equal one activity. Extracurricular activities for which such a resident district may charge up to $200 per activity for up to two activities under this subrule include interscholastic athletics, music, drama, and any other activity with a general fund expenditure exceeding $5,000 annually. A pupil may participate in additional extracurricular activities at the discretion of the resident district. The school district of residence may charge the pupil a fee for participation in such cocurricular or extracurricular activities equivalent to the fee charged to and paid in the same manner by other resident pupils.

Special education students. If a parent/guardian requests open enrollment for a pupil requiring special education, as provided by Iowa Code chapter 256B and 281—Chapter 41, this request shall receive consideration under the following conditions.

Appropriateness of program. The request shall be granted only if the receiving district is able to provide within that district the appropriate special education program for that student in accordance with Iowa rules of special education, 281—Chapter 41. This determination shall be made by the receiving district in consultation with the resident district and the appropriate area education agency(ies) before approval of the application. In a situation where the appropriateness of the program is in question, the pupil shall remain enrolled in the program of the resident district until a final determination is made, unless all parties otherwise agree, as provided in 281—Chapter 41. If the appropriateness of the special education program in the receiving district is at issue, the final determination of the appropriateness of a special education instructional program shall be the responsibility of the child’s individualized education program team, which shall include a representative
from the resident district that has the authority to commit district resources, and which decision is subject to the parent’s procedural safeguards under 281—Chapter 41.

17.11(2) Class size and caseload. The provisions of subrule 17.6(3) apply to requests for open enrollment for a child with a disability. The following conditions apply:

a. The enrollment of the child in the receiving district’s program would not cause the size of the class or caseload in that special education instructional program in the receiving district to exceed the maximum class size or caseload set forth in subrule 17.6(3).

b. If the child would be assigned to a general education class, there is sufficient classroom space, as established in subrule 17.6(3), for the general education class to which the child would be assigned.

17.11(3) Transportation. District transportation requirements, parent/guardian responsibilities and, where applicable, financial assistance for an open enrollment special education pupil shall be as provided by rules 281—17.9(282) and 281—41.412(256B,34CFR300).

17.11(4) Finance. The district of residence shall pay to the receiving district on the schedule set forth in subrule 17.10(5) the actual costs incurred by the receiving district in providing the appropriate special education program. These costs shall be based on the current year expenditures with needed adjustments made in the final payment. The responsibility for ensuring that an appropriate program is maintained for an open enrollment special education pupil shall rest with the resident district. The receiving district and the receiving area education agency director shall provide, at least on an annual basis, evaluation reports and information to the resident district on each special education open enrollment pupil. The receiving district shall provide notice to the resident district of all staffings scheduled for each open enrollment pupil. For an open enrolled special education pupil where the receiving district is located in an area education agency other than the area education agency within which the resident district is located, the resident district and the receiving district are required to forward a copy of any approved open enrollment request to the director of special education of their respective area education agencies. Any moneys received by the area education agency of the resident district for an approved open enrollment special education pupil shall be forwarded to the receiving district’s area education agency. For children requiring special education, the receiving district shall complete and provide to the district of residence the documentation necessary to seek Medicaid reimbursement for eligible services.

[ARC 3181C, IAB 7/5/17, effective 8/9/17; ARC 5651C, IAB 6/2/21, effective 7/7/21; ARC 5869C, IAB 8/25/21, effective 9/29/21]

281—17.12(282) Laboratory school provisions. Rescinded ARC 2746C, IAB 10/12/16, effective 11/16/16.


281—17.14(282) Court-ordered desegregation plans.

17.14(1) Applicability. These rules govern only the components of a court-ordered desegregation plan as the plan affects open enrollments.

17.14(2) Nature of court-ordered desegregation plan. The language of the court order shall be binding on a district’s implementation of open enrollment. The district shall notify the department of any court-ordered desegregation plan and any court-ordered modifications to that plan. This rule is intended to implement Iowa Code section 282.18 as amended by 2021 Iowa Acts, House File 228.

[ARC 5869C, IAB 8/25/21, effective 9/29/21]

281—17.15(282) Open enrollment and online coursework.

17.15(1) General. A school district may provide courses developed by private providers and delivered primarily over the Internet to pupils who are participating in open enrollment under Iowa Code section 282.18. However, if a student’s participation in open enrollment to receive educational instruction and course content delivered primarily over the Internet results in the termination of enrollment in the receiving district, the receiving district shall, within 30 days of the termination, notify the district of residence of the termination and the date of the termination.
17.15(2) Participation in activities in resident district. A pupil participating in open enrollment for purposes of receiving educational instruction and course content primarily over the Internet in accordance with Iowa Code section 256.7(32) may participate in any cocurricular or extracurricular activities offered to children in the pupil’s grade or group and sponsored by the district of residence under the same conditions and requirements as the pupils enrolled in the district of residence. The pupil may participate in not more than two cocurricular or extracurricular activities during a school year unless the resident district approves the student’s participation in additional activities. The student shall comply with the eligibility, conduct, and other requirements relating to the activity that are established by the district of residence for any student who applies to participate or who is participating in the activity.

[ARC 4296C, IAB 2/13/19, effective 3/20/19]

These rules are intended to implement Iowa Code section 282.18.

[Filed emergency 7/7/89—published 7/26/89, effective 7/7/89]
[Filed 2/2/90, Notices 7/26/89, 8/9/89—published 2/21/90, effective 3/28/90]
[Filed emergency 5/25/90—published 6/13/90, effective 5/25/90]
[Filed 9/28/90, Notice 6/13/90—published 10/17/90, effective 11/21/90]
[Filed 11/22/91, Notice 10/2/91—published 12/11/91, effective 1/15/92]
[Filed 8/26/92, Notice 6/24/92—published 9/16/92, effective 10/21/92]
[Filed 11/19/93, Notice 9/29/93—published 12/8/93, effective 1/12/94]
[Filed 11/17/94, Notice 9/28/94—published 12/7/94, effective 1/11/95]
[Filed 11/21/95, Notice 9/13/95—published 12/20/95, effective 1/24/96]
[Filed 9/13/96, Notice 7/17/96—published 10/9/96, effective 11/13/96]
[Filed 2/11/00, Notice 12/15/99—published 3/8/00, effective 4/12/00]
[Filed emergency 8/4/00—published 8/23/00, effective 8/7/00]
[Filed 4/19/02, Notice 2/6/02—published 5/15/02, effective 6/19/02]
[Filed 8/2/02, Notice 6/26/02—published 8/21/02, effective 9/25/02]
[Filed emergency 11/21/02—published 12/11/02, effective 11/21/02]
[Filed 1/17/03, Notice 12/11/02—published 2/5/03, effective 3/12/03]
[Filed 6/17/04, Notice 5/12/04—published 7/7/04, effective 8/11/04]
[Filed 11/15/06, Notice 10/11/06—published 12/6/06, effective 1/10/07]
[Filed 7/27/07, Notice 5/9/07—published 8/15/07, effective 9/19/07]
[Filed 2/8/08, Notice 12/19/07—published 2/27/08, effective 4/2/08]
[Filed 11/20/08, Notice 8/27/08—published 12/17/08, effective 1/21/09]
[Filed ARC 9261B (Notice ARC 9143B, IAB 10/6/10), IAB 12/15/10, effective 1/19/11]
[Filed ARC 0521C (Notice ARC 0384C, IAB 10/3/12), IAB 12/12/12, effective 1/16/13]
[Filed ARC 2746C (Notice ARC 2609C, IAB 7/6/16), IAB 10/12/16, effective 11/16/16]
[Filed ARC 3181C (Notice ARC 3031C, IAB 4/26/17), IAB 7/5/17, effective 8/9/17]
[Filed ARC 4296C (Notice ARC 4159C, IAB 12/5/18), IAB 2/13/19, effective 3/20/19]
[Filed ARC 5651C (Notice ARC 5463C, IAB 2/24/21), IAB 6/2/21, effective 7/7/21]
[Filed ARC 5869C (Notice ARC 5745C, IAB 6/30/21), IAB 8/25/21, effective 9/29/21]
[Filed ARC 6332C (Notice ARC 6184C, IAB 2/9/22), IAB 6/1/22, effective 7/6/22]
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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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 responsibilities identified in rule 657—8.3(155A).

[ARC 8673B, IAB 4/7/10, effective 6/1/10; ARC 0501C, IAB 12/12/12, effective 1/16/13; ARC 1961C, IAB 4/15/15, effective 5/20/15]

657—6.3(155A) Reference library. References may be printed or computer-accessed. A reference library shall be maintained which includes, at a minimum, one current reference from each of the following categories, including access to current periodic updates.

1. A reference including all pertinent Iowa laws, rules, and regulations that impact the pharmacy’s practice.
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.
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 2196C, IAB 10/14/15, effective 11/18/15]

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 and of the provisions for effective control against theft of, diversion of, or unauthorized access to prescription drugs, including those collected through an authorized collection program, records for such drugs and authorized collection program activities, and patient records as provided in 657—Chapters 10 and 21 and federal regulations for authorized controlled substance collection programs, which can be found at www.deadiversion.usdoj.gov/drug_disposal/.

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 subrules 6.7(2) and 6.7(4).

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.
a. In the absence of the pharmacist, the pharmacy shall be secured from public access and the pharmacy shall notify the public that the pharmacist is temporarily absent and that no prescriptions will be dispensed until the pharmacist returns. 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, the pharmacy technician or the pharmacy support person may not dispense or deliver any drug, chemical, device, or prepared prescription to a patient or patient’s agent.

b. 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, and documentation of such review shall be maintained for two years from the date of entry.

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.

6.7(4) Refill sales during pharmacist break. At the discretion of the on-duty supervising pharmacist and pursuant to established policies and procedures, the pharmacist may delegate to a technician the dispensing of previously verified prescriptions which have been identified to not require pharmacist counseling pursuant to rule 657—6.14(155A) when the pharmacist is on a break of limited duration and is absent from the pharmacy department.

6.7(5) Minimum physical security and monitoring system requirements. Each pharmacy located in Iowa shall develop and implement policies and procedures to ensure appropriate physical security and monitoring of the pharmacy to prevent unauthorized access to prescription drugs, including controlled substances, and pharmacy records. The physical security and monitoring shall include the components identified herein, and the policies and procedures shall establish the utilization of such components commensurate with the pharmacy operation. The policies and procedures shall establish the retention of documentation of activities or recordings retained from the alarm and video surveillance systems, as well as contingencies when the systems are temporarily unavailable.

a. No later than July 6, 2023, a basic alarm system.

b. No later than July 6, 2023, a video surveillance system, except in areas where drugs are stored in an automated medication dispensing system or an alternative electronic storage unit which uses biometric restricted access or other electronic monitoring mechanism.

c. Controlled access to computer records.

d. A designated location that can be monitored, away from drug storage and handling areas, where personal items of pharmacy staff may be stored while on site.

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, except as provided in 657—subrule 21.5(1). The original prescription shall be retained by the pharmacy filling the prescription and shall be maintained in the original format as received by the pharmacy. Dispensing documentation shall include the date of fill or refill; the name, strength, and National Drug Code (NDC)
of the actual drug product dispensed; and the initials or other unique identification of the pharmacist, pharmacist-intern, or technician in an approved technician product verification program. Dispensing documentation shall be maintained and be readily available.

[ARC 3638C, IAB 2/14/18, effective 3/21/18; ARC 5007C, IAB 3/25/20, effective 4/29/20]

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(8).

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) Authorized individuals and means of transmission. Individuals authorized to engage in the transfer of prescriptions include a pharmacist, a pharmacist-intern under the direct supervision of a pharmacist, and a certified pharmacy technician, except as prohibited in 657—subrule 3.23(1). The transferring individual may transmit the prescription and transfer information required under subrule 6.9(5) from the transferring pharmacy via electronic means pursuant to subrule 6.9(8) or, following direct communication between authorized individuals, via oral or facsimile transmission. The receiving individual shall ensure the prescription transfer record maintained in the receiving pharmacy contains all of the information required under subrule 6.9(7).

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 activity.

6.9(5) Record of transfer out. The individual 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 individual receiving the prescription drug order information;

(3) The name of the individual 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) Record of transfer received. The individual 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;
6.10(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, except as provided in 657—subrule 8.19(7) for epinephrine auto-injectors, 657—subrule 8.19(8) for opioid antagonists, or 657—subrule 8.19(9) for expedited partner therapy.

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)”;

3. If a pharmacist selects an interchangeable biological product for the biological product prescribed by a practitioner, the prescription container label shall identify the interchangeable biological product dispensed and may identify the biological product prescribed by the practitioner, such as “(interchangeable biological product) for (biological product)”;

h. The initials or other unique identification of the dispensing pharmacist, unless the identification of the pharmacist involved in each step of the prescription filling process is electronically documented and retrievable.

6.10(2) Exceptions. The requirements of subrule 6.10(1) do not apply to unit dose dispensing systems, 657—22.1(155A), 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 contain, at a minimum, the following information:

a. Full name of the patient;
b. Address and telephone number of the patient;
c. Patient’s date of birth;
d. Patient’s gender;
e. Known allergies;
f. 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 dispensed, and the name of the prescriber; and

g. Pharmacist comments relevant to the patient’s health care, 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, supplements, 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).

6.13(4) Expedited partner therapy. When a pharmacy dispenses a prescription drug pursuant to Iowa Code section 139A.41 and 657—subrule 8.19(9) for expedited partner therapy, a pharmacy is only required to maintain the information about the patient who is known to the pharmacy.

[ARC 3638C, IAB 2/14/18, effective 3/21/18; ARC 4903C, IAB 2/12/20, effective 3/18/20]

657—6.14(155A) Patient counseling and instruction. Every pharmacy that is open to the public and located in Iowa shall post in every prescription pickup area, including in every drive-through prescription pickup lane, in a manner clearly visible to patients, a notice that Iowa law requires the pharmacist to discuss with the patient any prescriptions dispensed to the patient that are new or a change in drug therapy.

6.14(1) Counseling required. Upon receipt of a new prescription drug order, or upon receipt of a change in drug therapy including but not limited to a change of dose, directions, or drug formulation, and following a prospective drug use review pursuant to rule 657—8.21(155A), a pharmacist or pharmacist-intern 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 select and use alternative forms of patient information which shall include information for the patient or patient’s caregiver to contact the pharmacist for further consultation. The manner in which the patient or caregiver contacts the pharmacist shall not cause the patient to incur any expense. “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 disorder, or a language barrier. “Not practicable” does not include pharmacy variables such as inadequate staffing, technology failure, or high prescription volume. 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 counseling was provided.

657—6.15(124,126) Return of drugs and devices. For the protection of the public health and safety, prescription drugs and devices 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 or device 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).

657—6.16(124,155A) Records. Every 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 record or last activity 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.

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) Storage of records. Original hard-copy prescriptions and other pharmacy records shall be maintained by the pharmacy for a minimum of two years from the date of the record in accordance with this subrule.
   a. Records shall be maintained within the licensed pharmacy department for a minimum of 12 months, except as provided herein. Pharmacy records less than 12 months old may be stored in a secure storage area outside the licensed pharmacy department, including at a remote location, if the pharmacy
has retained an electronic copy of the records in the pharmacy that is immediately available and if the original records are available within 72 hours of a request by the board or its authorized agent, unless such remote storage is prohibited under federal law.

b. Records more than 12 months old may be maintained in a secure storage area outside the licensed pharmacy department, including at a remote location, if the records are retrievable within 72 hours of a request by the board or its authorized agent, unless such remote storage is prohibited under federal law.

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, except as provided in 657—subrule 21.5(1).

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 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.

[Filed 5/16/67; amended 11/14/73]

[Filed 6/1/84, Notice 3/14/84—published 6/20/84, effective 7/25/84]

[Filed 5/14/86, Notice 4/9/86—published 6/4/86, effective 7/9/86]

[Filed 1/28/87, Notice 11/19/86—published 2/25/87, effective 4/1/87]

[Filed 11/25/87, Notice 10/7/87—published 12/16/87, effective 1/20/88]

[Filed emergency 1/21/88—published 2/10/88, effective 1/22/88]

[Filed 11/17/88, Notice 8/24/88—published 12/14/88, effective 1/18/89]

[Filed emergency 5/16/89—published 6/14/89, effective 5/17/89]

[Filed 9/12/89, Notice 6/14/89—published 10/4/89, effective 11/8/89]

[Filed emergency 5/10/91—published 5/29/91, effective 5/10/91]

[Filed 7/30/91, Notice 5/29/91—published 8/21/91, effective 9/25/91]

[Filed 9/23/93, Notice 5/26/93—published 10/13/93, effective 11/17/93]


[Filed 2/27/97, Notice 1/1/97—published 3/26/97, effective 4/30/97]

[Filed 9/16/97, Notice 7/16/97—published 10/8/97, effective 11/12/97]


[Filed 2/22/99, Notices 10/21/98—published 3/10/99, effective 4/14/99]


[Filed 2/7/01, Notice 10/18/00—published 3/7/01, effective 4/11/01]

[Filed 8/14/02, Notice 6/12/02—published 9/4/02, effective 10/9/02]

[Filed emergency 3/26/03 after Notice 11/13/02—published 4/16/03, effective 3/26/03]

[Filed 7/15/03, Notice 4/16/03—published 8/6/03, effective 9/10/03]

[Filed 10/22/04, Notice 3/31/04—published 11/10/04, effective 12/15/04]

[Filed 6/2/05, Notice 1/19/05—published 6/22/05, effective 7/27/05]

[Filed 6/2/05, Notice 3/16/05—published 6/22/05, effective 7/27/05]

[Filed 3/22/06, Notice 12/21/05—published 4/12/06, effective 5/17/06]

[Filed 3/22/06, Notice 1/18/06—published 4/12/06, effective 5/17/06]
[Filed 2/7/07, Notice 10/25/06—published 2/28/07, effective 4/4/07]
[Filed 8/2/07, Notice 6/20/07—published 8/29/07, effective 10/3/07]
[Filed 3/5/08, Notice 12/5/07—published 3/26/08, effective 4/30/08]
[Filed 11/24/08, Notice 10/8/08—published 12/17/08, effective 1/21/09]
[Filed ARC 7634B (Notice ARC 7447B, IAB 12/31/08), IAB 3/11/09, effective 4/15/09]
[Filed ARC 7636B (Notice ARC 7448B, IAB 12/31/08), IAB 3/11/09, effective 4/15/09]
[Filed ARC 8169B (Notice ARC 7926B, IAB 7/1/09), IAB 9/23/09, effective 10/28/09]
[Filed ARC 8540B (Notice ARC 8267B, IAB 11/4/09), IAB 2/24/10, effective 4/1/10]
[Filed ARC 8539B (Notice ARC 8269B, IAB 11/4/09), IAB 2/24/10, effective 4/1/10]
[Filed ARC 8673B (Notice ARC 8380B, IAB 12/16/09), IAB 4/7/10, effective 6/1/10]
[Filed ARC 9910B (Notice ARC 9787B, IAB 10/5/11), IAB 12/14/11, effective 1/18/12]
[Filed ARC 0343C (Notice ARC 0155C, IAB 6/13/12), IAB 10/3/12, effective 11/7/12]
[Filed ARC 0501C (Notice ARC 0375C, IAB 10/3/12), IAB 12/12/12, effective 1/16/13]
[Filed ARC 1308C (Notice ARC 1040C, IAB 10/2/13), IAB 2/5/14, effective 3/12/14]
[Filed ARC 1961C (Notice ARC 1793C, IAB 12/10/14), IAB 4/15/15, effective 5/20/15]
[Filed ARC 2194C (Notice ARC 1979C, IAB 4/29/15), IAB 10/14/15, effective 11/18/15]
[Filed ARC 2196C (Notice ARC 2065C, IAB 7/22/15), IAB 10/14/15, effective 11/18/15]
[Filed ARC 2408C (Notice ARC 2285C, IAB 12/9/15), IAB 2/17/16, effective 3/23/16]
[Filed ARC 2414C (Notice ARC 2288C, IAB 12/9/15), IAB 2/17/16, effective 3/23/16]
[Filed ARC 3638C (Notice ARC 3330C, IAB 9/27/17), IAB 2/14/18, effective 3/21/18]
[Filed ARC 4189C (Notice ARC 4030C, IAB 9/26/18), IAB 12/19/18, effective 1/23/19]
[Filed ARC 4903C (Notice ARC 4693C, IAB 10/9/19), IAB 2/12/20, effective 3/18/20]
[Filed ARC 5007C (Notice ARC 4695C, IAB 10/9/19), IAB 3/25/20, effective 4/29/20]
[Filed ARC 5542C (Notice ARC 5373C, IAB 1/13/21), IAB 4/7/21, effective 5/12/21]
[Filed ARC 5913C (Notice ARC 5704C, IAB 6/16/21), IAB 9/22/21, effective 10/27/21]
[Filed ARC 6330C (Amended Notice ARC 6179C, IAB 2/9/22; Notice ARC 5834C, IAB 8/11/21),
  IAB 6/1/22, effective 7/6/22]

^ 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 purpose of this chapter is to establish the minimum standards of pharmacy practice for the activities identified in this chapter. The requirements of these rules shall apply to all Iowa-licensed pharmacists, other registered pharmacy personnel, and all pharmacies, including owners, providing the services addressed in this chapter to patients in Iowa. These rules are in addition to rules of the board relating to specific types of pharmacy licenses issued by the board unless otherwise indicated by rule.

[ARC 3858C, IAB 6/20/18, effective 7/25/18]

657—8.2(155A) Definitions. For the purpose of this chapter, the following definitions shall apply:

“Board” means the Iowa board of pharmacy.

“Confidential information” means information accessed or maintained by the pharmacy in the patient’s or the pharmacy’s records which contains personally identifiable information that could be used to identify the patient. “Confidential information” 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.

“DEA” means the United States Department of Justice, Drug Enforcement Administration.

“Pharmacy support person” or “PSP” means a person, other than a member of the professional pharmacy staff, registered with the board who may perform nontechnical duties assigned by a supervising pharmacist under the pharmacist’s responsibility and supervision.

“Professional pharmacy staff” shall mean the professional employees of the pharmacy, including pharmacists, pharmacy technicians, and pharmacist-interns.

This rule is intended to implement Iowa Code chapter 155A.

[ARC 3858C, IAB 6/20/18, effective 7/25/18]

657—8.3(155A) Responsible parties.

8.3(1) Pharmacist in charge. One professionally competent, legally qualified pharmacist in charge in each pharmacy shall work cooperatively with the pharmacy, by and through its owner or license holder, and with all staff pharmacists to ensure 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. A part-time pharmacist in charge has the same obligations and responsibilities as a full-time pharmacist in charge.

8.3(2) Pharmacy. Each pharmacy, by and through its owner or license holder, shall work cooperatively with the pharmacist in charge and with all staff pharmacists to ensure 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. The pharmacy, by and through its owner or license holder, shall be responsible for employing a professionally competent, legally qualified pharmacist in charge. The pharmacy, by and through its owner or license holder, may be held responsible for unethical conduct or practices of any of the pharmacy staff.

8.3(3) Pharmacy and pharmacist in charge. The pharmacist in charge and the pharmacy, by and through its owner or license holder, shall share responsibility for, at a minimum, the following:

a. Ensuring that the pharmacy employs an adequate number of qualified personnel commensurate with the size and scope of services provided by the pharmacy.

b. Ensuring the availability of any equipment and references necessary for the particular practice of pharmacy.

c. 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, including controlled substances, devices, and pharmacy records, and to support the operations of the pharmacy.
d. Ensuring that the license, registration, or certification of each professional pharmacy staff member and the registration of each pharmacy support person are maintained in current and active status.
e. Ensuring that the pharmacy provides adequate security to prevent unauthorized access and diversion.

8.3(4) Pharmacist in charge and staff pharmacists. The pharmacist in charge and staff pharmacists shall share responsibility for, at a minimum, the following:
   a. Ensuring that a pharmacist performs prospective drug use review as specified in rule 657—8.21(155A).
   b. Ensuring that a pharmacist or pharmacist-intern provides patient counseling as specified in rule 657—6.14(155A).
   c. Dispensing drugs to patients, including the packaging, preparation, compounding, and labeling functions performed by pharmacy personnel.
   d. Delivering drugs to the patient or the patient’s agent.
   e. Ensuring that patient medication records are maintained as specified in rule 657—6.13(155A).
   f. Training and supervising pharmacist-interns, pharmacy technicians, pharmacy support persons, and other pharmacy employees.
   g. Procuring and storing prescription drugs and devices and other products dispensed from the pharmacy.
   h. Distributing and disposing of drugs from the pharmacy.
   i. 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.
   j. 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.

8.3(5) Pharmacy, pharmacist in charge, and staff pharmacists. The pharmacy, by and through its owner or license holder, the pharmacist in charge, and all staff pharmacists shall share responsibility for, at a minimum, the following:
   a. Establishing and periodically reviewing (by the pharmacy and the pharmacist in charge), implementing (by the pharmacist in charge), and complying (by the pharmacist in charge and staff pharmacists) with policies and procedures for all operations of the pharmacy. The policies and procedures shall identify the frequency of review.
   b. Establishing and maintaining effective controls against the theft or diversion of prescription drugs, including controlled substances, and records for such drugs.
   c. Establishing (by the pharmacy and the pharmacist in charge), implementing (by the pharmacist in charge), and utilizing (by the pharmacist in charge and staff pharmacists) an ongoing, systematic program of continuous quality improvement for achieving performance enhancement and ensuring the quality of pharmaceutical services.

8.3(6) 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.

657—8.4(155A) Pharmacist identification and staff logs.

8.4(1) Display of pharmacist license. During any period a pharmacist is working in a pharmacy, each pharmacist shall display, in a position visible to the public, an original license to practice pharmacy in Iowa. 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) Registration maintained of pharmacy personnel. Each pharmacist-intern, pharmacy technician, and pharmacy support person shall maintain current registration with the board. The
registration certificate or a copy of the registration certificate shall be readily retrievable upon request of the board or its authorized agent.

8.4(3) Identification codes. A permanent log of the initials or identification code identifying by name each pharmacist, pharmacist-intern, pharmacy technician, and pharmacy support person 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, pharmacy technician, and pharmacy support person can be identified.

8.4(4) 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(5) Identification. While on duty, pharmacy personnel shall wear visible identification that clearly identifies the person by licensed or registered title and includes at least the person’s first name.

[ARC 8673B, IAB 4/7/10, effective 6/1/10; ARC 9409B, IAB 3/9/11, effective 4/13/11; ARC 3858C, IAB 6/20/18, effective 7/25/18]

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 pursuant to rule 657—8.3(155A). Space and equipment shall be available in an amount and type to provide secure, environmentally controlled storage of drugs.

8.5(1) Refrigeration. The pharmacy shall maintain one or more refrigeration units, unless the pharmacy does not stock refrigerated items. The pharmacy shall document verification that the temperature of the refrigerator is maintained within a range compatible with the proper storage of drugs requiring refrigeration. If the temperature is manually or visually verified, a record of minimum daily verification shall be maintained.

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. A 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—7.5(124,155A). To ensure that secure closure, 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.

8.5(4) Remodel or relocation—inspection. A pharmacy planning to remodel or relocate a licensed pharmacy department on or within the premises currently occupied by the pharmacy department, or a pharmacy intending to remodel or install a sterile compounding facility or equipment, shall provide written notification to the board at least 30 days prior to commencement of the remodel, pharmacy relocation, or sterile compounding installation. The board may require on-site inspection of the facility, equipment, or pharmacy department prior to or during the pharmacy’s remodel, relocation, or opening. The board may also require on-site inspection of a temporary pharmacy location intended to be utilized during the remodel, construction, or relocation of the pharmacy department.

8.5(5) 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 animal or service-animal-in-training as defined in Iowa Code section 216C.1A.
8.5(6) Light, ventilation, temperature, and humidity. The pharmacy shall be properly lighted and ventilated. 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 and the pharmacy, by and through its owner or license holder, shall share the responsibility for ensuring 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. Established policies and procedures shall include a method to calibrate and verify the accuracy of the counting device. The pharmacy shall, at least quarterly, verify the accuracy of the device and maintain a dated record identifying the individual who performed the quarterly verification.

8.5(9) Authorized collection program. A pharmacy that is registered with the DEA to administer an authorized collection program shall provide adequate space, equipment, and supplies for such collection program pursuant to 657—Chapter 10 and federal regulations for authorized collection programs, which can be found at www.deadiversion.usdoj.gov/drug_disposal/.

8.5(10) Health of personnel. The pharmacist in charge or supervising pharmacist shall ensure that pharmacy personnel experiencing any health condition that may have an adverse effect on drug products or may pose a health or safety risk to others be prohibited from working in the pharmacy until such health condition is sufficiently resolved. All personnel who normally assist the pharmacist shall 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.

8.5(11) Hazardous drugs. The pharmacy shall ensure pharmacy personnel and patients are adequately protected from unnecessary exposure to hazardous drugs. As of December 1, 2019, the pharmacy shall be in compliance with United States Pharmacopeia (USP) General Chapter 800 for handling hazardous drugs. A pharmacy engaged in compounding of hazardous drugs may request delayed compliance for specific requirements in USP General Chapter 800 pertaining to compounding, in accordance with rule 657—20.5(126,155A).

[ARC 8671B, IAB 4/7/10, effective 5/12/10; ARC 8503C, IAB 12/12/12, effective 1/16/13; ARC 1961C, IAB 4/15/15, effective 5/20/15; ARC 2408C, IAB 2/17/16, effective 3/23/16; ARC 3858C, IAB 6/20/18, effective 7/25/18; ARC 4267C, IAB 1/30/19, effective 3/6/19; ARC 4454C, IAB 5/22/19, effective 6/26/19; ARC 5348C, IAB 12/30/20, effective 2/3/21]

657—8.6(155A) Health of personnel. Rescinded ARC 3858C, IAB 6/20/18, effective 7/25/18.

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 an Iowa-licensed distributor or, on a limited basis, from another licensed pharmacy or licensed practitioner located in the United States.

8.7(2) Manner of storage. Drugs and devices shall be stored in a manner to protect their identity and integrity.

8.7(3) Storage temperatures. All drugs and devices shall be stored at the proper temperature as provided in manufacturer labeling. In the absence of a specific temperature range, the pharmacy shall refer to storage conditions identified in United States Pharmacopeia chapter 659.

8.7(4) Product recall. There shall be a system for removing from use, including unit dose, any drugs and devices subjected to a product recall.

8.7(5) Outdated 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.
8.7(6) Records. All pharmacies shall maintain supplier invoices of prescription drugs and controlled substances upon which the actual date of receipt of the drugs by the pharmacist or other responsible individual is clearly recorded. All pharmacies shall maintain supplier credit memos. Pharmacy records of invoices and credit memos shall be maintained for at least two years from the date of the record. If the original supplier invoice or credit memo is received electronically, hard-copy record is not required.

[ARC 3858C; IAB 6/20/18, effective 7/25/18]

657—8.8(124,155A) Out-of-date drugs or devices. Rescinded ARC 3858C, IAB 6/20/18, effective 7/25/18.

657—8.9(124,155A) Records storage. Every 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 record or the date of last activity on the record unless a longer retention period is specified for the particular record.

8.9(1) Records less than 12 months old. Records shall be maintained within the licensed pharmacy department for a minimum of 12 months, except as provided herein. Pharmacy records less than 12 months old may be stored in a secure storage area outside the licensed pharmacy department, including at a remote location, if the pharmacy has retained electronic copies of the records in the pharmacy that are immediately available and if the original records are available within 72 hours of a request by the board or its authorized agent, unless such remote storage is prohibited under federal law.

8.9(2) Records more than 12 months old. Records more than 12 months old may be maintained in a secure storage area outside the licensed pharmacy department, including at a remote location, if the records are retrievable within 72 hours of a request by the board or its authorized agent, unless such remote storage is prohibited under federal law.

[ARC 8539B, IAB 2/24/10, effective 4/1/10; ARC 3858C, IAB 6/20/18, effective 7/25/18; ARC 5007C, IAB 3/25/20, effective 4/29/20]

657—8.10 Reserved.

657—8.11(147,155A) Unethical conduct or practice. The provisions of this rule apply to licensed pharmacies, licensed pharmacists, registered pharmacy technicians, registered pharmacy support persons, and registered pharmacist-interns.

8.11(1) Misrepresentative deeds. A pharmacy, pharmacist, technician, support person, or pharmacist-intern 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) Unethical conduct.
   a. A pharmacy, pharmacist, pharmacist-intern, technician, or support person shall not participate in any of the following types of unethical conduct:
      (1) Any activity that negates a patient’s freedom of choice of pharmacy services.
      (2) Providing prescription blanks or forms bearing the pharmacy’s name or other means of identification to any person authorized to prescribe, except that a hospital may make prescription blanks or forms bearing the hospital pharmacy’s name or other means of identification available to hospital staff prescribers, emergency department prescribers, and prescribers granted hospital privileges for the prescribers’ use during practice at or in the hospital.
      (3) Any financial arrangement or transaction that would violate federal healthcare fraud, waste, and abuse laws, including but not limited to the Stark Law, the False Claims Act, and the Anti-Kickback Statute.
   b. A purchasing pharmacist or pharmacy shall not engage in any activity or include in any agreement with a selling pharmacist or pharmacy any provision that would prevent or prohibit the prior notifications required in subrule 8.35(7).

8.11(3) Discrimination. A pharmacy, pharmacist, pharmacist-intern, technician, or pharmacy support person shall not 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(4) Unprofessional conduct or behavior. A pharmacy, pharmacist, pharmacist-intern, technician, or pharmacy support person shall not engage in unprofessional behavior in connection with the practice of pharmacy. 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, theft, and the refusal to provide reasonable information or answer reasonable questions for the benefit of the patient.

[ARC 95268, IAB 6/1/11, effective 7/6/11; ARC 3858C, IAB 6/20/18, effective 7/25/18]

657—8.12(126,147) Advertising. Prescription drug information, including price, 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 shall 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 board.

[ARC 3858C, IAB 6/20/18, effective 7/25/18]

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 child and dependent adult abuse record checks 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 request that the department of public safety perform 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 request that the department of human services perform a child and dependent adult abuse record 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.

[ARC 3858C, IAB 6/20/18, effective 7/25/18]
657—8.14(155A) Training and utilization of registered pharmacy staff. Pursuant to rule 657—8.3(155A), all Iowa-licensed pharmacies utilizing pharmacist-interns, pharmacy technicians, or pharmacy support persons shall have written policies and procedures for the training and utilization of pharmacist-interns, pharmacy technicians, and pharmacy support persons appropriate to the practice of pharmacy at that licensed location. Training shall be documented and maintained by the pharmacy for at least two years from the last date of employment or internship and shall be available for inspection by the board or its authorized agent. [ARC 8673B, IAB 4/7/10, effective 6/1/10; ARC 1961C, IAB 4/15/15, effective 5/20/15; ARC 3858C, IAB 6/20/18, effective 7/25/18]

657—8.15(155A) Delivery of prescription drugs and devices. A prescription order may be delivered to a patient at any location licensed as a pharmacy. Alternatively, a pharmacy may use the mail, a common carrier, or personal delivery to deliver a prescription order to any location requested by the patient. A pharmacy that delivers prescription orders by one or more alternate methods shall have policies and procedures to ensure patient confidentiality, prescription order accountability, and proper storage of prescription orders during delivery. When counseling is required pursuant to rule 657—6.14(155A), oral counseling shall be provided before the prescription order is delivered to the patient. Documentation of the delivery of prescription orders shall be maintained by the pharmacy for at least two years from the date of delivery. The term “patient” includes the patient and the patient’s authorized representatives. [ARC 5007C, IAB 3/25/20, effective 4/29/20]

657—8.16(124,155A) Confidential information.

8.16(1) Release of confidential information. Confidential information 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(2) Exceptions. Nothing in this rule shall prohibit a pharmacist 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 or pursuant to subrule 8.35(7) when the pharmacy is discontinuing operations.

b. Providing the patient with a copy of a nonrefillable prescription that is clearly marked as a copy and not to be filled.

c. Providing drug therapy information to authorized practitioners for their patients.

d. Disclosing information necessary for the processing of third-party payer claims on behalf of the patient.

8.16(3) Record disposal. Disposal of any materials containing or including patient-specific or confidential information shall be conducted in a manner to preserve patient confidentiality. [ARC 9526B, IAB 6/1/11, effective 7/6/11; ARC 3858C, IAB 6/20/18, effective 7/25/18]

657—8.17 Reserved.

657—8.18(124,155A) Electronic prescription mandate. Beginning January 1, 2020, all prescriptions shall be transmitted electronically to a pharmacy pursuant to rule 657—21.6(124,155A), except as provided in rule 657—21.8(124,155A). A pharmacist who receives a written, oral, or facsimile prescription shall not be required to verify that the prescription is subject to an exception provided in
657—8.19(124,126,155A) Manner of issuance of a prescription drug or medication order. A prescription drug order or medication order that is issued prior to January 1, 2020, or that is exempt from the electronic prescription mandate pursuant to rule 657—21.8(124,155A) may be transmitted from a prescriber or a prescriber’s agent to a pharmacy in written form, orally including telephone voice communication, by facsimile transmission as provided in rule 657—21.7(124,155A), or by electronic transmission in accordance with applicable federal and state laws, rules, and regulations. 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—21.6(124,155A).

8.19(1) Requirements for a prescription. A valid prescription drug order shall be based on a valid patient-prescriber relationship except as provided in subrule 8.19(7) for epinephrine auto-injectors and in subrule 8.19(8) for opioid antagonists.

a. Written, electronic, or facsimile prescription. In addition to the electronic prescription application and pharmacy prescription application requirements of this rule, a written, electronic, or facsimile prescription shall include:

1. The date issued.
2. The name and address of the patient except as provided in subrule 8.19(7) for epinephrine auto-injectors, subrule 8.19(8) for opioid antagonists, or subrule 8.19(9) for expedited partner therapy.
3. The name, strength, and quantity of the drug or device prescribed.
4. The name and address of the prescriber and, if the prescription is for a controlled substance, the prescriber’s DEA registration number.
5. The written or electronic signature of the prescriber.

b. Written prescription. In addition to the requirements of paragraph 8.19(1) “a,” a written prescription shall be manually signed, with ink or indelible pencil, by the prescriber. The requirement for manual signature shall not apply when an electronically prepared and signed prescription for a noncontrolled substance is printed on security paper as provided in 657—paragraph 21.6(2) “b.”

c. Facsimile prescription. In addition to the requirements of paragraph 8.19(1) “a,” a prescription transmitted via facsimile shall include:

1. The identification number of the facsimile machine used to transmit the prescription to the pharmacy.
2. The time and date of transmission of the prescription.
3. The name, address, telephone number, and facsimile number of the pharmacy to which the prescription is being transmitted.
4. If the prescription is for a controlled substance and in compliance with DEA regulations, the manual signature of the prescriber.

d. Electronic prescription. In addition to the requirements of paragraph 8.19(1) “a,” an electronically prepared prescription for a controlled or noncontrolled prescription drug or device that is electronically transmitted to a pharmacy shall include the prescriber’s electronic signature, except as provided herein.

1. An electronically prepared prescription for a controlled substance that is printed out or faxed by the prescriber or the prescriber’s agent shall be manually signed by the prescriber.
2. The prescriber shall ensure that the electronic prescription application used to prepare and transmit the electronic prescription complies with applicable state and federal laws, rules, and regulations regarding electronic prescriptions.
3. The prescriber or the prescriber’s agent shall provide verbal verification of an electronic prescription upon the request of the pharmacy.
4. An electronic prescription for a noncontrolled prescription drug or device that is transmitted by an authorized agent shall not be required to contain the prescriber’s electronic signature.
8.19(2) 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, rules, and regulations. In exercising professional judgment, the prescriber and the pharmacist shall take adequate measures to guard against the diversion of prescription drugs and controlled substances through prescription forgeries.

8.19(3) Transmitting agent. The prescriber may authorize an agent to transmit to the pharmacy a prescription drug order or medication order orally, by facsimile transmission, or by electronic transmission provided that the first and last names and title of the transmitting agent are 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, except as provided in paragraph 8.19(1)“d.” If transmitted by the prescriber’s agent, the first and last names and title of the transmitting agent shall be included in the order. If the prescription is for a controlled substance and is written or printed from an electronic prescription application, the prescription shall be manually signed by the prescriber. An electronically prepared prescription shall not be electronically transmitted to the pharmacy if the prescription has been printed prior to the electronic transmission. An electronically prepared and electronically transmitted prescription that is printed following the electronic transmission shall be clearly labeled as a copy, not valid for dispensing.

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 professional pharmacy staff through oral communication, in writing, by facsimile transmission, or by electronic transmission initiated by or directed by the prescriber.

(1) If the transmission is completed by the prescriber’s agent and the first and last names and title of the transmitting agent are 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 8.19(3)“a.”

8.19(4) Receiving agent. Regardless of the means of transmission to a pharmacy, only professional pharmacy staff shall be authorized to receive a new prescription drug or medication order from a prescriber or the prescriber’s agent. A technician trainee may receive a refill or renewal order from a prescriber or the prescriber’s agent only if the technician’s supervising pharmacist has authorized that function.

8.19(5) Legitimate purpose. The pharmacy and professional pharmacy staff shall ensure that the prescription drug or medication order, regardless of the means of transmission, has been issued for a legitimate medical purpose by a prescriber acting in the usual course of the prescriber’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.

8.19(6) Refills. A refill is one or more dispensings of a prescription drug or device that result in the patient’s receipt of the quantity authorized by the prescriber for a single fill as indicated on the prescription drug order.

a. Noncontrolled prescription drug or device. 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.

b. Controlled substance. A prescription for a Schedule III, IV, or V controlled substance may authorize no more than 5 refills within 6 months following the date on which the prescription is issued.

8.19(7) Epinephrine auto-injector prescription issued to school or facility. A physician, an advanced registered nurse practitioner, or a physician assistant may issue a prescription for one or more epinephrine auto-injectors in the name of a facility as defined in Iowa Code subsection 135.185(1), a school district, or an accredited nonpublic school. The prescription shall comply with all requirements of subrule 8.19(1) as applicable to the form of the prescription except that the prescription shall be issued in the name and address of the facility, the school district, or the accredited nonpublic school in lieu of the name and
address of a patient. Provisions requiring a preexisting patient-prescriber relationship shall not apply to a prescription issued pursuant to this subrule.

a. The pharmacy’s patient profile and record of dispensing of a prescription issued pursuant to this subrule shall be maintained in the name of the facility, school district, or accredited nonpublic school to which the prescription was issued and the drug was dispensed.

b. The label affixed to an epinephrine auto-injector dispensed pursuant to this subrule shall identify the name of the facility, school district, or accredited nonpublic school to which the prescription is dispensed.

8.19(8) Opioid antagonist prescription issued to law enforcement, fire department, or service program. A physician, an advanced registered nurse practitioner, or a physician assistant may issue a prescription for one or more opioid antagonists in the name of a law enforcement agency, fire department, or service program pursuant to Iowa Code section 147A.18 and rule 657—39.7(135,147A). The prescription shall comply with all requirements of subrule 8.19(1) as applicable to the form of the prescription except that the prescription shall be issued in the name of the law enforcement agency, fire department, or service program in lieu of the name and address of a patient. Provisions requiring a preexisting patient-prescriber relationship shall not apply to a prescription issued pursuant to this subrule.

a. The pharmacy’s patient profile and record of dispensing of an opioid antagonist pursuant to this subrule shall be maintained in the name of the law enforcement agency, fire department, or service program to which the prescription was issued and the drug was dispensed.

b. The label affixed to an opioid antagonist dispensed pursuant to this subrule shall identify the name of the law enforcement agency, fire department, or service program to which the prescription is dispensed and shall be affixed such that the expiration date of the drug is not rendered illegible.

8.19(9) Expedited partner therapy. Pursuant to Iowa Code section 139A.41, a physician, physician assistant, or advanced registered nurse practitioner may issue a prescription to one or more sexual partners of an infected patient for an oral antibiotic intended to treat a sexually transmitted chlamydia or gonorrhea infection. The prescription shall comply with all requirements of subrule 8.19(1) as applicable to the form of the prescription except that the prescription shall not be required to contain the patient name and address. The prescription shall indicate the antibiotic is being issued for the purpose of expedited partner therapy. Provisions requiring a preexisting patient-prescriber relationship shall not apply to a prescription issued pursuant to this subrule.

[ARC 8171B, IAB 9/23/09, effective 10/28/09; ARC 9912B, IAB 12/14/11, effective 1/18/12; ARC 2414C, IAB 2/17/16, effective 3/23/16, ARC 2827C, IAB 11/23/16, effective 11/3/16; ARC 3858C, IAB 6/20/18, effective 7/25/18; ARC 4580C, IAB 7/31/19, effective 9/4/19; ARC 4903C, IAB 2/12/20, effective 3/18/20]

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, any remaining prescription refills may be dispensed at the discretion of the pharmacist for a suitable amount of time so that the patient can establish care with a new provider and a new order can be issued. In determining the duration of which prescriptions may be dispensed, the pharmacist shall consider the patient’s health care status and access to health care services.

[ARC 3639C, IAB 2/14/18, effective 3/21/18]

657—8.21(155A) Prospective drug use review.

8.21(1) 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:

a. Overutilization or underutilization;

b. Therapeutic duplication;

c. Drug-disease contraindications;

d. Drug-drug interactions;

e. Incorrect drug dosage or duration of drug treatment;
f. Drug-allergy interactions;
g. Clinical abuse/misuse;
h. 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. Information that shall be obtained for the purpose of drug utilization review includes, but is not limited to, a complete list of prescription and nonprescription medications being used by the patient, patient allergies, and patient disease states. The collection of patient information to be used for drug utilization review may be delegated to a pharmacy technician or pharmacist-intern. The review and assessment of patient records shall not be delegated to pharmacy technicians or pharmacy support persons but may be delegated to registered pharmacist-interns under the direct supervision of the pharmacist.

8.21(2) A pharmacist shall be exempt from the requirements of subrule 8.21(1) when dispensing a prescription issued to an unnamed patient for an oral antibiotic pursuant to Iowa Code section 139A.41. [ARC 3858C, IAB 6/20/18, effective 7/25/18; ARC 4903C, IAB 2/12/20, effective 3/18/20; ARC 5350C, IAB 12/30/20, effective 2/3/21]

657—8.22(155A) Notification of interchangeable biological product selection. Pursuant to Iowa Code section 155A.32, when a pharmacist substitutes a biological product that is an interchangeable biological product for the biological product prescribed, the pharmacist or pharmacist’s designee shall, within five business days of dispensing the biological product, communicate to the prescriber the name and manufacturer of the biological product dispensed unless the prescription information has been entered into an electronic record system, such as an electronic medical record, electronic prescribing system, pharmacy benefit management system, or a pharmacy record to which the prescriber has access. The manner of communication to the prescriber may be via telephone, facsimile, electronic transmission, or other prevailing means.

This rule is intended to implement Iowa Code section 155A.32. [ARC 3858C, IAB 6/20/18, effective 7/25/18]

657—8.23(124,155A) Individuals qualified to administer. Rescinded ARC 6076C, IAB 12/15/21, effective 1/19/22.

657—8.24(155A) Documented verification. The pharmacist shall provide, document, and retain a record of 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. In an approved technician product verification program, the checking technician shall provide, document, and retain a record of the final verification for the accuracy of the patient’s prescription or medication order prior to the delivery of the medication to the patient or the patient’s representative.

[ARC 3858C, IAB 6/20/18, effective 7/25/18; ARC 5007C, IAB 3/25/20, effective 4/29/20]

657—8.25 Reserved.

657—8.26(155A) Continuous quality improvement program. Pursuant to rule 657—8.3(155A), each pharmacy licensed to provide pharmaceutical services to patients in Iowa shall implement or participate in a continuous quality improvement program (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 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.** Pursuant to rule 657—8.3(155A), each pharmacy shall have 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 quarterly, 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 but no more than three days following discovery of the event 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.

[ARC 1961C, IAB 4/15/15, effective 5/20/15; ARC 2413C, IAB 2/17/16, effective 3/23/16; ARC 3858C, IAB 6/6/07, effective 7/1/07; ARC 3858C, IAB 6/20/18, effective 7/25/18]

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(135,147A) Opioid antagonist dispensing by pharmacists by standing order. Rescinded ARC 3858C, IAB 6/20/18, effective 7/25/18.

657—8.32(124,155A) Individuals qualified to administer. Rescinded ARC 3858C, IAB 6/20/18, effective 7/25/18.

657—8.33(155A) Vaccine administration by pharmacists. Rescinded ARC 3858C, IAB 6/20/18, effective 7/25/18.


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. The current pharmacy license certificate shall be displayed in a position visible to the public. The board may issue any of the following types of pharmacy licenses: a general pharmacy license, a hospital pharmacy license, a limited use pharmacy license, or a nonresident pharmacy license. Nonresident pharmacy license applicants shall comply with board rules regarding nonresident pharmacy practice except when a waiver has been granted. Applicants for general or hospital pharmacy practice shall comply with board rules regarding general or hospital pharmacy practice except when a waiver has been granted. Any pharmacy that dispenses controlled substances to Iowa residents must also register pursuant to 657—Chapter 10.

8.35(1) Limited use pharmacy license. A limited use pharmacy license may be issued for nuclear pharmacy practice, correctional facility pharmacy practice, veterinary pharmacy practice, telepharmacy practice, and other limited use practice settings. Applications for a limited use pharmacy license shall be considered on a case-by-case basis.

8.35(2) Application. Applicants for initial licensure, license renewal, license reactivation, or license changes pursuant to subrule 8.35(6) shall complete the relevant pharmacy license application and shall include all required information and attachments. All pharmacy license applications require submission of a nonrefundable $135 license fee plus applicable penalty fees. The application shall include the signature of the pharmacy owner’s authorized representative and shall require at a minimum the following:

a. Disclosure of pharmacy ownership information, including information about the pharmacy’s registered agent;

b. Identification and signature of the pharmacist in charge;

c. The identification of and average number of hours worked by all pharmacists, pharmacist-interns, pharmacy technicians, and pharmacy support persons working in the pharmacy;
d. Criminal and disciplinary history information;

e. Description of the scope of services provided by the pharmacy; and

f. If the pharmacy is located outside of Iowa, identification of a registered agent located in Iowa.

8.35(3) License renewal. A pharmacy license shall be renewed before January 1 of each year. An initial pharmacy license issued between November 1 and December 31 shall not require renewal until the following calendar year. The nonrefundable fee for a timely license renewal shall be $135.

   a. Delinquent license grace period. A pharmacy license renewal application that is postmarked or hand-delivered to the board after January 1 but prior to February 1 following expiration shall be considered delinquent and shall require the nonrefundable payment of the renewal fee plus a penalty fee of $135. A pharmacy that submits a completed license renewal application, application fee, and penalty fee postmarked or delivered to the board office by January 31 shall not be subject to disciplinary action for continuing to operate in the month of January.

   b. Delinquent license reactivation beyond grace period. If a pharmacy license is not renewed prior to the expiration of the one-month grace period identified in paragraph 8.35(3)“a,” the pharmacy may not operate or provide pharmacy services to patients in the state of Iowa until the license is reactivated. A pharmacy without a current license may apply for license reactivation by submitting an application for reactivation and a nonrefundable $540 reactivation fee. As part of the reactivation application, the pharmacy shall disclose the prescriptions dispensed and the services, if any, that were provided to Iowa patients while the license was delinquent. A pharmacy that continues to operate or provide pharmacy services in Iowa without a current license may be subject to disciplinary sanctions.

8.35(4) Inspection of pharmacy location.

   a. A new pharmacy location in Iowa shall require an on-site inspection by an authorized agent of the board. Application for a pharmacy license and other required registrations shall be submitted to the board at least 14 days prior to the anticipated inspection. Any deficiencies identified during the inspection shall be corrected and verified by an authorized agent of the board prior to the issuance of the pharmacy license. Prescription drugs, including controlled substances, may not be delivered to a new pharmacy location prior to the delivery of the pharmacy license and registration certificates.

   b. A pharmacy location in Iowa which is applying for a different license type than previously held may be subject to an inspection prior to the issuance of the new license.

8.35(5) Failure to complete licensure. An application for a pharmacy license, including any other required registration applications, will become null and void if the applicant fails to complete the licensure process within six months of acceptance 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 a satisfactory inspection by an agent of the board pursuant to this rule. When an applicant fails to timely complete the licensure process, fees submitted with applications will not be transferred or refunded. If the applicant intends to proceed with a pharmacy license, a new application and fee shall be required.

8.35(6) Pharmacy license changes. When a pharmacy changes its name, location, ownership, pharmacist in charge, or license type, a completed pharmacy license application with a nonrefundable $135 fee shall be submitted to the board pursuant to subrule 8.35(2). Upon receipt of the completed application and fee, the board shall issue an updated pharmacy license certificate, pending any necessary inspection pursuant to paragraph 8.35(4)“b,” unless the board identifies any ground for denial of the license. Any restrictions or disciplinary history associated with the previous pharmacy shall remain unchanged. A pharmacy wishing to disassociate itself from the previously licensed pharmacy restrictions or disciplinary history may petition the board for such disassociation. The burden is on the pharmacy to demonstrate that the current pharmacy is not associated with or responsible for the pharmacy as it previously existed. The old license certificate shall be returned to the board within ten days of receiving the updated license certificate.

   a. Name. A change of the name under which the pharmacy is doing business shall require submission of a pharmacy license application and appropriate fee prior to the change of name.

   b. Location. A change of pharmacy location shall require submission of a pharmacy license application and appropriate fee prior to the change of location. A pharmacy undergoing a change in
location is required to notify patients of the change in accordance with paragraph 8.35(7) “d.” A change of pharmacy location in Iowa may require an on-site inspection of the new location as provided in subrule 8.35(4).

c. **Ownership.** A change in ownership of a pharmacy shall require submission of a pharmacy license application and appropriate fee prior to the change in ownership. A change of ownership occurs when the owner listed on the pharmacy’s most recent application changes or when there is a change affecting the majority ownership interest of the owner listed on the pharmacy’s most recent pharmacy application. A pharmacy undergoing a change in ownership is required to notify the pharmacist in charge and patients of the change in accordance with subrule 8.35(7). A change of ownership effectively consists of closing a pharmacy and opening a new pharmacy.

d. **Pharmacist in charge.** In addition to the requirements of this paragraph, a change of pharmacist in charge for a nonresident pharmacy shall require registration of the new permanent pharmacist in charge if the pharmacist in charge is not currently registered by the board or licensed to practice pharmacy in Iowa.

(1) If a permanent pharmacist in charge has been identified by the time of the vacancy, a pharmacy license application identifying the new pharmacist in charge, along with the appropriate fee, shall be submitted to the board within ten days of the change.

(2) 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 shall be submitted to the board within ten days of the vacancy.

(3) If a permanent pharmacist in charge was not identified within ten days of the vacancy, the pharmacy shall, within 90 days of the vacancy, identify a permanent pharmacist in charge. A pharmacy license application identifying the permanent pharmacist in charge, along with appropriate fee, shall be submitted to the board within ten days of the appointment of a permanent pharmacist in charge. The pharmacy license application and the pharmacist in charge registration application, if needed, including appropriate fees, shall be received by the board within 90 days of the original vacancy of the permanent pharmacist in charge position.

(4) If a permanent pharmacist in charge is out of the pharmacy for an extended leave of absence of no more than 120 days, the pharmacy may identify an interim pharmacist in charge and provide notice to the board of the interim pharmacist’s appointment. Identification of an interim pharmacist in charge shall not require submission of a new pharmacy license application and shall not result in a permanent change in pharmacist in charge on the pharmacy license. If a permanent pharmacist in charge is out of the pharmacy for an extended leave of absence greater than 120 days, the pharmacy shall initiate a change of pharmacist in charge in accordance with this rule.

e. **License type.** A change in pharmacy license type shall require submission of a pharmacy license application and appropriate fee prior to the change in license type. A pharmacy changing license type shall notify the pharmacist in charge and patients of the change in accordance with subrule 8.35(7).

f. **License change application submission.** An application for license change shall be timely submitted pursuant to this subrule. A licensed pharmacy that has timely submitted an application for license change and fee may continue to service Iowa patients while the license change is pending final approval. An applicant who has submitted an application for license change after the required date of submission pursuant to this subrule but within 30 days of the required date of submission shall be assessed a nonrefundable late penalty fee of $135 in addition to the license fee. An applicant who has submitted an application for license change 31 days or later following the required date of submission pursuant to this subrule shall be assessed a nonrefundable late penalty fee of $540.

8.35(7) **Closing or sale of a pharmacy.** A closing pharmacy shall ensure that all pharmacy records are transferred to another licensed pharmacy that agrees to act as custodian of the records for at least two years. A pharmacy shall not execute a sale or closing of a pharmacy unless there exists an adequate period of time prior to the pharmacy’s closing for delivery of the notifications to the pharmacist in charge, the board, the DEA, and pharmacy patients as required by this subrule. The executive director may exempt a pharmacy from one or more of the notification requirements in the event of an unforeseeable closure.
a. **Pharmacist in charge notification.** At least 40 days prior to the effective date of the sale or closing of a pharmacy, the pharmacist in charge of the closing pharmacy shall be notified of the proposed sale or closing. Information regarding the pending sale or closure of the pharmacy may be kept confidential until public notifications, which are required 30 days prior to the pharmacy’s closing, are made. The pharmacist in charge of the closing pharmacy shall provide input and direction to the pharmacy owner regarding the responsibilities of the closing pharmacy, including the notifications, deadlines, and timelines established by this subrule. The pharmacist in charge of the purchasing or receiving pharmacy shall be notified of the pending transaction at least 30 days prior to the sale or closure of the pharmacy.

b. **Board and DEA notifications.** At least 30 days prior to the closing of a pharmacy, a written notice shall be sent to the board. Notification to the DEA shall be pursuant to federal regulation. Notification to the board shall include:

(1) The anticipated date of closing or transfer of prescription drugs or records.

(2) 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.

(3) The name, address, DEA registration number, Iowa pharmacy license number, and CSA registration number of the location at which records will be maintained.

c. **Terms of sale or purchase.** If the closing is due to the sale of the pharmacy, a copy of the sale or purchase agreement, not including information regarding the monetary terms of the transaction, shall be submitted to the board upon the request of the board. The agreement shall include a written assurance from the closing pharmacy to the purchasing pharmacy that the closing pharmacy has given or will be giving notice to its patients as required by this subrule.

d. **Patient notification.** At least 30 days prior to closing, a closing pharmacy shall make a reasonable effort to notify all patients who had a prescription filled by the closing pharmacy within the last 18 months that the pharmacy intends to close, including the anticipated closing date.

(1) Written notification shall identify the pharmacy that will be receiving the patient’s records. The notification shall advise patients that all patient records will be transferred to the identified pharmacy and that patients may contact the closing pharmacy to request the transfer of remaining refills to a pharmacy of the patient’s choice. The notification shall also advise patients that after the date of closing, patients may contact the pharmacy to which the records have been transferred.

(2) Written notification shall be delivered to each patient at the patient’s last address on file with the closing pharmacy by direct mail or personal delivery. A pharmacy shall not be required to provide written notice to more than one patient within the same household.

(3) Public notice shall be provided in a location and manner clearly visible to patients in the pharmacy pickup locations including drive-through prescription pickup lanes, on pharmacy or retail store entry and exit doors, and at pharmacy prescription counters.

e. **Patient communication by receiving pharmacy.** A pharmacy receiving the patient records of another pharmacy shall not contact the patients of the closing pharmacy until after the transfer of those patient records from the closing pharmacy to the receiving pharmacy and after the closure of the closing pharmacy.

f. **Prescription drug inventory.** 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 maintained in the records of the purchasing pharmacy for at least two years.

(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 rule 657—10.19(124).

(3) The inventory of all noncontrolled prescription drugs shall include the name, strength, dosage form, and quantity, which may be estimated.
(4) Controlled substances and prescription drugs 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 drugs.

g. Return of certificates and forms. The pharmacy license certificate and CSA registration certificate of the closing or selling pharmacy shall be returned to the board within ten days of closing or sale. The pharmacy shall be responsible for complying with federal DEA regulations for the cancellation and return of DEA forms and certificates.

h. Signs at closed pharmacy location. 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. Nothing in this paragraph shall prohibit the display of a public notice to patients, as required in paragraph 8.35(7) “d,” for a reasonable period not to exceed six months following the pharmacy’s closing.

8.35(8) Reporting discipline and criminal convictions. A pharmacy shall, no later than 30 days after the final action, provide written notice to the board of any discipline imposed by any licensing authority on any license or registration held by the pharmacy. Discipline may include, but is not limited to, fine or civil penalty, citation or reprimand, probationary period, suspension, revocation, or voluntary surrender. A pharmacy shall, no later than 30 days after a conviction, provide written notice to the board of any criminal conviction of the pharmacy or of any pharmacy owner when that conviction is related to prescription drugs or to the operation of the pharmacy. The term criminal conviction includes instances when the judgment of conviction or sentence is deferred.

8.35(9) License verification fee. The board may require a nonrefundable fee of $15 for completion of a request for written license verification of any pharmacy license.

[ARC 8673B, IAB 4/7/10, effective 6/1/10; ARC 9526B, IAB 6/1/11, effective 7/6/11 (See Delay note at end of chapter); ARC 9693B, IAB 9/7/11, effective 8/11/11; ARC 0504C, IAB 12/12/12, effective 1/16/13; ARC 1962C, IAB 4/15/15, effective 5/20/15; ARC 3236C, IAB 8/2/17, effective 9/6/17; ARC 3345C, IAB 9/27/17, effective 11/1/17; ARC 3858C, IAB 6/20/18, effective 7/25/18; ARC 4268C, IAB 1/30/19, effective 3/6/19; ARC 5007C, IAB 3/25/20, effective 4/29/20; ARC 6073C, IAB 12/15/21, effective 1/19/22]

657—8.36 to 8.39 Reserved.

657—8.40(155A.84GA, ch63) Pharmacy pilot or demonstration research projects. Rescinded ARC 3858C, IAB 6/20/18, effective 7/25/18.

These rules are intended to implement Iowa Code sections 124.101, 124.301, 124.306, 124.308, 126.10, 126.11, 126.16, 135C.33, 147.7, 147.55, 147.72, 147.74, 147.76, 155A.2 through 155A.4, 155A.6, 155A.10, 155A.12 through 155A.15, 155A.19, 155A.20, 155A.27 through 155A.29, 155A.31 through 155A.35, and 155A.41.

[Filed 4/11/68; amended 11/14/73]
[Filed 11/24/76, Notice 10/20/76—published 12/15/76, effective 1/19/77]
[Filed 11/9/77, Notice 10/5/77—published 11/30/77, effective 1/4/78]
[Filed emergency 12/9/77—published 12/28/77, effective 12/9/77]
[Filed 10/20/78, Notice 8/9/78—published 11/15/78, effective 1/9/79]
[Filed 12/2/78, Notice 11/15/78—published 1/10/79, effective 2/14/79]
[Filed 12/21/78, Notice 11/15/78—published 1/10/79, effective 2/14/79]
[Filed 12/7/79, Notice 10/3/79—published 12/26/79, effective 1/30/80]
[Filed emergency 4/22/80—published 5/14/80, effective 4/22/80]
[Filed 12/1/80, Notice 10/15/80—published 12/24/80, effective 1/28/81]
[Filed 2/12/81, Notice 12/24/80—published 3/4/81, effective 4/8/81]
[Filed 5/27/81, Notice 4/1/81—published 6/24/81, effective 7/29/81]
[Filed emergency 7/28/81—published 8/19/81, effective 8/1/81]
[Filed emergency 9/14/81—published 9/30/81, effective 9/30/81]
[Filed 7/28/82, Notice 3/17/82—published 8/18/82, effective 9/22/82]
[Filed emergency 8/26/82—published 9/15/82, effective 9/22/82]
[Filed 9/10/82, Notice 6/9/82—published 9/29/82, effective 11/8/82]
[Filed emergency 10/6/82—published 10/27/82, effective 10/27/82]◊
[Filed emergency 12/2/82—published 12/22/82, effective 12/22/82]
[Filed 11/18/83, Notice 8/3/83—published 12/7/83, effective 1/11/84]
[Filed 1/13/84, Notice 11/9/83—published 2/1/84, effective 3/7/84]
[Filed 6/22/84, Notice 4/11/84—published 7/18/84, effective 8/22/84]
[Filed emergency 7/13/84—published 8/1/84, effective 7/13/84]
[Filed 9/21/84, Notice 7/18/84—published 10/10/84, effective 11/14/84]
[Filed 2/22/85, Notice 11/21/84—published 3/13/85, effective 4/18/85]
[Filed emergency 6/18/85—published 7/3/85, effective 7/1/85]
[Filed 8/30/85, Notice 7/3/85—published 9/25/85, effective 10/30/85]◊
[Filed 11/27/85, Notice 8/28/85—published 12/18/85, effective 1/22/86]
[Filed 9/19/86, Notice 6/4/86—published 10/8/86, effective 11/12/86]
[Filed 1/28/87, Notice 11/19/86—published 2/25/87, effective 4/1/87]
[Filed emergency 1/21/88—published 2/10/88, effective 1/22/88]
[Filed 1/21/88, Notice 11/4/87—published 2/10/88, effective 3/16/88]
[Filed 11/17/88, Notice 8/24/88—published 12/14/88, effective 1/18/89]◊
[Filed emergency 5/16/89—published 6/14/89, effective 5/17/89]
[Filed 12/26/89, Notice 10/4/89—published 1/24/90, effective 2/28/90]
[Filed 3/19/90, Notice 1/10/90—published 4/18/90, effective 5/23/90]
[Filed 8/31/90, Notice 6/13/90—published 9/19/90, effective 10/24/90]
[Filed 1/29/91, Notice 6/13/90—published 2/20/91, effective 3/27/91]
[Filed 1/29/91, Notice 9/19/90—published 2/20/91, effective 3/27/91]
[Filed 4/26/91, Notice 2/20/91—published 5/15/91, effective 6/19/91]
[Filed emergency 5/10/91—published 5/29/91, effective 5/10/91]
[Filed 7/30/91, Notice 5/29/91—published 8/21/91, effective 9/25/91]
[Filed 1/21/92, Notice 10/16/91—published 2/19/92, effective 3/25/92]
[Filed 3/12/92, Notice 1/8/92—published 4/1/92, effective 5/6/92]
[Filed 5/21/92, Notice 4/1/92—published 6/10/92, effective 7/15/92]
[Filed 10/22/92, Notice 9/2/92—published 11/11/92, effective 1/1/93]
[Filed 9/23/93, Notice 5/26/93—published 10/13/93, effective 11/17/93]
[Filed 3/22/95, Notice 11/9/94—published 4/12/95, effective 5/31/95]
[Filed 10/6/95, Notices 6/7/95, 8/16/95—published 10/25/95, effective 1/1/96]
[Filed emergency 12/14/95—published 1/3/96, effective 1/1/96]
[Filed 12/10/96, Notice 8/28/96—published 1/1/97, effective 2/5/97]
[Filed 2/27/97, Notice 8/28/96—published 3/26/97, effective 4/30/97]
[Filed 2/27/97, Notice 1/1/97—published 3/26/97, effective 4/30/97]
[Filed 6/23/97, Notice 3/26/97—published 7/16/97, effective 8/20/97]
[Filed 11/19/97, Notice 10/8/97—published 12/17/97, effective 1/21/98]
[Filed 7/31/98, Notice 5/20/98—published 8/26/98, effective 10/15/98]
[Filed 11/23/99, Notice 6/2/99—published 12/15/99, effective 1/19/00]
[Filed 2/18/00, Notice 12/15/99—published 3/22/00, effective 4/26/00]
[Filed 11/9/00, Notice 4/19/00—published 11/29/00, effective 1/3/01]
[Filed 8/14/02, Notice 6/12/02—published 9/4/02, effective 10/9/02]
[Filed 3/11/04, Notice 8/6/03—published 3/31/04, effective 5/5/04]
[Filed emergency 7/16/04 after Notice 6/9/04—published 8/4/04, effective 7/16/04]
[Filed 10/22/04, Notice 3/31/04—published 11/10/04, effective 12/15/04]
[Filed 10/22/04, Notice 5/12/04—published 11/10/04, effective 12/15/04]
[Filed 6/2/05, Notice 3/16/05—published 6/22/05, effective 7/27/05]
[Filed emergency 6/30/05 after Notice 5/11/05—published 7/20/05, effective 7/1/05]
[Filed 3/22/06, Notice 1/18/06—published 4/12/06, effective 5/17/06]
[Filed 5/17/06, Notice 4/12/06—published 6/7/06, effective 7/12/06]
[Filed 5/17/06, Notice 2/15/06—published 6/7/06, effective 10/1/06]
[Filed 11/30/06, Notice 9/27/06—published 12/20/06, effective 1/24/07]
[Filed 2/7/07, Notice 10/25/06—published 2/28/07, effective 4/4/07]
[Filed 5/14/07, Notice 2/28/07—published 6/6/07, effective 7/11/07)\]
[Filed 8/3/07, Notice 5/9/07—published 8/29/07, effective 10/3/07]
[Filed 8/3/07, Notice 6/20/07—published 8/29/07, effective 10/3/07]

[Filed emergency 11/13/07 after Notice 8/29/07—published 12/5/07, effective 11/13/07]
[Filed 11/13/07, Notice 8/29/07—published 12/5/07, effective 1/9/08]
[Filed 5/19/08, Notice 3/26/08—published 6/18/08, effective 7/23/08]
[Filed 9/5/08, Notice 7/2/08—published 9/24/08, effective 10/29/08]

[Filed ARC 7636B (Notice ARC 7448B, IAB 12/31/08, IAB 3/11/09, effective 4/15/09)]
[Filed ARC 8171B (Notice ARC 7910B, IAB 7/1/09, IAB 9/23/09, effective 10/28/09)]
[Filed ARC 8539B (Notice ARC 8269B, IAB 11/4/09, IAB 2/24/10, effective 4/1/10)]
[Filed ARC 8673B (Notice ARC 8380B, IAB 12/16/09, IAB 4/7/10, effective 6/1/10)]
[Filed ARC 8671B (Notice ARC 8414B, IAB 12/30/09, IAB 4/7/10, effective 5/12/10)]
[Filed ARC 9409B (Notice ARC 9194B, IAB 11/3/10, IAB 3/9/11, effective 4/13/11)]
[Filed ARC 9526B (Notice ARC 9295B, IAB 12/29/10, IAB 6/1/11, effective 7/6/11)\]
[Editorial change: IAC Supplement 6/29/11]

[Filed Emergency ARC 9693B, IAB 9/7/11, effective 8/11/11]
[Filed ARC 9912B (Notice ARC 9671B, IAB 8/10/11, IAB 12/14/11, effective 1/18/12)]
[Filed ARC 0393C (Notice ARC 0256C, IAB 8/8/12, IAB 10/17/12, effective 11/21/12)]
[Filed ARC 0503C (Notice ARC 0371C, IAB 10/3/12, IAB 12/12/12, effective 1/16/13)]
[Filed ARC 0504C (Notice ARC 0351C, IAB 10/3/12, IAB 12/12/12, effective 1/16/13)]

[Filed Emergency After Notice ARC 1030C (Notice ARC 0883C, IAB 7/24/13, IAB 9/18/13, effective 9/1/13)]
[Filed ARC 1032C (Notice ARC 0882C, IAB 7/24/13, IAB 9/18/13, effective 10/23/13)]
[Filed ARC 1576C (Notice ARC 1411C, IAB 4/2/14, IAB 8/20/14, effective 9/24/14)]
[Filed ARC 1786C (Notice ARC 1652C, IAB 10/1/14, IAB 12/10/14, effective 1/14/15)]
[Filed ARC 1961C (Notice ARC 1793C, IAB 12/10/14, IAB 4/15/15, effective 5/20/15)]
[Filed ARC 1962C (Notice ARC 1792C, IAB 12/10/14, IAB 4/15/15, effective 5/20/15)]
[Filed ARC 2408C (Notice ARC 2285C, IAB 12/9/15, IAB 2/17/16, effective 3/23/16)]
[Filed ARC 2413C (Notice ARC 2307C, IAB 12/9/15, IAB 2/17/16, effective 3/23/16)]
[Filed ARC 2414C (Notice ARC 2288C, IAB 12/9/15, IAB 2/17/16, effective 3/23/16)]

[Filed Emergency After Notice ARC 2827C (Notice ARC 2721C, IAB 9/28/16, IAB 11/23/16, effective 11/3/16)]
[Filed ARC 3236C (Notice ARC 3037C, IAB 4/26/17, IAB 8/2/17, effective 9/6/17)]
[Filed ARC 3345C (Notice ARC 3136C, IAB 6/21/17, IAB 9/27/17, effective 11/1/17)]
[Filed ARC 3639C (Notice ARC 3371C, IAB 10/11/17, IAB 2/14/18, effective 3/21/18)]
[Filed ARC 3858C (Notice ARC 3509C, IAB 12/20/17, IAB 6/20/18, effective 7/25/18)]
[Filed ARC 4267C (Notice ARC 4029C, IAB 9/26/18, IAB 1/30/19, effective 3/6/19)]
[Filed ARC 4268C (Notice ARC 4092C, IAB 10/24/18, IAB 1/30/19, effective 3/6/19)]
[Filed ARC 4454C (Amended Notice ARC 4172C, IAB 12/19/18; Notice ARC 3978C, IAB 8/29/18), IAB 5/22/19, effective 6/26/19]
[Filed ARC 4580C (Notice ARC 4386C, IAB 4/10/19), IAB 7/31/19, effective 9/4/19]
[Filed ARC 4903C (Notice ARC 4693C, IAB 10/9/19), IAB 2/12/20, effective 3/18/20]
[Filed ARC 5007C (Notice ARC 4695C, IAB 10/9/19), IAB 3/25/20, effective 4/29/20]
[Filed ARC 5348C (Notice ARC 5113C, IAB 7/29/20), IAB 12/30/20, effective 2/3/21]
[Filed ARC 5350C (Notice ARC 5115C, IAB 7/29/20), IAB 12/30/20, effective 2/3/21]
[Filed ARC 6073C (Notice ARC 5835C, IAB 8/11/21), IAB 12/15/21, effective 1/19/22]
[Filed ARC 6076C (Notice ARC 5833C, IAB 8/11/21), IAB 12/15/21, effective 1/19/22]
[Filed ARC 6330C (Amended Notice ARC 6179C, IAB 2/9/22; Notice ARC 5834C, IAB 8/11/21), IAB 6/1/22, effective 7/6/22]

◊ Two or more ARCs

1 July 6, 2011, effective date of 8.35(7) delayed 70 days by the Administrative Rules Review Committee at its meeting held June 14, 2011.
CHAPTER 10
CONTROLLED SUBSTANCES
[Prior to 2/10/88, see Pharmacy Examiners[620] Ch 8]

657—10.1(124) Purpose and scope. This chapter establishes the minimum standards for any activity that involves controlled substances. Any person or business that manufactures; distributes; dispenses; prescribes; conducts instructional activities, research, or chemical analysis with; or imports or exports controlled substances listed in Schedules I through V of Iowa Code chapter 124 in or into the state of Iowa, or that proposes to engage in such activities, shall obtain and maintain a registration issued by the board unless exempt from registration pursuant to rule 657—10.8(124). A person or business required to be registered shall not engage in any activity for which registration is required until the application for registration is granted and the board has issued a certificate of registration to such person or business. A registration is not transferable to any person or business. 
[ARC 3345C, IAB 9/27/17, effective 11/1/17]

657—10.2(124) Definitions. For the purposes of this chapter, the following definitions shall apply:

“Authorized collection program” means a program administered by a registrant that has modified its registration with DEA to collect controlled substances for the purpose of disposal. Federal regulations for such programs can be found at www.deadiversion.usdoj.gov/drug_disposal/. Modification to the registrant’s Iowa controlled substances Act registration shall not be required.

“Board” means the Iowa board of pharmacy.

“CSA” means the Iowa uniform controlled substances Act.

“CSA registration” or “registration” means the registration issued by the board pursuant to the CSA that signifies the registrant’s authorization to engage in registered activities with controlled substances.

“DEA” means the United States Department of Justice, Drug Enforcement Administration.

“Individual practitioner” means a physician or surgeon (M.D.), osteopathic physician or surgeon (D.O.), dentist (D.D.S. or D.M.D.), doctor of veterinary medicine (D.V.M.), podiatric physician (D.P.M.), optometrist (O.D.), physician assistant (P.A.), resident physician, advanced registered nurse practitioner (A.R.N.P.), or prescribing psychologist.

“Prescription monitoring program,” “PMP,” or “program” means the program established pursuant to 657—Chapter 37 for the collection and maintenance of PMP information and for the provision of PMP information to authorized individuals.
[ARC 3345C, IAB 9/27/17, effective 11/1/17; ARC 4455C, IAB 5/22/19, effective 6/26/19]

657—10.3(124) Who shall register. The following persons or businesses shall register on forms provided by the board:

1. Manufacturers, distributors, importers, and exporters located in Iowa. Effective January 1, 2018, nonresident manufacturers, distributors, importers, and exporters distributing controlled substances into Iowa.

2. Reverse distributors located in Iowa. Effective January 1, 2018, nonresident reverse distributors engaging in the transfer of controlled substances with registrants located in Iowa.

3. Individual practitioners located in Iowa who are administering, dispensing, or prescribing controlled substances and individual practitioners located outside of Iowa who are dispensing or prescribing controlled substances via telehealth services to patients located in Iowa.

4. Pharmacies located in Iowa that are dispensing controlled substances. Effective January 1, 2018, pharmacies located outside of Iowa that are delivering controlled substances to patients located in Iowa.

5. Hospitals located in Iowa that are administering or dispensing controlled substances. Effective January 1, 2018, hospitals located outside of Iowa that are administering or dispensing controlled substances to patients located in Iowa.

6. Emergency medical service programs that are administering controlled substances to patients located in Iowa.

7. Care facilities that are located in Iowa.
8. Researchers, analytical laboratories, and teaching institutions that are located in Iowa.
9. Animal shelters and dog training facilities that are located in Iowa.

[ARC 3345C, IAB 9/27/17, effective 11/1/17]

657—10.4 Reserved.

657—10.5(124) Application. Applicants for initial registration, registration renewal pursuant to rule 657—10.6(124), or modifications pursuant to rule 657—10.9(124) shall complete the appropriate application and shall include all required information and attachments.

10.5(1) Signature requirements. Each application, attachment, or other document filed as part of an application shall be signed by the applicant as follows:

a. If the applicant is an individual practitioner, the practitioner shall sign the application and supporting documents.

b. If the applicant is a business, the application and supporting documents shall be signed by the person ultimately responsible for the security and maintenance of controlled substances at the registered location. If the applicant is a pharmacy, the responsible individual shall be the pharmacist in charge, unless the applicant petitions the board for an alternate responsible individual.

10.5(2) Prescribing practitioner PMP registration required. A prescribing practitioner, except for a licensed veterinarian, shall register for the PMP at the same time the prescribing practitioner applies for registration.

10.5(3) Registration fee exemptions. The registration fee is waived for federal, state, and local law enforcement agencies and for the following federal and state institutions: hospitals, health care or teaching institutions, and analytical laboratories authorized to possess, manufacture, distribute, and dispense controlled substances in the course of official duties. In order to enable law enforcement agency laboratories to obtain and transfer controlled substances for use as standards in chemical analysis, such laboratories shall maintain a registration to conduct chemical analysis (analytical laboratory). Such laboratories shall be exempt from any registration fee. Exemption from payment of any fees as provided in this subrule does not relieve the entity of registration or of any other requirements or duties prescribed by law.

10.5(4) Fees. Each application shall include a nonrefundable registration fee, except as provided in subrule 10.5(3), of $90 per biennium, which may be prorated to the expiration date of the applicant’s underlying professional license or other board license if applicable, and may include a nonrefundable surcharge of not more than 25 percent of the registration fee for deposit into the program fund.

[ARC 3345C, IAB 9/27/17, effective 11/1/17; ARC 4455C, IAB 5/22/19, effective 6/26/19]

657—10.6(124) Registration renewal. Each registration shall be renewed prior to its expiration. A registrant may renew its registration up to 60 days prior to the registration expiration. The nonrefundable fee for registration renewal shall be $90 per biennium and may include a nonrefundable surcharge of not more than 25 percent of the registration fee for deposit into the program fund.

10.6(1) Delinquent registration grace period. A registration renewal application that is submitted after expiration but within 30 days following expiration shall be considered delinquent and shall require the nonrefundable payment of the application fee plus a nonrefundable late penalty fee of $90 and may require payment of a surcharge of not more than 25 percent of the applicable fees for deposit into the program fund. A registrant that submits a completed registration renewal application, nonrefundable late application fee, and nonrefundable late penalty fee within 30 days following expiration shall not be subject to disciplinary action for continuing to operate in the 30 days following expiration.

10.6(2) Delinquent registration reactivation beyond grace period. If a registration renewal application is not postmarked or hand-delivered to the board office within 30 days following the registration’s expiration date, the registrant may not conduct operations that involve controlled substances until the registrant reactivates the registration. A registrant may apply for reactivation by submitting a registration application for reactivation. The nonrefundable fee for reactivation shall be $360 and may include a nonrefundable surcharge of not more than 25 percent of the applicable fee for deposit into the program fund. As part of the reactivation application, the registrant shall disclose
the activities conducted with respect to controlled substances while the registration was expired. A registrant that continues to conduct activities with respect to controlled substances without an active registration may be subject to disciplinary sanctions.

[ARC 3345C, IAB 9/27/17, effective 11/1/17; ARC 4455C, IAB 5/22/19, effective 6/26/19]

657—10.7(124) Separate registration for independent activities; coincident activities. The following activities are deemed to be independent of each other and shall require separate registration. Any person or business engaged in more than one of these activities shall be required to separately register for each independent activity, provided, however, that registration in an independent activity shall authorize the registrant to engage in activities identified coincident with that independent activity.

10.7(1) Manufacturing controlled substances. A person or business registered to manufacture controlled substances in Schedules I through V may distribute any substances for which registration to manufacture was issued. A person or business registered to manufacture controlled substances in Schedules II through V may conduct chemical analysis and preclinical research, including quality control analysis, with any substances listed in those schedules for which the person or business is registered to manufacture.

10.7(2) Distributing controlled substances. This independent activity includes the delivery, other than by administering or dispensing, of controlled substances listed in Schedules I through V. No coincident activities are authorized.

10.7(3) Dispensing, administering, prescribing, or instructing with controlled substances. These independent activities include, but are not limited to, prescribing, administering, and dispensing by individual practitioners; dispensing by pharmacies and hospitals; and conducting instructional activities with controlled substances listed in Schedules II through V. A person or business registered for these independent activities may conduct research and instructional activities with those substances for which the person or business is registered to the extent authorized under state law. If an entity that engages in the distribution, administration, dispensing, or storing of controlled substances maintains multiple licenses, such as a hospital that has both inpatient and outpatient pharmacies, a separate registration shall be maintained for each license.

10.7(4) Conducting research with controlled substances listed in Schedule I. A researcher may manufacture or import the substances for which registration was issued provided that such manufacture or import is permitted under the federal DEA registration. A researcher may distribute the substances for which registration was issued to persons or businesses registered or authorized to conduct research with that class of substances or registered or authorized to conduct chemical analysis with controlled substances.

10.7(5) Conducting research with controlled substances listed in Schedules II through V. A researcher may conduct chemical analysis with controlled substances in those schedules for which registration was issued, may manufacture such substances if and to the extent such manufacture is permitted under the federal DEA registration, and may import such substances for research purposes. A researcher may distribute controlled substances in those schedules for which registration was issued to persons registered or authorized to conduct chemical analysis, instructional activities, or research with such substances, and to persons exempt from registration pursuant to Iowa Code section 124.302(3), and may conduct instructional activities with controlled substances.

10.7(6) Conducting chemical analysis with controlled substances. A person or business registered to conduct chemical analysis with controlled substances listed in Schedules I through V may manufacture and import controlled substances for analytical or instructional activities; may distribute such substances to persons registered or authorized to conduct chemical analysis, instructional activities, or research with such substances and to persons exempt from registration pursuant to Iowa Code section 124.302(3); may export such substances to persons in other countries performing chemical analysis or enforcing laws relating to controlled substances or drugs in those countries; and may conduct instructional activities with controlled substances.
10.7(7) Importing or exporting controlled substances. A person or business registered to import controlled substances listed in Schedules I through V may distribute any substances for which such registration was issued.
[ARC 3345C, IAB 9/27/17, effective 11/1/17]

657—10.8(124) Separate registrations for separate locations; exemption from registration. A separate registration is required for each principal place of business or professional practice location where controlled substances are manufactured, distributed, imported, exported, dispensed, stored, or collected for the purpose of disposal unless the person or business is exempt from registration pursuant to Iowa Code section 124.302(3), this rule, or federal regulations.

10.8(1) Warehouse. A warehouse where controlled substances are stored by or on behalf of a registered person or business shall be exempt from registration except as follows:

a. Registration of the warehouse shall be required if such controlled substances are distributed directly from that warehouse to registered locations other than the registered location from which the substances were delivered to the warehouse.

b. Registration of the warehouse shall be required if such controlled substances are distributed directly from that warehouse to persons exempt from registration pursuant to Iowa Code section 124.302(3).

10.8(2) Sales office. An office used by agents of a registrant where sales of controlled substances are solicited, made, or supervised shall be exempt from registration. Such office shall not contain controlled substances, except substances used for display purposes or for lawful distribution as samples, and shall not serve as a distribution point for filling sales orders.

10.8(3) Prescriber’s office. An office used by a prescriber who is registered at another location and where controlled substances are prescribed but where no supplies of controlled substances are maintained shall be exempt from registration. However, a prescriber who practices at more than one office location where controlled substances are administered or otherwise dispensed as a regular part of the prescriber’s practice shall register at each location wherein the prescriber maintains supplies of controlled substances.

10.8(4) Prescriber in hospital. A prescriber who is registered at another location and who treats patients and may order the administration of controlled substances in a hospital other than the prescriber’s registered practice location shall not be required to obtain a separate registration at the location of the hospital.

10.8(5) Affiliated interns, residents, or foreign physicians. An individual practitioner who is an intern, resident, or foreign physician may dispense and prescribe controlled substances under the registration of the hospital or other institution which is registered and by whom the practitioner is employed provided that:

a. The hospital or other institution by which the individual practitioner is employed has determined that the practitioner is permitted to dispense or prescribe drugs by the appropriate licensing board.

b. Such individual practitioner is acting only in the scope of employment or practice in the hospital, institution, internship program, or residency program.

c. The hospital or other institution authorizes the intern, resident, or foreign physician to dispense or prescribe under the hospital registration and designates a specific internal code number, letters, or combination thereof which shall be appended to the institution’s DEA registration number, preceded by a hyphen (e.g., AP1234567-10 or AP1234567-12).

d. The hospital or institution maintains a current list of internal code numbers identifying the corresponding individual practitioner, available for the purpose of verifying the authority of the prescribing individual practitioner.
[ARC 3345C, IAB 9/27/17, effective 11/1/17]

657—10.9(124) Modification or termination of registration. A registered individual or business shall apply to modify a current registration as provided by this rule. When submission of an application and fee is required, such application and fee shall be timely submitted pursuant to rule 657—10.5(124). A registrant which has timely submitted an application for registration modification and fee may continue to service Iowa patients while the registration modification is pending final approval. A registrant which
has submitted an application for registration modification after the required date of submission pursuant to this rule but within 30 days of the required date of submission shall be assessed a nonrefundable late penalty fee of $90 in addition to the application fee. A registrant which has submitted an application for registration modification 31 days or later following the required date of submission pursuant to this rule shall be assessed a nonrefundable late penalty fee of $360.

10.9(1) Change of substances authorized. Any registrant shall apply to modify the substances authorized by the registration by submitting a written request to the board. The request shall include the registrant’s name, address, telephone number, registration number, and the substances or schedules to be added to or removed from the registration and shall be signed by the same person who signed the most recent application for registration or registration renewal. No fee shall be required for the modification.

10.9(2) Change of address of registered location.
   a. Individual practitioner or researcher. An entity registered as an individual practitioner or researcher shall apply to change the address of the registered location by submitting a written request to the board. The request shall include the registrant’s name, current address, new address, telephone number, effective date of the address change, and registration number, and shall be signed by the registered individual practitioner or the same person who signed the most recent application for registration or registration renewal. No fee shall be required for the modification.
   b. Pharmacy, hospital, care facility; service program, manufacturer; distributor; analytical laboratory, teaching institution, importer; or exporter. An entity registered as a pharmacy, hospital, care facility, service program, manufacturer, distributor, analytical laboratory, teaching institution, importer, or exporter shall apply to change the address of the registered location by submitting a completed application and fee for registration as provided in rule 657—10.5(124). The registrant shall submit a completed application and fee for change in registration simultaneously with any other required application pursuant to the board’s rules for the applicable license or registration. In the absence of a simultaneous license or registration application, the registrant shall submit a completed application and fee for change in registration no less than 30 days in advance of the change of address.

10.9(3) Change of registrant’s name.
   a. Individual practitioner or researcher. An entity registered as an individual practitioner or researcher shall apply to change the registrant’s name by submitting a written request to the board. The request shall include the registrant’s current name, new name, address, telephone number, effective date of the name change, and registration number, and shall be signed by the registered individual practitioner or the same person who signed the most recent application for registration or registration renewal. No fee shall be required for the modification. Change of name, as used in this paragraph, refers to a change of the legal name of the registrant and does not authorize the transfer of a registration issued to an individual practitioner or researcher to another individual practitioner or researcher.
   b. Pharmacy, hospital, care facility, service program, manufacturer, distributor; analytical laboratory, teaching institution, importer, or exporter. An entity registered as a pharmacy, hospital, care facility, service program, manufacturer, distributor, analytical laboratory, teaching institution, importer, or exporter shall apply to change the registrant name by submitting a completed application and fee for registration as provided in rule 657—10.5(124). The registrant shall submit a completed application and fee for change in registration simultaneously with any other required application pursuant to the board’s rules for the applicable license or registration. In the absence of a simultaneous license or registration application, the registrant shall submit a completed application and fee for change in registration no less than 30 days in advance of the change of registrant’s name.

10.9(4) Change of ownership of registered business entity. A change of immediate ownership of a pharmacy, hospital, care facility, service program, manufacturer, distributor, analytical laboratory, teaching institution, importer, or exporter shall require the submission of a completed application and fee for registration as provided in rule 657—10.5(124). The registrant shall submit a completed application and fee for change in registration simultaneously with any other required application pursuant to the board’s rules for the applicable license or registration. In the absence of a simultaneous license or registration application, the registrant shall submit a completed application and fee for change in registration no less than 30 days in advance of the change of registrant’s ownership.
10.9(5) 

Change of responsible individual. Any registrant, except an individual practitioner or researcher or a pharmacy or hospital, shall apply to change the responsible individual authorized by the registration by submitting a written request to the board. The request shall include the registrant’s name, address, and telephone number; the name and title of the current responsible individual and of the new responsible individual; the effective date of the change; and the registration number and shall be signed by the new responsible individual. No fee shall be required for the modification.

a. Individual practitioners and researchers. Responsibility under a registration issued to an individual practitioner or researcher shall remain with the named individual practitioner or researcher. The responsible individual under such registration may not be changed or transferred.

b. Pharmacy, hospital, care facility, service program, manufacturer, distributor, analytical laboratory, teaching institution, importer, or exporter. The registrant shall submit a completed application and fee for change in registration simultaneously with any other required application pursuant to the board’s rules for the applicable license or registration. In the absence of a simultaneous license or registration application, the registrant shall submit a completed application and fee for change in registration within ten days of the identification of a new responsible individual.

10.9(6) 

Termination of registration. A registration issued to an individual or business shall terminate when the registered individual or business ceases legal existence, discontinues business, or discontinues professional practice. A registration issued to an individual shall terminate upon the death of the individual.

10.9(7) 

Cancellation of registration. An individual registrant who no longer needs a registration due to discontinuation of practice in Iowa or discontinuation of possessing, administering, dispensing, or prescribing controlled substances shall contact the board to request cancellation of the registration. An individual registrant may renew the registration upon a return to practice in Iowa or a return to possessing, administering, dispensing, or prescribing controlled substances by submitting an application and a nonrefundable fee for registration renewal of $90 per biennium and a nonrefundable surcharge of not more than 25 percent of the registration fee for deposit into the program fund.

[ARC 3345C, IAB 9/27/17, effective 11/1/17; ARC 4455C, IAB 5/22/19, effective 6/26/19; ARC 5096C, IAB 7/15/20, effective 8/19/20]

657—10.10(124) Denial of application or discipline of registration.

10.10(1) 

Grounds for denial or discipline. The board may deny any application or discipline any registration upon a finding that the applicant or registrant:

a. Has furnished false or fraudulent material information.

b. Has had the applicant’s or registrant’s federal registration to manufacture, distribute, or dispense controlled substances suspended, revoked, or otherwise sanctioned.

c. Has been convicted of a public offense under any state or federal law relating to any controlled substance. For the purpose of this rule only, a conviction shall include a plea of guilty, a forfeiture of bail or collateral deposited to secure a defendant’s appearance in court which forfeiture has not been vacated, or a finding of guilt in a criminal action even if entry of the judgment or sentence has been withheld and the applicant or registrant has been placed on probation.

d. Has committed such acts as would render the applicant’s or registrant’s registration under Iowa Code section 124.303 inconsistent with the public interest as determined by that section.

e. Has been subject to discipline by the applicant’s or registrant’s respective professional licensing board and the discipline revokes or suspends the applicant’s or registrant’s professional license or otherwise disciplines the applicant’s or registrant’s professional license in a way that restricts the applicant’s or registrant’s authority to handle or prescribe controlled substances. A copy of the record of licensee discipline or a copy of the licensee’s surrender of the professional license shall be conclusive evidence.

f. Has failed to obtain or maintain active registration while engaged in activities which require registration.

10.10(2) 

Considerations in denial of application or discipline of registration. In determining the public interest, the board shall consider all the following factors:
a. Maintenance of effective controls against diversion of controlled substances into channels other than legitimate medical, scientific, or industrial channels.
b. Compliance with applicable state and local law.
c. Any convictions of the applicant or registrant under any federal and state laws relating to any controlled substance.
d. Past experience in the manufacture or distribution of controlled substances, and the existence in the applicant’s or registrant’s establishment of effective controls against diversion.
e. Furnishing by the applicant of false or fraudulent material in any application filed under this chapter.
f. Suspension or revocation of the applicant’s or registrant’s federal registration to manufacture, distribute, or dispense controlled substances as authorized by federal law.
g. Any other factors relevant to and consistent with the public health and safety.
h. Failure of a prescribing practitioner, except a licensed veterinarian, to register with the PMP pursuant to subrule 10.5(2).

10.10(3) Proceedings.
a. Prior to denying an application for registration, the board shall serve upon the applicant a notice of intent to deny the application. An applicant has 30 days to appeal a notice of intent to deny the application. If the notice of intent to deny the application is timely appealed, a notice of hearing shall be issued, initiating a contested case proceeding governed by 657—Chapter 35. Proceedings to refuse renewal of a registration shall not abate the existing registration, which shall remain in effect pending the outcome of the contested case proceeding. A registration may be disciplined in accordance with 657—Chapters 35 and 36.
b. Prior to sanctioning a registration, the board shall serve upon the registrant a notice of hearing and statement of charges. The notice shall contain a statement of the basis therefore and shall call upon the registrant to appear before an administrative law judge or the board at a time and place not less than 30 days after the date of service of the notice. The notice shall also contain a statement of the legal basis for such hearing and for the sanction of registration and a summary of the matters of fact and law asserted. Proceedings to refuse renewal of registration shall not abate the existing registration, which shall remain in effect pending the outcome of the administrative hearing unless the board issues an order of immediate suspension. A registration may be disciplined in accordance with 657—Chapters 35 and 36.

10.10(4) Disposition of controlled substances. Upon service of an order of the board suspending or revoking a registration, the registrant shall deliver all affected controlled substances in the registrant’s possession to the board or authorized agent of the board. Upon receiving the affected controlled substances from the registrant, the board or its authorized agent shall place all such substances under seal and retain the sealed controlled substances pending final resolution of any appeals or until a court of competent jurisdiction directs otherwise. No disposition may be made of the substances under seal until the time for filing an appeal has elapsed or until all appeals have been concluded unless a court, upon application, orders the sale of perishable substances and the deposit of proceeds of the sale with the court. Upon a revocation order’s becoming final, all such controlled substances may be forfeited to the state.

[ARC 4455C, IAB 5/22/19, effective 6/26/19]

657—10.11(124,147,155A) Registration verification. The board may require a nonrefundable fee of $15 for completion of a request for written verification of any registration.

[ARC 4455C, IAB 5/22/19, effective 6/26/19]

657—10.12(124) Inspection. The board may inspect, or cause to be inspected, the establishment of an applicant or registrant. The board shall review the application for registration and other information regarding an applicant or registrant in order to determine whether the applicant or registrant has met the applicable standards of Iowa Code chapter 124 and these rules.

[ARC 3345C, IAB 9/27/17, effective 11/1/17]
657—10.13(124) **Security requirements.** All registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the board shall use the security requirements set forth in these rules as standards for the physical security controls and operating procedures necessary to prevent diversion.

10.13(1) **Physical security.** Physical security controls shall be commensurate with the schedules and quantity of controlled substances in the possession of the registrant in normal business operation. A registrant shall periodically review and adjust security measures based on rescheduling of substances or changes in the quantity of substances in the possession of the registrant.

a. Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet or safe.

b. Controlled substances listed in Schedules II through V may be stored in a securely locked, substantially constructed cabinet or safe. However, pharmacies and hospitals may disperse these substances throughout the stock of noncontrolled substances in a manner so as to obstruct the theft or diversion of the controlled substances.

c. Controlled substances collected via an authorized collection program for the purpose of disposal shall be stored pursuant to federal regulations, which can be found at www.deadiversion.usdoj.gov/drug_disposal/.

10.13(2) **Factors in evaluating physical security systems.** In evaluating the overall security system of a registrant or applicant necessary to maintain effective controls against theft or diversion of controlled substances, the board may consider any of the following factors it deems relevant to the need for strict compliance with the requirements of this rule:

a. The type of activity conducted.

b. The type, form, and quantity of controlled substances handled.

c. The location of the premises and the relationship such location bears to security needs.

d. The type of building construction comprising the facility and the general characteristics of the building or buildings.

e. The type of vault, safe, and secure enclosures available.

f. The type of closures on vaults, safes, and secure enclosures.

g. The adequacy of key control systems or combination lock control systems.

h. The adequacy of electronic detection and alarm systems, if any.

i. The adequacy of supervision over employees having access to controlled substances, to storage areas, or to manufacturing areas.

j. The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any.

k. The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel.

l. The availability of local police protection or of the registrant’s or applicant’s security personnel.

m. The adequacy of the registrant’s or applicant’s system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances.

10.13(3) **Manufacturing and compounding storage areas.** Raw materials, bulk materials awaiting further processing, and finished products which are controlled substances listed in any schedule shall be stored pursuant to federal laws and regulations.

[ARC 3345C, IAB 9/27/17, effective 11/1/17]

657—10.14(124) **Accountability of controlled substances.** The registrant shall maintain ultimate accountability of controlled substances and records maintained at the registered location.

10.14(1) **Records.** Pursuant to rule 657—10.36(124,155A), records shall be available for inspection and copying by the board or its authorized agents for two years from the date of the record.

10.14(2) **Policies and procedures.** The registrant shall have policies and procedures that identify, at a minimum:
a. Adequate storage for all controlled substances to ensure security and proper conditions with respect to temperature and humidity.

b. Access to controlled substances and records of controlled substances by employees of the registrant.

c. Proper disposition of controlled substances.

d. To the extent possible, a separation of duties related to the purchasing, receiving, stocking, dispensing, and reconciling of controlled substance inventory.

e. The reconciliation of controlled substances in Schedule II pursuant to subrule 10.18(4).

f. The accountability measures for controlled substances in Schedules III through V pursuant to rule 657—10.20(124).

g. A controlled substance accountability program to document review of controlled substance inventory adjustments, review patterns of controlled substance loss, and create an action plan following a report of theft or loss pursuant to subrule 10.21(5).

[ARC 3345C, IAB 9/27/17, effective 11/1/17; ARC 6330C, IAB 6/1/22, effective 7/6/22]

657—10.15 Reserved.

657—10.16(124) Receipt and disbursement of controlled substances. Each transfer of a controlled substance between two registrants, to include a transfer between two separately registered locations regardless of any common ownership, except as provided in subrule 10.16(2), shall require a record of the transaction. Each registrant shall maintain a copy of the record for at least two years from the date of the transfer. Records of the transfer of Schedule II controlled substances shall be created and maintained separately from records of the transfer of Schedules III through V controlled substances pursuant to rule 657—10.36(124,155A). Upon receipt of a controlled substance, the individual responsible for receiving the controlled substance shall date and sign the receipt record.

10.16(1) Record. The record, unless otherwise provided in these rules or pursuant to federal law, shall include the following:

a. The name of the substance.

b. The strength and dosage form of the substance.

c. The number of units or commercial containers acquired from other registrants, including the date of receipt and the name, address, and DEA registration number of the registrant from which the substances were acquired.

d. The number of units or commercial containers distributed to other registrants, including the date of distribution and the name, address, and DEA registration number of the registrant to which the substances were distributed.

e. The number of units or commercial containers disposed of in any other manner, including the date and manner of disposal and the name, address, and DEA registration number of the registrant to which the substances were distributed for disposal, if appropriate.

10.16(2) Distribution of samples and other complimentary packages. Complimentary packages and samples of controlled substances may be distributed to practitioners pursuant to federal and state law only if the person distributing the items provides to the practitioner a record that contains the information found in this subrule. The individual responsible for receiving the controlled substances shall sign and date the record.

a. The name, address, and DEA registration number of the supplier.

b. The name, address, and DEA registration number of the practitioner.

c. The name, strength, dosage form, and quantity of the specific controlled substances delivered.

d. The date of delivery.

[ARC 3345C, IAB 9/27/17, effective 11/1/17]

657—10.17(124) Ordering or distributing Schedule I or II controlled substances. A registrant authorized to order or distribute Schedule I or II controlled substances shall do so only pursuant to
657—10.18(124) Schedule II perpetual inventory. Each registrant located in Iowa that maintains Schedule II controlled substances shall maintain a perpetual inventory system for all Schedule II controlled substances pursuant to this rule. All records relating to the perpetual inventory shall be maintained at the registered location and shall be available for inspection and copying by the board or its representative for a period of two years from the date of the record. The perpetual inventory shall accurately reflect the on-hand inventory of Schedule II substances, and the registrant is responsible for ensuring that the perpetual inventory record is accurate and matches the actual on-hand inventory at all times.

10.18(1) Record format. The perpetual inventory record may be maintained in a manual or an electronic record format. Any electronic record shall provide for hard-copy printout of all transactions recorded in the perpetual inventory record for any specified period of time and shall state the current inventory quantities of each drug at the time the record is printed.

10.18(2) Information included. The perpetual inventory record shall identify all receipts for and disbursements of Schedule II controlled substances by drug or by national drug code (NDC) number. The record shall be updated to identify each receipt, disbursement, and current balance of each individual drug or NDC number. The record shall also include incident reports and reconciliation records pursuant to subrules 10.18(3) and 10.18(4).

10.18(3) Changes to a record. If a perpetual inventory record is able to be changed, the individual making a change to the record shall complete an incident report documenting the change. The incident report shall identify the specific information that was changed including the information before and after the change, shall identify the individual making the change, and shall include the date and the reason the record was changed. If the electronic record system documents within the perpetual inventory record all of the information that must be included in an incident report, a separate report is not required.

10.18(4) Reconciliation. The registrant shall be responsible for reconciling or ensuring the completion of a reconciliation of the perpetual inventory balance with the physical inventory of all Schedule II controlled substances at least annually. Any discrepancies discovered during reconciliation shall be investigated and reported to the pharmacist in charge or responsible individual immediately but no later than one business day following the discovery. The registrant shall determine the need for further investigation, and significant losses shall be reported to the board pursuant to rule 657—10.21(124) and to the DEA pursuant to federal DEA regulations. Periodic reconciliation records shall be maintained and available for review and copying by the board or its authorized agents for a period of two years from the date of the record. The reconciliation process shall be completed using the following procedures or a combination thereof:

a. The individual responsible for a disbursement shall verify that the physical inventory matches the perpetual inventory following each transaction and documents that reconciliation in the perpetual inventory record. If controlled substances are maintained on the patient care unit, the nurse or other responsible licensed health care provider verifies that the physical inventory matches the perpetual inventory following each dispensing and documents that reconciliation in the perpetual inventory record. If any Schedule II controlled substances in the registrant’s current inventory have been disbursed and verified in this manner within the year and there are no discrepancies noted, no additional reconciliation action is required. A perpetual inventory record for a drug that has had no activity within the year shall be reconciled pursuant to paragraph 10.18(4)“b.”

b. A physical count of each Schedule II controlled substance stocked by the registrant that has not been reconciled pursuant to paragraph 10.18(4)“a” shall be completed at least once each year, and that count shall be reconciled with the perpetual inventory record balance. The physical count and reconciliation may be completed over a period of time not to exceed one year in a manner that ensures that the perpetual inventory and the physical inventory of Schedule II controlled substances are annually reconciled. The individual performing the reconciliation shall record the date, the time, the individual’s
initials or unique identification, and any discrepancies between the physical inventory and the perpetual inventory.

[ARC 3345C, IAB 9/27/17, effective 11/1/17; ARC 5349C, IAB 12/30/20, effective 2/3/21; ARC 6330C, IAB 6/1/22, effective 7/6/22]

657—10.19(124) Physical count and record of inventory. Each registrant shall be responsible for taking a complete and accurate inventory of all stocks of controlled substances under the control of the registrant pursuant to this rule. The responsible individual may delegate the actual taking of any inventory.

10.19(1) Record and procedure. Each inventory record, except the periodic count and reconciliation required pursuant to subrule 10.18(4), shall comply with the requirements of this subrule and shall be maintained for a minimum of two years from the date of the inventory.
   a. Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date and at the time the inventory is taken.
   b. Each inventory shall be maintained in a handwritten, typewritten, or electronically printed form at the registered location. An inventory of Schedule II controlled substances shall be maintained separately from an inventory of all other controlled substances.
   c. Controlled substances shall be deemed to be on hand if they are in the possession of or under the control of the registrant. Controlled substances on hand shall include prescriptions prepared for dispensing to a patient but not yet delivered to the patient, substances maintained in emergency medical service programs, care facility or hospice emergency supplies, outdated or adulterated substances pending destruction, and substances stored in a warehouse on behalf of the registrant. Controlled substances obtained through an authorized collection program for the purpose of disposal shall not be examined, inspected, counted, sorted, inventoried, or otherwise handled.
   d. A separate inventory shall be made for each registered location and for each independent activity registered except as otherwise provided under federal law.
   e. The inventory shall be taken either prior to opening or following the close of business on the inventory date, and the inventory record shall identify either opening or close of business.
   f. The inventory record, unless otherwise provided under federal law, shall include the following information:
      (1) The name of the substance.
      (2) The strength and dosage form of the substance.
      (3) The quantity of the substance, which shall be an exact count or measure of the substance and may not be an estimated count or measure, except for liquid products packaged in nonincremented containers, which may be estimated to the nearest one-fourth container.
      (4) Information required of authorized collection programs pursuant to federal regulations for such collection programs.
      (5) The signature of the person or persons responsible for taking the inventory.
      (6) The date and time (opening or closing) of the inventory.

10.19(2) Initial inventory. A new registrant shall take an inventory of all stocks of controlled substances on hand on the date the new registrant first engages in the manufacture, distribution, storage, or dispensing of controlled substances. If the registrant commences business or the registered activity with no controlled substances on hand, the initial inventory shall record that fact.

10.19(3) Annual inventory. After the initial inventory is taken, a registrant shall take a new inventory of all stocks of controlled substances on hand at least annually. The annual inventory may be taken on any date that is within 372 days after the date of the previous annual inventory.

10.19(4) Change of ownership, pharmacist in charge, or registered location.
   a. When there is a change in ownership or location for a registration, an inventory shall be taken of all controlled substances in compliance with subrule 10.19(1). The inventory shall be taken following the close of business on the last day under terminating ownership or at the location being vacated. The inventory shall serve as the ending inventory for the terminating owner or location being vacated, as well as a record of the beginning inventory for the new owner or location.
b. When there is a change of pharmacist in charge, including when the incoming pharmacist in charge is temporary or interim pursuant to 657—paragraph 8.35(6) “d,” an inventory shall be taken of all controlled substances in compliance with subrule 10.19(1). An inventory shall be taken following the close of business on the last day of duty of the outgoing pharmacist in charge. The inventory may serve as the beginning inventory for the incoming pharmacist in charge, unless the incoming pharmacist in charge did not immediately assume the duties of pharmacist in charge following the outgoing pharmacist in charge. Any lapse in time between the outgoing pharmacist in charge and the incoming pharmacist in charge shall cause an inventory to be taken prior to the opening of business on the first day of duty of the incoming pharmacist in charge. An inventory count shall not be required in the case of an interim pharmacist in charge if the pharmacy maintains perpetual inventory logs for all controlled substances pursuant to rule 657—10.20(124).

10.19(5) Discontinuing registered activity. A registrant shall take an inventory of controlled substances at the close of business the last day the registrant is engaged in registered activities. If the registrant is selling or transferring the remaining controlled substances to another registrant, this inventory shall serve as the ending inventory for the registrant discontinuing business as well as a record of additional or starting inventory for the registrant to which the substances are transferred.

10.19(6) New or rescheduled controlled substances. On the effective date of the addition of a previously noncontrolled substance to any schedule of controlled substances or the rescheduling of a previously controlled substance to another schedule, any registrant who possesses the newly scheduled or rescheduled controlled substance shall take an inventory of all stocks of the substance on hand. That inventory record shall be maintained with the most recent controlled substances inventory record. Thereafter, the controlled substance shall be included in the appropriate schedule of each inventory made by the registrant.

[ARC 3345C, IAB 9/27/17, effective 11/1/17; ARC 6330C, IAB 6/1/22, effective 7/6/22]

657—10.20(124) Schedule III through V accountability. A registrant shall ensure accountability of Schedule III through V controlled substances through one or more of the measures identified herein.

1. Perpetual inventory log, which may be maintained by electronic means, so long as the system complies with the perpetual inventory requirements in rule 657—10.18(124).
2. Documented audit and reconciliation of all controlled substances every six months.
3. Routine documented cycle counts of substances, so long as all controlled substances are counted every 90 days and identified discrepancies are investigated and documented.
4. Other measure preapproved by the board.

[ARC 6330C, IAB 6/1/22, effective 7/6/22]

657—10.21(124) Report of theft or loss. A registrant shall report to the board and the DEA any theft or significant loss of controlled substances when the loss is attributable to other than inadvertent error. Thefts or other losses of controlled substances shall be reported whether or not the controlled substances are subsequently recovered or the responsible parties are identified and action taken against them.

10.21(1) Immediate notice to board. If the theft was committed by a registrant or licensee of the board, or if there is reason to believe that the theft was committed by a registrant or licensee of the board, the registrant from which the controlled substances were stolen shall notify the board immediately upon discovery of the theft and shall identify to the board the registrant or licensee suspected of the theft.

10.21(2) Immediate notice to DEA. A registrant shall deliver notice, immediately upon discovery of a reportable theft or loss of controlled substances, to the Des Moines DEA field office via telephone, facsimile, or a brief written message explaining the circumstances of the theft or loss.

10.21(3) Timely report submission. Within 14 calendar days of discovery of the theft or loss, a registrant shall submit directly to the DEA a Form 106 or alternate required form via the DEA website at www.deadiversion.usdoj.gov/. A copy of the report that was completed and submitted to the DEA shall be immediately submitted to the board via facsimile, email attachment, or personal or commercial delivery.

10.21(4) Record maintained. A copy of the report shall be maintained in the registrant’s files for a minimum of two years following the date the report was completed.
10.21(5) Action plan following loss. Within seven days following the report of theft or loss, a registrant shall develop and initiate implementation of an action plan to address the conditions which contributed to the theft or loss. The action plan shall include any directives, including, but not limited to, inventory counts, audits, and perpetual inventory counts provided by a board compliance officer.

[ARC 3345C, IAB 9/27/17, effective 11/1/17; ARC 6330C, IAB 6/1/22, effective 7/6/22]

657—10.22(124) Disposal of registrant stock. A registrant shall dispose of controlled substances pursuant to the requirements of this rule. Disposal records shall be maintained by the registrant for at least two years from the date of the record.

10.22(1) Registrant stock supply. Controlled substances shall be removed from current inventory and disposed of by one of the following procedures.

a. The registrant shall utilize the services of a DEA-registered and Iowa-licensed reverse distributor.

b. The board may authorize and instruct the registrant to dispose of the controlled substances in one of the following manners:

(1) By delivery to an agent of the board or to the board office.

(2) By destruction of the drugs in the presence of a board officer, agent, inspector, or other authorized individual.

(3) By such other means as the board may determine to ensure that drugs do not become available to unauthorized persons.

10.22(2) Waste resulting from administration or compounding. Except as otherwise specifically provided by federal or state law or rules of the board, the unused portion of a controlled substance resulting from administration to a patient from a registrant’s stock or emergency supply or resulting from drug compounding operations may be destroyed or otherwise disposed of by the registrant, a certified paramedic, or a pharmacist in witness of one other licensed health care provider or a registered pharmacy technician 18 years of age or older pursuant to this subrule. A written record of the wastage shall be made and maintained by the registrant for a minimum of two years following the wastage. The record shall include the following:

a. The controlled substance wasted.

b. The date of wastage.

c. The quantity or estimated quantity of the wasted controlled substance.

d. The source of the controlled substance, including identification of the patient to whom the substance was administered or the drug compounding process utilizing the controlled substance.

e. The reason for the waste.

f. The signatures of both individuals involved in the wastage.

[ARC 3345C, IAB 9/27/17, effective 11/1/17; ARC 4455C, IAB 5/22/19, effective 6/26/19]

657—10.23(124) Disposal of previously dispensed controlled substances.

10.23(1) Registrant disposal. Except as provided in 657—Chapter 23 for care facilities, a registrant may not dispose of previously dispensed controlled substances unless the registrant has modified its registration with DEA to administer an authorized collection program. A registrant shall not take possession of a previously dispensed controlled substance except for reuse for the same patient or except as provided in paragraph 10.23(2)“b.”

10.23(2) Hospice disposal.

a. An employee of a hospice program, acting within the scope of employment, may dispose of a controlled substance of a hospice program patient following the death of the patient or the expiration of the controlled substance pursuant to and in compliance with federal law.

b. A physician of a hospice program patient may dispose of a patient’s controlled substance which is no longer required due to a change in the patient’s care plan.

[ARC 3345C, IAB 9/27/17, effective 11/1/17; ARC 4455C, IAB 5/22/19, effective 6/26/19]

657—10.24(124,126,155A) Prescription requirements. All prescriptions for controlled substances shall be dated as of, and signed on, the day issued. Controlled substances prescriptions shall be valid for
six months following date of issue. A prescription for a Schedule III, IV, or V controlled substance may include authorization to refill the prescription no more than five times within the six months following date of issue. A prescription for a Schedule II controlled substance shall not be refilled. Beginning January 1, 2020, all prescriptions for controlled substances shall be transmitted electronically to a pharmacy pursuant to rule 657—21.6(124,155A), except as provided in rule 657—21.8(124,155A).

10.24(1) Form of prescription. All prescriptions for controlled substances shall bear the full name and address of the patient; the drug name, strength, dosage form, quantity prescribed, and directions for use; and the name, address, and DEA registration number of the prescriber. All prescriptions for controlled substances issued by individual prescribers shall include the legibly preprinted, typed, or hand-printed name of the prescriber as well as the prescriber’s written or electronic signature. A prescription for a controlled substance issued prior to January 1, 2020, or for a prescription for a controlled substance that is exempt from the electronic prescription mandate pursuant to rule 657—21.8(124,155A), may be transmitted via nonelectronic methods as described in this rule.

a. When an oral order is not permitted, or when a prescriber is unable to prepare and transmit an electronic prescription in compliance with DEA requirements for electronic prescriptions, prescriptions shall be written with ink, indelible pencil, or typed print and shall be manually signed by the prescriber. If the prescriber utilizes an electronic prescription application that meets DEA requirements for electronic prescriptions, the prescriber may electronically prepare and transmit a prescription for a controlled substance to a pharmacy that utilizes a pharmacy prescription application that meets DEA requirements for electronic prescriptions.

b. A prescriber’s agent may prepare a prescription for the review, authorization, and manual or electronic signature of the prescriber, but the prescribing practitioner is responsible for the accuracy, completeness, and validity of the prescription.

c. An electronic prescription for a controlled substance shall not be transmitted to a pharmacy except by the prescriber in compliance with DEA regulations.

d. A prescriber shall securely maintain the unique authentication credentials issued to the prescriber for utilization of the electronic prescription application and authentication of the prescriber’s electronic signature. Unique authentication credentials issued to any individual shall not be shared with or disclosed to any other prescriber, agent, or individual.

e. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by this rule.

10.24(2) Verification by pharmacist.

a. The pharmacist shall verify the authenticity of the prescription with the individual prescriber or the prescriber’s agent in each case when a written or oral prescription for a Schedule II controlled substance is presented for filling and neither the prescribing individual practitioner issuing the prescription nor the patient or patient’s agent is known to the pharmacist. The pharmacist shall verify the authenticity of the prescription with the individual prescriber or the prescriber’s agent in any case when the pharmacist questions the validity of, including the legitimate medical purpose for, the prescription. The pharmacist is required to record the manner by which the prescription was verified and include the pharmacist’s name or unique identifier.

b. A pharmacist who receives a written, oral, or facsimile prescription shall not be required to verify that the prescription is subject to an exception to the electronic prescription mandate provided in rule 657—21.8(124,155A) and may dispense a prescription drug pursuant to an otherwise valid written, oral, or facsimile prescription pursuant to this rule.

10.24(3) Intern, resident, foreign physician. An intern, resident, or foreign physician exempt from registration pursuant to subrule 10.8(5) shall include on all prescriptions issued the hospital’s registration number and the special internal code number assigned by the hospital in lieu of the prescriber’s registration number required by this rule. Each prescription shall include the stamped or legibly printed name of the prescribing intern, resident, or foreign physician as well as the prescriber’s signature.

10.24(4) Valid prescriber/patient relationship. Once the prescriber/patient relationship is broken and the prescriber is no longer available to treat the patient or to oversee the patient’s use of the controlled
substance, a prescription shall lose its validity. A prescriber/patient relationship shall be deemed broken when the prescriber dies, retires, or moves out of the local service area or when the prescriber’s authority to prescribe is suspended, revoked, or otherwise modified to exclude authority for the schedule in which the prescribed substance is listed. The pharmacist, upon becoming aware of the situation, shall cancel the prescription and any remaining refills. However, the pharmacist shall exercise prudent judgment based upon individual circumstances to ensure that the patient is able to obtain a sufficient amount of the drug to continue treatment until the patient can reasonably obtain the service of another prescriber and a new prescription can be issued.

10.24(5) Facsimile transmission of a controlled substance prescription. With the exception of an authorization for emergency dispensing as provided in rule 657—10.26(124), a prescription for a controlled substance in Schedules II, III, IV and V may be transmitted via facsimile from a prescriber to a pharmacy only as provided in rule 657—21.7(124,155A).

657—10.25(124) Dispensing records. Each registrant shall create a record of controlled substances dispensed to a patient or research subject.

10.25(1) Record maintained and available. The record shall be maintained for two years from the date of dispensing and be available for inspection and copying by the board or its authorized agents.

10.25(2) Record contents. The record shall include the following information:

a. The name and address of the person to whom dispensed.

b. The date of dispensing.

c. The name or NDC number, strength, dosage form, and quantity of the substance dispensed.

d. The name of the prescriber, unless dispensed by the prescriber.

e. The unique identification of each technician, pharmacist, pharmacist-intern, prescriber, or prescriber’s agent involved in dispensing.

f. The serial number or unique identification number of the prescription.

657—10.26(124) Schedule II emergency prescriptions.

10.26(1) Emergency situation defined. For the purposes of authorizing an oral or facsimile transmission of a prescription for a Schedule II controlled substance listed in Iowa Code section 124.206, the term “emergency situation” means those situations in which the prescribing practitioner determines that all of the following apply:

a. Immediate administration of the controlled substance is necessary for proper treatment of the intended ultimate user.

b. No appropriate alternative treatment is available, including administration of a drug that is not a Schedule II controlled substance.

c. It is not reasonably possible for the prescribing practitioner to provide a manually signed written prescription to be presented to the pharmacy before the pharmacy dispenses the controlled substance, or the prescribing practitioner is unable to provide a DEA-compliant electronic prescription to the pharmacy before the pharmacy dispenses the controlled substance.

10.26(2) Requirements of emergency prescription. In the case of an emergency situation as defined in subrule 10.26(1), a pharmacist may dispense a controlled substance listed in Schedule II pursuant to a facsimile transmission or upon receiving oral authorization of a prescribing individual practitioner provided that:

a. The quantity prescribed and dispensed is limited to the smallest available quantity to meet the needs of the patient during the emergency period. Dispensing beyond the emergency period requires a written prescription manually signed by the prescribing individual practitioner or a DEA-compliant electronic prescription.

b. If the pharmacist does not know the prescribing individual practitioner, the pharmacist shall make a reasonable effort to determine that the authorization came from an authorized prescriber. The pharmacist shall record the manner by which the authorization was verified and include the pharmacist’s name or unique identification.
c. The pharmacist shall prepare a temporary written record of the emergency prescription. The temporary written record shall consist of a hard copy of the facsimile transmission or a written record of the oral transmission authorizing the emergency dispensing. A written record is not required to consist of a handwritten record and may be a printed facsimile or a print of a computer-generated record of the prescription if the printed record includes all of the required elements for the prescription. If the emergency prescription is transmitted by the practitioner’s agent, the record shall include the first and last names and title of the individual who transmitted the prescription.

d. If the emergency prescription is transmitted via facsimile transmission, the means of transmission shall not obscure or render the prescription information illegible due to security features of the paper utilized by the prescriber to prepare the written prescription, and the hard-copy record of the facsimile transmission shall not be obscured or rendered illegible due to such security features.

e. Within seven days after authorizing an emergency prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of rule 657—10.24(124,126,155A), the prescription shall have written on its face “Authorization for Emergency Dispensing” and the date of the emergency order. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it must be postmarked within the seven-day period. The written prescription shall be attached to and maintained with the temporary written record prepared pursuant to paragraph 10.26(2) “c.”

f. The pharmacist shall notify the board and the DEA if the prescribing individual fails to deliver a written prescription. Failure of the pharmacist to so notify the board and the DEA, or failure of the prescribing individual to deliver the required written prescription as herein required, shall void the authority conferred by this subrule.

g. Pursuant to federal law and subrule 10.27(3), the pharmacist may fill a partial quantity of an emergency prescription so long as the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed and that the remaining portions are filled no later than 72 hours after the prescription is issued.

[ARC 3345C, IAB 9/27/17, effective 11/1/17]

657—10.27(124) Schedule II prescriptions—partial filling. The partial filling of a prescription for a controlled substance listed in Schedule II is permitted as provided in this rule and federal regulations.

10.27(1) Insufficient supply on hand. If the pharmacist is unable to supply the full quantity authorized in a prescription and makes a notation of the quantity supplied on the prescription record, a partial fill of the prescription is permitted. The remaining portion of the prescription must be filled within 72 hours of the first partial filling. If the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall so notify the prescriber. No further quantity may be supplied beyond 72 hours without a new prescription.

10.27(2) Long-term care or terminally ill patient. A prescription for a Schedule II controlled substance written for a patient in a long-term care facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units as provided by this subrule.

a. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist shall contact the practitioner prior to partially filling the prescription. Both the pharmacist and the practitioner have a corresponding responsibility to ensure that the controlled substance is for a terminally ill patient.

b. The pharmacist shall record on the prescription whether the patient is “terminally ill” or an “LTCF patient.” For each partial filling, the dispensing pharmacist shall record on the back of the prescription or on another appropriate uniformly maintained and readily retrievable record, the date of the partial filling, the quantity dispensed, the remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist.

c. The total quantity of Schedule II controlled substances dispensed in all partial fillings shall not exceed the total quantity prescribed. Schedule II prescriptions for patients in an LTCF or for patients
with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of the drug.

d. Information pertaining to current Schedule II prescriptions for patients in an LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system pursuant to rule 657—21.5(124,155A).

10.27(3) Patient or prescriber request. At the request of the patient or prescriber, a prescription for a Schedule II controlled substance may be partially filled pursuant to this subrule and federal law. The total quantity dispensed in all partial fillings shall not exceed the total quantity prescribed. Except as provided in paragraph 10.26(2) "g," the remaining portion of a prescription partially filled pursuant to this subrule may be filled within 30 days of the date the prescription was issued.

[ARC 3345C, IAB 9/27/17, effective 11/1/17; ARC 4455C, IAB 5/22/19, effective 6/26/19]

657—10.28(124) Schedule II medication order. Schedule II controlled substances may be administered or dispensed to institutionalized patients pursuant to a medication order as provided in 657—subrule 7.13(1) or rule 657—23.9(124,155A), as applicable.

[ARC 3345C, IAB 9/27/17, effective 11/1/17; ARC 3850C, IAB 6/20/18, effective 7/25/18]

657—10.29(124) Schedule II—issuing multiple prescriptions. An individual prescriber may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance pursuant to the provisions and limitations of this rule.

10.29(1) Refills prohibited. The issuance of refills for a Schedule II controlled substance is prohibited. The use of multiple prescriptions for the dispensing of Schedule II controlled substances, pursuant to this rule, ensures that the prescriptions are treated as separate dispensing authorizations and not as refills of an original prescription.

10.29(2) Legitimate medical purpose. Each separate prescription issued pursuant to this rule shall be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of the prescriber’s professional practice.

10.29(3) Dates and instructions. Each prescription issued pursuant to this rule shall be dated as of and manually or electronically signed by the prescriber on the day the prescription is issued. Each separate prescription, other than the first prescription if that prescription is intended to be filled immediately, shall contain written instructions indicating the earliest date on which a pharmacist may fill each prescription.

10.29(4) Authorized fill date unalterable. Regardless of the provisions of rule 657—10.30(124), when a prescription contains instructions from the prescriber indicating that the prescription shall not be filled before a certain date, a pharmacist shall not fill the prescription before that date. The pharmacist shall not contact the prescriber for verbal authorization to fill the prescription before the fill date originally indicated by the prescriber pursuant to this rule.

10.29(5) Number of prescriptions and authorized quantity. An individual prescriber may issue for a patient as many separate prescriptions, to be filled sequentially pursuant to this rule, as the prescriber deems necessary to provide the patient with adequate medical care. The cumulative effect of the filling of each of these separate prescriptions shall result in the receipt by the patient of a quantity of the Schedule II controlled substance not exceeding a 90-day supply.

10.29(6) Prescriber’s discretion. Nothing in this rule shall be construed as requiring or encouraging an individual prescriber to issue multiple prescriptions pursuant to this rule or to see the prescriber’s patients once every 90 days when prescribing Schedule II controlled substances. An individual prescriber shall determine, based on sound medical judgment and in accordance with established medical standards, how often to see patients and whether it is appropriate to issue multiple prescriptions pursuant to this rule.

[ARC 3345C, IAB 9/27/17, effective 11/1/17; ARC 4580C, IAB 7/31/19, effective 9/4/19]

657—10.30(124) Schedule II—changes to a prescription. With appropriate verification, a pharmacist may add information provided by the patient or patient’s agent, such as the patient’s address, to a Schedule II controlled substance prescription.
10.30(1) Changes prohibited. A pharmacist shall never change the patient’s name, the controlled substance prescribed except for generic substitution, or the name or signature of the prescriber.

10.30(2) Changes authorized. After consultation with the prescriber or the prescriber’s agent and documentation of such consultation, a pharmacist may change or add the following information on a Schedule II controlled substance prescription:
   a. The drug strength.
   b. The dosage form.
   c. The drug quantity.
   d. The directions for use.
   e. The date the prescription was issued.
   f. The prescriber’s address or DEA registration number.

657—10.31 Reserved.

657—10.32(124) Schedule III, IV, or V prescription. No prescription for a controlled substance listed in Schedule III, IV, or V shall be filled or refilled more than six months after the date on which it was issued nor be refilled more than five times. Beginning January 1, 2020, all prescriptions for controlled substances shall be transmitted electronically to a pharmacy pursuant to rule 657—21.6(124,155A), except as provided in rule 657—21.8(124,155A).

10.32(1) Record. Each filling and refilling of a prescription shall be entered in a uniformly maintained and readily retrievable record in accordance with rule 657—10.25(124). If the pharmacist merely initials or affixes the pharmacist’s unique identifier and dates the back of the prescription, it shall be deemed that the full face amount of the prescription has been dispensed.

10.32(2) Oral refill authorization. The prescribing practitioner may authorize additional refills of Schedule III, IV, or V controlled substances on the original prescription through an oral refill authorization transmitted to an authorized individual at the pharmacy provided the following conditions are met:
   a. The total quantity authorized, including the amount of the original prescription, does not exceed five refills nor extend beyond six months from the date of issuance of the original prescription.
   b. The pharmacist, pharmacist-intern, or technician who obtains the oral authorization from the prescriber who issued the original prescription documents, on or with the original prescription, the date authorized, the quantity of each refill, the number of additional refills authorized, and the unique identification of the authorized individual.
   c. The quantity of each additional refill is equal to or less than the quantity authorized for the initial filling of the original prescription.
   d. The prescribing practitioner must execute a new and separate prescription for any additional quantities beyond the five-refill, six-month limitation.

10.32(3) Partial fills. The partial filling of a prescription for a controlled substance listed in Schedule III, IV, or V is permissible provided that each partial fill is recorded in the same manner as a refill pursuant to subrule 10.32(1). The total quantity dispensed in all partial fills shall not exceed the total quantity prescribed.

10.32(4) Medication order. A Schedule III, IV, or V controlled substance may be administered or dispensed to institutionalized patients pursuant to a medication order as provided in 657—subrule 7.13(1) or rule 657—23.9(124,155A), as applicable.

657—10.33(124,155A) Dispensing Schedule V controlled substances without a prescription. A controlled substance listed in Schedule V, which substance is not a prescription drug as determined under the federal Food, Drug, and Cosmetic Act, and excepting products containing ephedrine, pseudoephedrine, or phenylpropanolamine, may be dispensed or administered without a prescription by a pharmacist to a purchaser at retail pursuant to the conditions of this rule.
10.33(1) **Who may dispense.** Dispensing shall be by a licensed Iowa pharmacist or by a registered pharmacist-intern under the direct supervision of a pharmacist preceptor. This subrule does not prohibit, after the pharmacist has fulfilled the professional and legal responsibilities set forth in this rule and has authorized the dispensing of the substance, the completion of the actual cash or credit transaction or the delivery of the substance by a nonpharmacist.

10.33(2) **Frequency and quantity.** Dispensing at retail to the same purchaser in any 48-hour period shall be limited to no more than one of the following quantities of a Schedule V controlled substance:

a. 240 cc (8 ounces) of any controlled substance containing opium.

b. 120 cc (4 ounces) of any other controlled substance.

c. 48 dosage units of any controlled substance containing opium.

d. 24 dosage units of any other controlled substance.

10.33(3) **Age of purchaser.** The purchaser shall be at least 18 years of age.

10.33(4) **Identification.** The pharmacist shall require every purchaser under this rule who is not known by the pharmacist to present a government-issued photo identification, including proof of age when appropriate.

10.33(5) **Record.** A bound record book (i.e., with pages sewn or glued to the spine) for dispensing of Schedule V controlled substances pursuant to this rule shall be maintained by the pharmacist. The book shall contain the name and address of each purchaser, the name and quantity of controlled substance purchased, the date of each purchase, and the name or unique identification of the pharmacist or pharmacist-intern who approved the dispensing of the substance to the purchaser.

10.33(6) **Prescription not required under other laws.** No other federal or state law or regulation requires a prescription prior to distributing or dispensing the Schedule V controlled substance.

[ARC 3345C, IAB 9/27/17, effective 11/1/17]

657—10.34(124) **Dispensing products containing ephedrine, pseudoephedrine, or phenylpropanolamine without a prescription.** A product containing ephedrine, pseudoephedrine, or phenylpropanolamine, which substance is a Schedule V controlled substance and is not listed in another controlled substance schedule, may be dispensed or administered without a prescription by an authorized dispenser pursuant to 657—Chapter 100 to a purchaser at retail pursuant to the conditions of this rule.

10.34(1) **Who may dispense.** Dispensing shall be by an authorized dispenser pursuant to 657—Chapter 100. This subrule does not prohibit, after the dispenser has fulfilled the professional and legal responsibilities set forth in this rule and has authorized the dispensing of the substance, the completion of the actual cash or credit transaction or the delivery of the substance by another pharmacy employee.

10.34(2) **Packaging of nonliquid forms.** A nonliquid form of a product containing ephedrine, pseudoephedrine, or phenylpropanolamine includes gel caps. Nonliquid forms of these products to be sold pursuant to this rule shall be packaged either in blister packaging with each blister containing no more than two dosage units or, if blister packs are technically infeasible, in unit dose packets or pouches.

10.34(3) **Frequency and quantity.** Dispensing without a prescription to the same purchaser within any 30-day period shall be limited to products collectively containing no more than 7,500 mg of ephedrine, pseudoephedrine, or phenylpropanolamine; dispensing without a prescription to the same purchaser within a single calendar day shall not exceed 3,600 mg.

10.34(4) **Age of purchaser.** The purchaser shall be at least 18 years of age.

10.34(5) **Identification.** The dispenser shall require every purchaser under this rule to present a current government-issued photo identification, including proof of age when appropriate. The dispenser shall be responsible for verifying that the name on the identification matches the name provided by the purchaser and that the photo image depicts the purchaser.

10.34(6) **Record.** Purchase records shall be recorded in the real-time electronic pseudoephedrine tracking system (PTS) established and administered by the governor’s office of drug control policy pursuant to 657—Chapter 100. If the PTS is unavailable for use, the purchase record shall be recorded in an alternate format and submitted to the PTS as provided in 657—subrule 100.3(4).
a. **Alternate record contents.** The alternate record shall contain the following:

1. The name, address, and signature of the purchaser.
2. The name and quantity of the product purchased, including the total milligrams of ephedrine, pseudoephedrine, or phenylpropanolamine contained in the product.
3. The date and time of the purchase.
4. The name or unique identification of the dispenser who approved the dispensing of the product.

b. **Alternate record format.** The record shall be maintained using one of the following options:

1. A hard-copy record.
2. A record in the pharmacy’s electronic prescription dispensing record-keeping system that is capable of producing a hard-copy printout of a record.
3. A record in an electronic data collection system that captures each of the data elements required by this subrule and that is capable of producing a hard-copy printout of a record.

c. **PTS records retrieval.** Pursuant to 657—subrule 100.4(6), the pharmacy shall be able to produce a hard-copy printout of transactions recorded in the PTS by the pharmacy for one or more specific products for a specified period of time upon request by the board or its representative or to such other persons or governmental agencies authorized by law to receive such information.

### 10.34(7) Notice required.

The pharmacy shall ensure that the following notice is provided to purchasers of ephedrine, pseudoephedrine, or phenylpropanolamine products and that the notice is displayed with or on the electronic signature device or is displayed in the dispensing area and visible to the public:

“Warning: Section 1001 of Title 18, United States Code, states that whoever, with respect to the logbook, knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact, or makes any materially false, fictitious, or fraudulent statement or representation, or makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry, shall be fined not more than $250,000 if an individual or $500,000 if an organization, imprisoned not more than five years, or both.”

[ARC 3345C, IAB 9/27/17, effective 11/1/17; ARC 4701C, IAB 10/9/19, effective 11/13/19]

### 657—10.35 Reserved.

#### 657—10.36(124,155A) Records.

Every record required to be kept under this chapter or under Iowa Code chapter 124 shall be kept by the registrant and be available for inspection and copying by the board or its representative for at least two years from the date of such record except as otherwise required in these rules. Controlled substances records shall be maintained in a readily retrievable manner that establishes the receipt and distribution of all controlled substances. Original records more than 12 months old may be maintained in a secure remote storage area unless such remote storage is prohibited under federal law. If the secure storage area is not located within the same physical structure as the registrant, the records must be retrievable within 48 hours of a request by the board or its authorized agent.

**10.36(1) Schedule I and II records.** Records of controlled substances listed in Schedules I and II shall be maintained separately from all other records of the registrant.

**10.36(2) Schedule III, IV, and V records.** Records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the required information is readily retrievable from the ordinary business records of the registrant.

**10.36(3) Date of record.** The date on which a controlled substance is actually received, imported, distributed, exported, disposed of, or otherwise transferred shall be used as the date of receipt, importation, distribution, and transfer.

[ARC 3345C, IAB 9/27/17, effective 11/1/17]

### 657—10.37 Reserved.

#### 657—10.38(124) Revision of controlled substances schedules.

**10.38(1) Designation of new controlled substance.** The board may designate any new substance as a controlled substance to be included in any of the schedules in Iowa Code chapter 124 no sooner than
30 days following publication in the Federal Register of a final order so designating the substance under federal law. Designation of a new controlled substance under this subrule shall be temporary as provided in Iowa Code section 124.201(4).

10.38(2) *Objection to designation of a new controlled substance.* The board may object to the designation of any new substance as a controlled substance within 30 days following publication in the Federal Register of a final order so designating the substance under federal law. The board shall file objection to the designation of a substance as controlled, shall afford all interested parties an opportunity to be heard, and shall issue the board’s decision on the new designation as provided in Iowa Code section 124.201(4).

10.38(3) *Cannabis-derived products.* If a cannabis-derived product or investigational product approved as a prescription drug medication by the United States Food and Drug Administration is added to, eliminated from or revised in the federal schedule of controlled substances by the DEA and notice of the addition, elimination or revision is given to the board, the board shall similarly add, eliminate or revise the prescription drug medication in the schedule of controlled substances. Such action by the board shall be immediately effective upon the date of publication of the final regulation containing the addition, elimination or revision in the Federal Register.

[ARC 3345C, IAB 9/27/17, effective 11/1/17; ARC 3743C, IAB 4/11/18, effective 5/16/18; ARC 5346C, IAB 12/30/20, effective 2/3/21]

657—10.39(124) *Temporary designation of controlled substances.*

10.39(1) Amend Iowa Code section 124.204(2) by adding the following new paragraphs:

*bt.* N-phenyl-N-(1-(2-phenylpropyl)piperidin-4-yl)propionamide. Other name: beta-methyl fentanyl.

*bu.* N-(1-phenethylpiperidin-4-yl)-N,3-diphenylpropanamide. Other names: beta-phenyl fentanyl, 3-phenylpropanoyl fentanyl.

*bv.* N-(1-(2-fluorophenethyl)piperidin-4-yl)-N-(2-fluorophenyl)propionamide. Other name: 2′-Fluoro ortho-fluorofentanyl, 2′-fluoro 2-fluorofentanyl.

*bw.* N-(1-(4-methylphenethyl)piperidin-4-yl)-N-phenylacetamide. Other name: 4′-Methyl acetyl fentanyl.

*bx.* N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)butyramide. Other names: ortho-Fluorobutyryl fentanyl, 2-fluorobutyryl fentanyl.

*by.* N-(2-methylphenyl)-N-(1-phenethylpiperidin-4-yl)acetamide. Other names: ortho-Methyl acetyl fentanyl, 2-methyl acetyl fentanyl.

*bz.* 2-methoxy-N-(2-methylphenyl)-N-(1-phenethylpiperidin-4-yl)acetamide. Other names: ortho-Methyl methoxyacetyl fentanyl, 2-methyl methoxyacetyl fentanyl.

*ca.* N-(4-methylphenyl)-N-(1-phenethylpiperidin-4-yl)propionamide. Other names: para-Methylfentanyl, 4-methylfentanyl.

*cb.* N-(1-phenethylpiperidin-4-yl)-N-phenylbenzamide. Other names: Phenyl fentanyl, benzoyl fentanyl.

*cc.* N-(1-phenethylpiperidin-4-yl)-N-phenylthiophene-2-carboxamide. Other names: Thiofuranyl fentanyl, 2-thiofuranyl fentanyl, thiophene fentanyl.

*cd.* Ethyl (1-phenethylpiperidin-4-yl)(phenyl)carbamate. Other name: fentanyl carbamate.

*ce.* N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)acrylamide. Other name: ortho-Fluoroacryl fentanyl.

*cf.* N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide. Other name: ortho-Fluoroisobutyryl fentanyl.

*cg.* N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)furan-2-carboxamide. Other name: para-Fluoro furanyl fentanyl.

10.39(2) Amend Iowa Code section 124.204(9) by adding the following new paragraph:

*y.* 1-(1-(1-(4-bromophenyl)ethyl)piperidin-4-yl)-1,3-dihydro-2H-benzimidazole-2-one. Other names: bromophone, 1-[1-(1-(4-bromophenyl)ethyl)-4-piperidinyl]-1,3-dihydro-2H-benzimidazole-2-one.
10.39(3) Amend Iowa Code section 124.206(2) “a” by rescinding and replacing the introductory text as follows:

a. Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate excluding apomorphine, thebaine-derived butorphanol, dextrophan, nalbuphine, naldemedine, nalmefene, naloxegol, naloxone, 6beta-naltrexol, naltrexone, and samidorphan, and their respective salts, but including the following:

10.39(4) Amend Iowa Code section 124.210(6) by adding the following new paragraph:

n. Serdexmethylphenidate.

10.39(5) Amend Iowa Code section 124.212(5) by adding the following new paragraph:

f. Lasmlandian [2,4,6-trifluoro-N-[(1-methyl)piperidine-4-carbonyl]pyridine-2-yl-benzamide].

10.39(6) Amend Iowa Code section 124.204(4) by adding the following new paragraphs:

av. methyl 2-(1-(4-fluorobutyl)-1H-indazole-3-carboxamido)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate. Other names: 4F-MDMB-BINACA, 4F-MDMB-BUTINACA.

aw. 1-(4-methoxyphenyl)-N-methylpropan-2-amine. Other names: para-methoxymethamphetamine, PMMA.

10.39(7) Amend Iowa Code section 124.204(6) by adding the following new paragraph:

i. 4,4’-Dimethylaminorex. Other names: 4,4’-DMAR; 4,5-dihydro-4-methyl-5-(4-methylphenyl)-2-oxazolamine; 4-methyl-5-(4-methylphenyl)-4,5-dihydro-1,3-oxazol-2-amine.

[ARC 5914C, IAB 9/22/21, effective 10/27/21; ARC 6074C, IAB 12/15/21, effective 1/1/22; ARC 6255C, IAB 3/23/22, effective 4/27/22]

657—10.40(124) Excluded and exempt substances. The Iowa board of pharmacy hereby excludes from all schedules the current list of “Excluded Nonnarcotic Products” identified in Title 21, CFR Part 1308, Section 22. With the exception of listed butalbital products, the board hereby excludes from all schedules the current list of “Exempted Prescription Products” described in Title 21, CFR Part 1308, Section 32. Copies of such lists may be obtained by written request to the board office at 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688.

[ARC 3345C, IAB 9/27/17, effective 11/1/17; ARC 4455C, IAB 5/22/19, effective 6/26/19]

657—10.41(124) Anabolic steroid defined. Anabolic steroid, as defined in Iowa Code section 126.2(2), includes any substance identified as such in Iowa Code section 124.208(6) or 126.2(2).

[ARC 3345C, IAB 9/27/17, effective 11/1/17]


657—10.43(124) Reporting discipline and criminal convictions. A registrant shall provide written notice to the board of any disciplinary or enforcement action imposed by any licensing or regulatory authority on any license or registration held by the registrant no later than 30 days after the final action. Discipline may include, but is not limited to, fine or civil penalty, citation or reprimand, probationary period, suspension, revocation, and voluntary surrender. A registrant shall provide written notice to the board of any criminal conviction of the registrant or of any owner that is related to the operation of the registered location no later than 30 days after the conviction. The term criminal conviction includes instances when the judgment of conviction or sentence is deferred.

[ARC 3345C, IAB 9/27/17, effective 11/1/17]

657—10.44(124) Discipline. Pursuant to 657—Chapter 36, the board may fine, suspend, revoke, or impose other disciplinary sanctions on a registration for any of the following:

1. Any violation of the federal Food, Drug, and Cosmetic Act or federal regulations promulgated under the Act.

2. Any conviction of a crime related to controlled substances committed by the registrant, or if the registrant is an association, joint stock company, partnership, or corporation, by any managing officer.
3. Refusing access to the registered location or registrant records to an agent of the board for the purpose of conducting an inspection or investigation.

4. Failure to maintain registration pursuant to 657—Chapter 10.

5. Any violation of Iowa Code chapter 124, 124B, 126, 155A, or 205, or any rule of the board, including the disciplinary grounds set forth in 657—Chapter 36.

These rules are intended to implement Iowa Code sections 124.201, 124.301 to 124.308, 124.402, 124.403, 124.501, 126.2, 126.11, 147.88, 155A.13, 155A.17, 155A.26, 155A.37, and 205.3.

Filed 9/29/71; amended 8/9/72, 12/15/72, 11/14/73, 8/14/74, 4/8/75
Filed 11/24/76, Notice 10/20/76—published 12/15/76, effective 1/19/77
Filed 11/9/77, Notice 8/24/77—published 11/30/77, effective 1/4/78
Filed 10/20/78, Notices 8/9/78, 9/6/78—published 11/15/78, effective 1/9/79
Filed 8/28/79, Notice 5/30/79—published 9/19/79, effective 10/24/79
Filed 2/12/81, Notice 12/24/80—published 3/4/81, effective 7/1/81
Filed 7/24/81, Notice 5/13/81—published 8/19/81, effective 9/23/81
Filed emergency 12/14/81—published 1/6/82, effective 1/6/82
Filed emergency 10/6/82—published 10/27/82, effective 10/27/82
Filed 6/16/83, Notice 5/11/83—published 7/6/83, effective 8/10/83
Filed 2/23/84, Notice 11/23/83—published 3/14/84, effective 4/18/84
Filed emergency 8/10/84—published 8/29/84, effective 8/10/84
Filed emergency 6/14/85—published 7/3/85, effective 6/14/85
Filed emergency 8/30/85—published 9/25/85, effective 9/6/85
Filed emergency 12/4/85—published 1/1/86, effective 12/5/85
Filed emergency 5/14/86—published 6/4/86, effective 5/16/86
Filed 5/14/86, Notice 4/9/86—published 6/4/86, effective 7/9/86
Filed 1/28/87, Notice 11/19/86—published 2/25/87, effective 4/1/87
Filed emergency 7/24/87—published 8/12/87, effective 7/24/87
Filed 8/5/87, Notice 6/3/87—published 8/26/87, effective 9/30/87
Filed emergency 1/21/88—published 2/10/88, effective 1/22/88
Filed emergency 8/5/88—published 8/24/88, effective 8/5/88
Filed emergency 10/13/88—published 11/2/88, effective 10/13/88
Filed emergency 5/16/89—published 6/14/89, effective 5/17/89
Filed emergency 9/12/89—published 10/4/89, effective 9/13/89
Filed 1/19/90, Notice 11/29/89—published 2/7/90, effective 3/14/90
Filed 8/31/90, Notice 6/13/90—published 9/19/90, effective 10/24/90
Filed emergency 1/29/91—published 2/20/91, effective 2/27/91
Filed 1/29/91, Notice 9/19/90—published 2/20/91, effective 3/27/91
Filed emergency 2/27/91—published 3/20/91, effective 2/27/91
Filed 4/26/91, Notice 2/20/91—published 5/15/91, effective 6/19/91
Filed emergency 5/10/91—published 5/29/91, effective 5/10/91
Filed 7/30/91, Notice 5/29/91—published 8/21/91, effective 9/25/91
Filed emergency 9/23/91—published 10/16/91, effective 9/23/91
Filed emergency 10/18/91—published 11/13/91, effective 10/21/91
Filed 3/12/92, Notice 1/8/92—published 4/1/92, effective 5/6/92
Filed 5/21/92, Notice 4/1/92—published 6/10/92, effective 7/15/92
Filed emergency 8/10/92—published 9/2/92, effective 8/10/92
Filed 10/22/92, Notice 9/2/92—published 11/11/92, effective 1/1/93
Filed 9/23/93, Notice 5/26/93—published 10/13/93, effective 11/17/93
Filed 3/22/95, Notice 11/9/94—published 4/12/95, effective 5/31/95
Filed 12/6/95, Notice 8/16/95—published 1/3/96, effective 2/7/96
Filed 11/19/97, Notice 10/8/97—published 12/17/97, effective 1/21/98
Filed 7/31/98, Notice 5/20/98—published 8/26/98, effective 9/30/98
Filed emergency 8/18/99—published 9/8/99, effective 8/18/99
Filed emergency 7/18/00—published 8/9/00, effective 7/18/00
Filed 8/14/02, Notice 6/12/02—published 9/4/02, effective 10/9/02
Filed emergency 12/13/02—published 1/8/03, effective 12/13/02
Filed emergency 7/16/04 after Notice 6/9/04—published 8/4/04, effective 7/16/04
Filed 10/22/04, Notice 3/31/04—published 11/10/04, effective 12/15/04
Filed emergency 5/3/05—published 5/25/05, effective 5/21/05
Filed emergency 6/30/05 after Notice 5/11/05—published 7/20/05, effective 7/1/05
Filed 8/9/05, Notice 5/25/05—published 8/31/05, effective 10/5/05
Filed 3/22/06, Notice 12/21/05—published 4/12/06, effective 5/17/06
Filed 3/22/06, Notice 1/18/06—published 4/12/06, effective 5/17/06
Filed 5/17/06, Notice 4/12/06—published 6/7/06, effective 7/12/06
Filed 2/7/07, Notice 10/25/06—published 2/28/07, effective 4/4/07
Filed 5/14/07, Notice 2/28/07—published 6/6/07, effective 7/11/07
Filed emergency 8/2/07—published 8/29/07, effective 8/2/07
Filed emergency 11/13/07 after Notice 8/29/07—published 12/5/07, effective 11/13/07
Filed ARC 7636B (Notice ARC 7448B, IAB 12/31/08), IAB 3/11/09, effective 4/15/09
Filed ARC 7906B, IAB 7/1/09, effective 6/22/09
Filed ARC 8172B (Notice ARC 7908B, IAB 7/1/09), IAB 9/23/09, effective 10/28/09
Filed Emergency ARC 8411B, IAB 12/30/09, effective 12/1/09
Filed ARC 8539B (Notice ARC 8269B, IAB 11/4/09), IAB 2/24/10, effective 4/1/10
Filed ARC 8892B (Notice ARC 8667B, IAB 4/7/10), IAB 6/30/10, effective 9/1/10
Filed Emergency ARC 8989B, IAB 8/11/10, effective 7/21/10
Filed Emergency ARC 9000B, IAB 8/11/10, effective 7/22/10
Filed Emergency ARC 9091B, IAB 9/22/10, effective 8/30/10
Filed ARC 9410B (Notice ARC 9196B, IAB 11/3/10), IAB 3/9/11, effective 4/13/11
Filed ARC 9912B (Notice ARC 9671B, IAB 8/10/11), IAB 12/14/11, effective 1/18/12
Filed ARC 0504C (Notice ARC 0351C, IAB 10/3/12), IAB 12/12/12, effective 1/16/13
Filed ARC 0749C (Notice ARC 0652C, IAB 3/20/13), IAB 5/29/13, effective 7/3/13
Filed Emergency ARC 0893C, IAB 8/7/13, effective 7/9/13
Filed Emergency ARC 1408C, IAB 4/2/14, effective 3/13/14
Filed ARC 1575C (Notice ARC 1407C, IAB 4/2/14), IAB 8/20/14, effective 9/24/14
Filed ARC 1787C (Notice ARC 1647C, IAB 10/1/14), IAB 12/10/14, effective 1/14/15
Filed ARC 2195C (Notice ARC 2064C, IAB 7/22/15), IAB 10/14/15, effective 11/18/15
Filed ARC 2407C (Notice ARC 2287C, IAB 12/9/15), IAB 2/17/16, effective 3/23/16
Filed ARC 2408C (Notice ARC 2285C, IAB 12/9/15), IAB 2/17/16, effective 3/23/16
Filed ARC 3100C (Notice ARC 2858C, IAB 12/7/16), IAB 6/7/17, effective 7/12/17
Filed ARC 3345C (Notice ARC 3136C, IAB 6/21/17), IAB 9/27/17, effective 11/1/17
Filed ARC 3743C (Notice ARC 3505C, IAB 12/20/17), IAB 4/11/18, effective 5/16/18
Filed ARC 3857C (Notice ARC 3506C, IAB 12/20/17), IAB 6/20/18, effective 7/25/18
Filed ARC 3859C (Notice ARC 3511C, IAB 12/20/17), IAB 6/20/18, effective 7/25/18
Filed ARC 3860C (Notice ARC 3701C, IAB 3/28/18), IAB 6/20/18, effective 7/25/18
Filed ARC 3984C (Notice ARC 3758C, IAB 4/25/18), IAB 8/29/18, effective 10/3/18
Filed Emergency ARC 4085C, IAB 10/24/18, effective 10/3/18
Filed ARC 4269C (Notice ARC 4086C, IAB 10/24/18), IAB 1/30/19, effective 3/6/19
[Filed ARC 4455C (Notice ARC 4290C, IAB 2/13/19), IAB 5/22/19, effective 6/26/19]
[Filed ARC 4580C (Notice ARC 4386C, IAB 4/10/19), IAB 7/31/19, effective 9/4/19]
[Filed ARC 4701C (Notice ARC 4570C, IAB 7/31/19), IAB 10/9/19, effective 11/13/19]
[Filed ARC 4797C (Notice ARC 4592C, IAB 8/14/19), IAB 12/4/19, effective 1/8/20]
[Filed ARC 4904C (Notice ARC 4692C, IAB 10/9/19), IAB 2/12/20, effective 3/18/20]
[Filed ARC 5096C (Notice ARC 4837C, IAB 1/1/20), IAB 7/15/20, effective 8/19/20]
[Filed ARC 5346C (Notice ARC 5155C, IAB 8/26/20), IAB 12/30/20, effective 2/3/21]
[Filed ARC 5347C (Notice ARC 5195C, IAB 9/23/20), IAB 12/30/20, effective 2/3/21]
[Filed ARC 5349C (Notice ARC 5114C, IAB 7/29/20), IAB 12/30/20, effective 2/3/21]
[Filed ARC 5541C (Notice ARC 5365C, IAB 12/30/20), IAB 4/7/21, effective 5/12/21]
[Filed ARC 5914C (Notice ARC 5705C, IAB 6/16/21), IAB 9/22/21, effective 10/27/21]
[Filed ARC 6074C (Notice ARC 5837C, IAB 8/11/21), IAB 12/15/21, effective 1/19/22]
[Filed ARC 6255C (Notice ARC 6082C, IAB 12/15/21), IAB 3/23/22, effective 4/27/22]
[Filed ARC 6330C (Amended Notice ARC 6179C, IAB 2/9/22; Notice ARC 5834C, IAB 8/11/21), IAB 6/1/22, effective 7/6/22]

◊ Two or more ARCs
1 Effective date delayed 70 days by the Administrative Rules Review Committee at its meeting held September 11, 1991.
CHAPTER 20
COMPOUNDING PRACTICES

657—20.1(124,126,155A) Purpose and scope. The requirements of this chapter apply to compounded preparations that are dispensed, distributed, or administered to an ultimate user in the state of Iowa, regardless of the location of the pharmacy or outsourcing facility where the preparation was compounded. This chapter applies to compounded preparations intended for humans and animals. In addition to the requirements in this chapter, all pharmacies and outsourcing facilities engaged in compounding shall comply with all applicable federal laws and regulations governing compounding and all applicable state laws, rules and regulations governing the practice of pharmacy. In the event the requirements in this chapter directly conflict with any federal law or regulation, the federal law or regulation shall supersede the requirements in this chapter. The requirements of 657—Chapter 16 apply to the compounding of radiopharmaceuticals. The requirements of 657—Chapter 41 apply to outsourcing facilities.

[ARC 2194C, IAB 10/14/15, effective 11/18/15; ARC 3238C, IAB 8/2/17, effective 9/6/17]

657—20.2(124,126,155A) Definitions. For purposes of this chapter, the following definitions apply:

“Anticipatory compounding” means the compounding of preparations in advance of the pharmacy’s receipt of patient-specific prescriptions.

“Batch preparation compounding” means anticipatory compounding, compounding preparations intended for multiple disbursements, or compounding preparations in a multiple-dose container for administration to more than one patient.

“Beyond-use date” means the date after which a compounded preparation should not be used, determined from the date that the preparation is compounded.

“Bulk drug substance” means any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug. The term does not include intermediates used in the synthesis of such substances.

“Compounding” means the combining, mixing, diluting, pooling, flavoring, or otherwise altering of a drug or bulk drug substance to create a drug. Compounding includes the preparation of drugs or devices in which all bulk drug substances and components are nonprescription products. Compounding does not include the use of a flavoring agent to flavor a drug pursuant to rule 657—20.13(124,126,155A), nor do it include mixing or reconstituting a drug according to the product’s manufacturer label.

“FDA” means the Food and Drug Administration of the U.S. Department of Health and Human Services.

“Flavoring agent” means a therapeutically inert, nonallergenic substance consisting of inactive ingredients that is added to a drug to improve the drug’s taste and palatability.

“NABP information sharing network” means the information sharing network developed by the National Association of Boards of Pharmacy that collects, assesses, and allows review and sharing of pharmacy compounding information as described in the Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products between the board and the United States Food and Drug Administration.

“Office use” means that a compounded product has been prepared and distributed to a practitioner for administration to a patient by the practitioner in the course of the practitioner’s professional practice. A compounded product distributed to a practitioner for “office use” shall not require a patient-specific prescription and may not be further distributed to another practitioner or dispensed to a patient for self-administration, except as provided in subrule 20.15(2).

“Outsourcing facility” or “facility” means any compounding facility that is registered as an outsourcing facility, as defined in 21 U.S.C. Section 353b, that distributes sterile compounded human drug products without a patient-specific prescription to an authorized agent or practitioner in this state.

“USP” means United States Pharmacopeia.

[ARC 2194C, IAB 10/14/15, effective 11/18/15; ARC 2559C, IAB 6/8/16, effective 7/13/16; ARC 3238C, IAB 8/2/17, effective 9/6/17; ARC 6076C, IAB 12/15/21, effective 1/19/22; ARC 6331C, IAB 6/1/22, effective 7/6/22]
657—20.3(124,126,155A) Nonsterile compounding. Iowa-licensed pharmacies that compound nonsterile preparations for ultimate users in the state of Iowa shall follow the current revision of USP Chapter 795 standards. Additional USP chapters incorporated by reference into USP Chapter 795 shall also be followed.

[ARC 2194C, IAB 10/14/15, effective 11/18/15]

657—20.4(124,126,155A) Sterile compounding. Iowa-licensed pharmacies that compound sterile preparations for ultimate users in the state of Iowa shall follow the current revision of USP Chapter 797 standards. Additional USP chapters incorporated by reference into USP Chapter 797 shall also be followed.

[ARC 2194C, IAB 10/14/15, effective 11/18/15]

657—20.5(126,155A) Delayed compliance. A pharmacy that cannot meet the requirements for full compliance with applicable USP chapters by the enforcement date established by USP shall not engage in compounding until the pharmacy is in full compliance with all requirements or the board has approved delayed compliance for the specific requirement or requirements requested. The board may establish a committee to grant or deny requests for delayed compliance. The board or committee may grant a request for delayed compliance only if the pharmacy can demonstrate progress toward full compliance and adequate protection of the public health, safety, and welfare during the period of delayed compliance. The board or committee may only grant a request for delayed compliance of specific requirements in applicable USP chapters for a maximum of 18 months.

[ARC 2194C, IAB 10/14/15, effective 11/18/15; ARC 3238C, IAB 8/2/17, effective 9/6/17; ARC 4454C, IAB 5/22/19, effective 6/26/19]

657—20.6(126,155A) Compounding standards for outsourcing facilities. An FDA-registered outsourcing facility shall be properly licensed in Iowa pursuant to 657—Chapter 41 and shall follow the FDA's current good manufacturing practices (cGMPs) for outsourcing facilities when compounding preparations for use in Iowa.

[ARC 2194C, IAB 10/14/15, effective 11/18/15; ARC 3238C, IAB 8/2/17, effective 9/6/17]

657—20.7 and 20.8 Reserved.

657—20.9(124,155A) Prescriber/patient/pharmacist relationship. All compounded preparations shall be dispensed pursuant to a patient-specific prescription unless the compounded preparation is distributed pursuant to rule 657—20.15(124,126,155A) or 657—20.16(124,126,155A). A prescription for a compounded preparation shall be authorized by the prescriber for a specific patient. Prescriptions for all compounded preparations shall be maintained on file at the dispensing pharmacy.

[ARC 2194C, IAB 10/14/15, effective 11/18/15]

657—20.10(126,155A) Anticipatory compounding.

20.10(1) Outsourcing facilities. Outsourcing facilities are authorized to engage in anticipatory compounding. Outsourcing facilities are not required to obtain patient-specific prescriptions in order to distribute compounded preparations.

20.10(2) Pharmacies. Pharmacies may engage in anticipatory compounding only if the anticipatory compounding is based on a history of receiving valid prescriptions generated solely within an established prescriber/patient/pharmacist relationship, so long as each compounded preparation is dispensed pursuant to a patient-specific prescription.

[ARC 2194C, IAB 10/14/15, effective 11/18/15]

657—20.11(126,155A) Prohibition on resale of compounded preparations. The sale of compounded preparations to other pharmacies, prescribers, or entities, except as explicitly authorized by this chapter, is considered manufacturing.

[ARC 2194C, IAB 10/14/15, effective 11/18/15; ARC 3238C, IAB 8/2/17, effective 9/6/17]
657—20.12(126,155A) Compounding copies of an approved drug. A pharmacy or outsourcing facility may only compound preparations that are essentially copies of approved drugs if the compounded preparation is changed to produce for an individual patient a clinically significant difference to meet a medical need as determined and authorized by the prescriber. A pharmacy or outsourcing facility may compound a preparation that is essentially a copy of an approved drug if the approved drug is identified as currently in shortage on the FDA drug shortages database published on the FDA website, www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

20.12(1) Essentially a copy. The board may consider the existence of the following factors as an indication that a compounded preparation is essentially a copy of an approved drug:

a. The compounded preparation has the same active pharmaceutical ingredient(s) as the commercially available drug product;

b. The active pharmaceutical ingredient(s) has the same, similar, or an easily substitutable dosage strength; and

c. The commercially available drug product can be used by the same route of administration as prescribed for the compounded preparation.

20.12(2) Clinically significant difference. The prescription for a compounded preparation that is essentially a copy of an approved drug shall clearly indicate the relevant change and the significant clinical difference produced for the patient. A prescription that identifies only a patient name and compounded preparation formulation is insufficient documentation for a pharmacy or outsourcing facility to rely upon to conclude that the prescriber made a determination regarding a clinically significant difference.

[ARC 2194C, IAB 10/14/15, effective 11/18/15; ARC 3238C, IAB 8/2/17, effective 9/6/17]

657—20.13(124,126,155A) Use of flavoring agents. A flavoring agent may be added to a drug at the discretion of the pharmacist or upon the request of the prescriber, the patient, or the patient’s agent. The pharmacist may add flavoring agents not to exceed 5 percent of the total volume of the drug to which the flavoring agents are added. The pharmacist shall label the flavored drug with a beyond-use date no greater than 14 days past the date the flavoring agent is added if the drug is required to be stored in a refrigerator. A different beyond-use date or alternate storage conditions may be indicated if such variation is supported by peer-reviewed medical literature. The pharmacist shall electronically or manually document that a flavoring agent was added to a drug, and such documentation shall be made available for inspection and copying upon the request of the board or an agent of the board.

[ARC 2194C, IAB 10/14/15, effective 11/18/15]

657—20.14 Reserved.

657—20.15(124,126,155A) Compounding for office use.

20.15(1) Human compounded preparations. Only an FDA-registered outsourcing facility properly licensed in Iowa pursuant to 657—Chapter 41 may distribute to a practitioner for office use human compounded preparations without a patient-specific prescription.

20.15(2) Veterinary compounded preparations. Veterinary compounded preparations may be sold to a practitioner for office use if the preparations are compounded by an Iowa-licensed pharmacy or outsourcing facility and sold directly to the practitioner by the pharmacy or outsourcing facility. Veterinary compounded preparations sold to a practitioner for office use may be dispensed to the owner of a veterinary patient to treat an immediate medical need when timely access to a patient-specific supply of compounded medication is not available, no commercially available product can meet the need of the patient, lack of treatment will likely result in patient harm, and the supply does not exceed 14 days.

20.15(3) Office use. Compounded preparations distributed for office use pursuant to subrule 20.15(1) or 20.15(2) and in accordance with the labeling requirements of subrule 20.15(4) do not require a patient-specific prescription but do require that the compounded preparation be administered to a patient in the course of the practitioner’s professional practice. Compounded preparations distributed
for office use pursuant to this rule shall not be further distributed to other practitioners or dispensed to a patient for self-administration, except as provided in subrule 20.15(2).

20.15(4) Labeling. Compounded preparations for office use, in addition to the labeling requirements specified in rule 657—20.19(124,126,155A), shall include on the prescription label the practitioner’s name in place of the patient’s name. The label shall state “For Office Use Only—Not for Resale.” If the sterility or integrity of the compounded preparation cannot be maintained after the initial opening of the container, the label shall state “Single-Dose Only.”

[ARC 2194C, IAB 10/14/15, effective 11/18/15; ARC 2559C, IAB 6/8/16, effective 7/13/16; ARC 3238C, IAB 8/2/17, effective 9/6/17; ARC 6331C, IAB 6/1/22, effective 7/6/22]

657—20.16(124,126,155A) Compounding for hospital use. Compounded preparations distributed or dispensed to a hospital or hospital pharmacy pursuant to this rule shall be administered to an individual patient in the hospital.

20.16(1) By an FDA-registered outsourcing facility. Only an FDA-registered outsourcing facility properly licensed in Iowa pursuant to 657—Chapter 41 may distribute human compounded preparations to a hospital or hospital pharmacy in the absence of a patient-specific prescription. The compounded preparation shall be labeled in compliance with subrule 20.19(3).

20.16(2) By a pharmacy that is not an FDA-registered outsourcing facility. Human compounded preparations that are not compounded at an FDA-registered outsourcing facility may be dispensed to a hospital or hospital pharmacy by an Iowa-licensed pharmacy pursuant to a prescriber’s authorization for administration to a specific patient. The compounded preparation shall be labeled in compliance with subrule 20.19(2).

[ARC 2194C, IAB 10/14/15, effective 11/18/15; ARC 3238C, IAB 8/2/17, effective 9/6/17]

657—20.17 and 20.18 Reserved.

657—20.19(124,126,155A) Labeling. The label, or attached auxiliary labeling if necessary, affixed to the container of any compounded preparation dispensed or distributed into or within Iowa shall contain at least the information identified in one of the following subrules, as applicable.

20.19(1) General pharmacy or outpatient dispensing. The label shall meet the labeling requirements of 657—subrule 6.10(1) and shall include the following additional information:

a. The name and concentration of each active ingredient.
b. The date that the preparation was compounded.
c. The beyond-use date of the compounded preparation.
d. Special storage and handling instructions, if applicable.
e. The statement “COMPOUNDED PREPARATION” or a reasonable comparable alternative statement that prominently identifies the drug as a compounded preparation.
f. If the compounded preparation is sterile, the word “STERILE.”
g. If the compounded preparation was prepared from batch preparation compounding, the batch identification or control number.

20.19(2) Hospital pharmacy or inpatient administration. The label shall meet the labeling requirements of 657—subrule 22.1(3) and shall include the following additional information:

a. The name and concentration of each active ingredient.
b. The date that the preparation was compounded.
c. The beyond-use date of the compounded preparation.
d. If the compounded preparation was prepared from batch preparation compounding, the batch identification or control number.
e. Special storage and handling instructions, if applicable.

20.19(3) Outsourcing facility distribution or dispensing. The label, or auxiliary labeling if necessary, shall include the following information:

a. The statement “THIS IS A COMPOUNDED DRUG” or a reasonable comparable alternative statement that prominently identifies the drug as a compounded preparation.
b. The name, address, and telephone number of the outsourcing facility that compounded the preparation.

c. The established name of the preparation.

d. The dosage form and strength.

e. The quantity of the preparation.

f. The date that the preparation was compounded.

g. The beyond-use date of the compounded preparation.

h. Storage and handling instructions.

i. The lot or batch identification or control number.

j. The national drug code number, if available.

k. The statement “Not for resale” and, if the preparation is dispensed or distributed other than pursuant to a patient-specific prescription, the statement “OFFICE USE ONLY.”

l. The following additional information, which can be included on the labeling of a container (such as a plastic bag containing individual product syringes) from which individual units of the drug are removed for dispensing or for administration if there is not space on the label for such information:

1) Directions for use including, as appropriate, dosage and administration;

2) A list of the active and inactive ingredients, identified by established name and quantity or proportion of each ingredient;

3) FDA contact information (www.fda.gov/medwatch and 1-800-FDA-1088 or successor website or telephone number) to facilitate adverse event reporting.

m. If the preparation is compounded pursuant to a prescription for a specific patient, the label shall also include the label requirements in 657—subrule 6.10(1).

n. If the preparation is compounded for office use, the label shall also include the label requirements in subrule 20.15(4).

[ARC 2194C, IAB 10/14/15, effective 11/18/15; ARC 3238C, IAB 8/2/17, effective 9/6/17]

657—20.20(126,155A) Labeling for batch preparation compounding. Compounded preparations resulting from batch preparation compounding shall be labeled with the following information until such time as the preparations are labeled pursuant to rule 657—20.19(124,126,155A) for distribution to hospitals or practitioners or for dispensing or administration to patients:

1. The date that the preparation was compounded.

2. Compounded preparation name or formula.

3. Dosage form.

4. Strength.

5. Quantity per container.

6. Unique internal batch identification or control number.

7. Beyond-use date.

8. Special storage and handling instructions, if applicable.

[ARC 2194C, IAB 10/14/15, effective 11/18/15]

657—20.21 and 20.22 Reserved.

657—20.23(124,126,155A) Records. All records required by this chapter shall be retained as original records of the pharmacy or outsourcing facility and shall be readily available for inspection and photocopying by agents of the board or other authorized authorities for at least two years following the date of the record. Records shall allow for the identification of all ingredients used in compounding, all personnel involved in compounding, and all personnel involved in reviewing compounded preparations. The pharmacy or outsourcing facility shall maintain records documenting the disbursements from each batch of a compounded preparation.

[ARC 2194C, IAB 10/14/15, effective 11/18/15]

657—20.24(155A) Annual reporting of interstate distribution of compounded preparations.
20.24(1) No later than April 1, 2022, and annually thereafter, each licensed pharmacy located in
Iowa that distributed compounded preparations for human use interstate in the previous calendar year
shall report compounding data to the NABP information sharing network.

20.24(2) Compounding data may include, but not be limited to:

a. Whether the pharmacy engaged in the following activities during the identified calendar year:
   (1) Sterile human drug compounding;
   (2) Nonsterile human drug compounding;
   (3) Patient-specific compounding; and
   (4) Non-patient-specific compounding.

b. The number of prescription orders for compounded human drugs sent out from the pharmacy.

c. The number of prescription orders for compounded human drugs dispensed at the pharmacy.

(d) The total number of prescription orders for compounded human drugs distributed interstate.

e. The number of prescription orders for sterile compounded human drugs distributed interstate.

f. The names of states into which the pharmacy distributed compounded human drugs during the
   identified calendar year.

g. Whether compounded human drugs are distributed without patient-specific prescriptions.

[ARC 6076C, IAB 12/15/21, effective 1/19/22]

These rules are intended to implement Iowa Code sections 124.302, 124.303, 124.306, 124.308,

[Filed 10/6/95, Notice 8/16/95—published 10/25/95, effective 11/29/95]
[Filed 12/10/96, Notice 8/28/96—published 1/1/97, effective 2/5/97]
[Filed 2/27/97, Notice 1/1/97—published 3/26/97, effective 4/30/97]
[Filed 10/24/02, Notice 7/24/02—published 11/13/02, effective 12/18/02]
[Filed 3/11/04, Notice 8/6/03—published 3/31/04, effective 5/5/04]
[Filed 6/2/05, Notice 1/19/05—published 6/22/05, effective 7/27/05]
[Filed 2/7/07, Notice 10/25/06—published 2/28/07, effective 4/4/07]
[Filed 3/5/08, Notice 12/5/07—published 3/26/08, effective 4/30/08]
[Filed ARC 0596C (Notice ARC 0374C, IAB 10/3/12), IAB 2/6/13, effective 3/13/13]
[Filed ARC 2194C (Notice ARC 1979C, IAB 4/29/15), IAB 10/14/15, effective 11/18/15]
[Filed ARC 2559C (Notice ARC 2418C, IAB 2/17/16), IAB 6/8/16, effective 7/13/16]
[Filed ARC 3238C (Notice ARC 3038C, IAB 4/26/17), IAB 8/2/17, effective 9/6/17]
[Filed ARC 4454C (Amended Notice ARC 4172C, IAB 12/19/18; Notice ARC 3978C, IAB 8/29/18),
   IAB 5/22/19, effective 6/26/19]
[Filed ARC 6076C (Notice ARC 5833C, IAB 8/11/21), IAB 12/15/21, effective 1/19/22]
[Filed ARC 6331C (Notice ARC 6178C, IAB 2/9/22), IAB 6/1/22, effective 7/6/22]
CHAPTER 634
DRIVER EDUCATION

761—634.1(321) Information and location. Applications, forms and information regarding this chapter are available by mail from the Motor Vehicle Division, Iowa Department of Transportation, P.O. Box 9204, Des Moines, Iowa 50306-9204; in person at 6310 SE Convenience Blvd., Ankeny, Iowa; by telephone at (515)244-8725; by facsimile at (515)239-1837; or on the department’s website at www.iowadot.gov.

[ARC 4909C, IAB 2/12/20, effective 3/18/20; ARC 6062C, IAB 12/1/21, effective 1/5/22]

761—634.2(321) Definitions.

“Behind-the-wheel instruction” means the street or highway driving instruction component of an approved driver education course.

“Instructor,” for purposes of this chapter, means a person certified to provide behind-the-wheel instruction.

“Laboratory instruction” includes instruction received by a student while the student is in the driver education vehicle or adjacent to it as referred to in paragraphs 634.4(2)”c” and 634.4(2)”d” and may also include range or simulation as referred to in paragraphs 634.4(2)”h” and 634.4(2)”i.”

“Serious injury” means the same as defined in Iowa Code section 702.18.

“Teacher” means the same as defined in Iowa Code section 272.1.

[ARC 4909C, IAB 2/12/20, effective 3/18/20]

761—634.3 Reserved.

761—634.4(321) Driver education course standards and requirements.

634.4(1) Course approval. Any school district, area education agency, merged area school, other agency or person planning to offer a driver education course must receive course approval, which includes approval of all teachers and instructors listed on the application, from the department prior to the beginning of the first class that is offered and annually thereafter. The agency or institution or person shall apply for course approval in a manner determined by the department. Course approval must be renewed annually. The approval is valid for one calendar year or a remaining calendar year and expires on December 31. The application for course renewal shall be submitted to the department within 60 days of the expiration date, unless otherwise approved by the department.

634.4(2) Course requirements. Driver education courses provided by approved programs must comply with the following:

a. Schools shall provide for each student a minimum of 1800 minutes in classroom instruction, plus 360 minutes in supervised laboratory instruction, exclusive of observation time, in a dual-control motor vehicle.

b. Each student shall be scheduled to receive classroom or laboratory instruction each week of the course. Except upon showing of good cause, laboratory instruction shall not conclude later than 45 days after classroom instruction has been completed. When the driver education course provider determines there is good cause, the laboratory instruction shall not conclude later than 90 days after classroom instruction has been completed. For the purpose of this paragraph, “good cause” means an unanticipated event causing a delay in the student’s ability to complete the laboratory instruction if the event is beyond the student’s control.

c. Behind-the-wheel instruction shall be limited to a maximum of 30 minutes per student per session and a maximum of 60 minutes in a single day.

d. Two or more students shall be scheduled for all behind-the-wheel instruction to ensure that appropriate observation time is experienced.

e. Routine maintenance of motor vehicles to maximize energy efficiency and safety shall be included in classroom instruction.

f. Operation of motor vehicles to maximize energy efficiency and safety shall be included in classroom instruction.
g. Each school district shall provide students who are absent from instruction an opportunity to make up a reasonable amount of time and coursework.

h. When driving simulators are used for part of the behind-the-wheel driving experience, four hours of simulator experience shall be considered equal to one hour of behind-the-wheel driving in the car. However, in addition to simulator time, a minimum of three hours of on-street, behind-the-wheel driving must be completed.

i. When driving ranges are used in driver education courses, two hours of range experience shall be considered equal to one hour of on-street, behind-the-wheel driving. However, in addition to range time, a minimum of three hours of on-street, behind-the-wheel driving must be completed.

j. Motor vehicles which are designed primarily for carrying nine or fewer occupants, excluding motorcycles and mopeds, are the only motor vehicles approved for use in driver education courses, and each shall be equipped with a dual control. In addition, all driver education vehicles shall have an inside rearview mirror and an outside rearview mirror mounted on each side of the vehicle.

k. The driver education teacher or instructor shall verify at the beginning of each course that each student possesses a valid instruction permit or driver’s license. Each student shall be responsible for possessing an instruction permit or driver’s license throughout all laboratory instruction and report any suspension, revocation or cancellation of the instruction permit or driver’s license to the driver education teacher or instructor prior to attending laboratory instruction.

634.4(3) Experimental program. Approval of an experimental program may be granted by the department if based on student or school district need for improved instruction. The maximum duration of an experimental program shall be three years. Annual documentation of the effectiveness of instruction is required and must be submitted to the department subsequent to program completion. [ARC 4909C, IAB 2/12/20, effective 3/18/20; ARC 6337C, IAB 6/1/22, effective 7/6/22]

761—634.5 Reserved.

761—634.6(321) Instructor qualifications, application and certification.

634.6(1) Behind-the-wheel instructor qualifications. To qualify to provide behind-the-wheel instruction, the person must:

a. Hold a valid driver’s license that permits unaccompanied driving, other than a motorized bicycle license or a temporary restricted license.

b. Have a clear driving record for the previous two years. A clear driving record means the person has:

(1) Not been identified as a candidate for driver’s license suspension under the habitual violator provisions of rule 761—615.13(321) or the serious violation provisions of rule 761—615.17(321).

(2) No driver’s license suspensions, revocations, denials, cancellations, disqualifications or bars.

(3) Not committed an offense that would result in driver’s license suspension, revocation, denial, cancellation, disqualification or bar.

(4) No record of a contributive motor vehicle accident that caused the death or serious injury of another person.

(5) No record of two or more contributive motor vehicle accidents in a two-year period.

c. Meet the requirements for either a licensed teacher in 282—subrule 13.28(4) or a certified behind-the-wheel instructor in this chapter.

634.6(2) Behind-the-wheel instructor’s certification requirements. Except as otherwise provided in this chapter, the following requirements shall apply to a behind-the-wheel instructor:

a. An applicant for an initial behind-the-wheel instructor’s certification or a renewal shall apply to the department in a manner determined by the department.

(1) If the application is for an initial behind-the-wheel instructor’s certification, instructor approval is valid for a calendar year or the remainder of a calendar year. The instructor approval expires on December 31 but remains valid for an additional 30 days after the expiration date.

(2) If the application is to renew a behind-the-wheel instructor’s certification, a person shall do all of the following:
1. Apply to the department annually. Instructor approval is valid for a calendar year or the remainder of a calendar year. The instructor approval expires on December 31 but remains valid for an additional 30 days after the expiration date. An application for renewal of instructor approval shall be submitted within 60 days of the expiration date, unless otherwise approved by the department.

2. Provide behind-the-wheel instruction for a minimum of 12 clock hours during each calendar year.

b. Beginning January 1, 2021, a person shall complete at least one state-sponsored or state-approved behind-the-wheel instructor refresher course biennially. The state-sponsored or state-approved course may include electronic completion or remote attendance options, as approved by the department. The department may develop a special course for licensed teachers or peace officers who qualify to provide behind-the-wheel instruction under subrule 634.6(3) or 634.6(5), which shall be reserved only for licensed teachers or peace officers who qualify as behind-the-wheel instructors.

c. Upon certification, but prior to providing behind-the-wheel instruction, the person shall:

   (1) Authorized by the Iowa board of educational examiners to provide behind-the-wheel driving instruction.

   (2) Employed by a public or licensed commercial or private provider of the approved driver education course.

634.6(3) Instructor’s certification for licensed teachers. A teacher licensed by the Iowa board of educational examiners as provided in 282—subrule 13.28(4) shall be included as an approved instructor on an annual driver education course approval as referenced in subrules 634.4(1) and 634.8(1), and except for the requirements in paragraphs 634.6(2) “a” and 634.6(2) “c,” a teacher shall meet the requirements in subrule 634.6(2) to be certified by the department to provide behind-the-wheel instruction.

634.6(4) Instructor application and certification for a teacher with an expired teacher’s license. A teacher who holds an expired initial, standard, exchange, or master educator license with an endorsement for driver education as provided in 282—subrule 13.28(4) shall meet the requirements in subrule 634.6(2) to be certified by the department to provide behind-the-wheel instruction.

634.6(5) Instructor application and certification for active peace officers and retired peace officers.

   a. A person who is an active peace officer or a retired peace officer as referenced in Iowa Code section 321.178 shall do all of the following to be certified by the department to provide behind-the-wheel instruction:

      (1) Be at least 25 years of age.

      (2) Submit Form 431233 certifying the person’s status as an active or retired peace officer.

      (3) Meet all other requirements of subrule 634.6(2), except peace officers or retired peace officers who otherwise qualify under this subrule are not required to meet the requirement of subparagraph 634.6(2) “c” (1).

   b. A retired peace officer is only required to submit Form 431233, required under paragraph 634.6(5) “a,” to the department once unless the form is invalid or not accepted by the department.

634.6(6) Instructor application and certification for persons other than licensed teachers, peace officers or retired peace officers.

   a. A person who is not licensed by the Iowa board of educational examiners to provide classroom driver education as provided in 282—subrule 13.28(4), who does not hold an expired teacher’s license as referenced in subrule 634.6(4), or who is not a peace officer or a retired peace officer as referenced in Iowa Code section 321.178, shall do all of the following to be certified by the department to provide behind-the-wheel instruction:

      (1) Be at least 25 years of age.

      (2) Meet the requirements in subrule 634.6(2), except that a person certified under this subrule shall complete the instructor refresher course referenced in paragraph 634.6(2) “b” annually until January 1, 2021, and thereafter shall complete the course biennially.

      (3) Have successfully completed the instructor preparation requirements of this subrule, as evidenced by written attestations on a form provided by the department from both the classroom instructor and behind-the-wheel observer. The person seeking a behind-the-wheel certification must
apply to the department within 12 months of completion of the instructor preparation course. The department-approved instructor preparation course shall:

1. Consist of 24 clock hours of classroom instruction and 12 clock hours of observed behind-the-wheel instruction.

2. Include, at a minimum, classroom instruction on topics including the psychology of the young driver, behind-the-wheel teaching techniques, and driving route selection. Classroom instruction shall be delivered by staff from a driver education teacher preparation program that is approved by the Iowa board of educational examiners. The duration of a classroom instruction section shall not exceed four hours. Video-conferencing may be used for course delivery.

3. Include observation of behind-the-wheel instruction provided by a person licensed to teach driver education who is specially trained by a driver education teacher preparation program that is approved by the Iowa board of educational examiners and that is designed to observe, coach, and evaluate behind-the-wheel instructor candidates. The duration of a behind-the-wheel session shall not exceed four hours. A dual-controlled motor vehicle must be used.

   b. Reserved.

634.6(7) Behind-the-wheel certification—reissuance.

   a. A person whose behind-the-wheel certification has expired and is past the renewal period may be reissuued a behind-the-wheel certification without having to retake the behind-the-wheel instructor preparation course only if the person meets all of the following criteria:

      (1) The person held a valid behind-the-wheel certification within the two years immediately preceding the application.

      (2) The person provided a minimum of 12 clock hours of behind-the-wheel instruction within the two years immediately preceding the application.

      (3) The person completed at least one state-sponsored or state-approved behind-the-wheel instructor refresher course within the two calendar years immediately preceding the application unless otherwise exempt under this chapter.

      (4) The person completed a minimum of 12 clock hours shadowing a teacher licensed by the Iowa board of educational examiners as provided in 282—subrule 13.28(4) through a department-approved driver education program within 90 days immediately preceding the application.

   b. Upon certification, but prior to providing behind-the-wheel instruction, the person shall do all of the following:

      (1) Be authorized by the Iowa board of educational examiners to provide behind-the-wheel driving instruction unless otherwise exempt under this chapter.

      (2) Be employed by a public or licensed commercial or private provider of the approved driver education course and work under the supervision of a person licensed by the Iowa board of educational examiners as provided in 282—subrule 13.28(4).

761—634.7(321) Instructor disqualification, investigation and cancellation.

634.7(1) Disqualifications. A person shall be disqualified by the department from certification as a behind-the-wheel driving instructor for any of the reasons for which the executive director of the Iowa board of educational examiners would deny an application for licensure, certification or authorization as provided in rule 282—11.35(272).

634.7(2) Investigation. The department may investigate an applicant for a behind-the-wheel instructor’s certification or an instructor to determine if the applicant or instructor meets the requirements for certification. The investigation may include but is not limited to an inquiry into the applicant’s or instructor’s criminal history from the department of public safety.

634.7(3) Cancellation. The department shall cancel the behind-the-wheel instructor’s certification of an individual who no longer qualifies under this chapter.

761—634.8(321) Private and commercial driver education schools. The department licenses private and commercial driver education schools as follows:
634.8(1) **Course approval.** Before becoming licensed, a driver education school must receive course approval, which includes approval of all teachers and instructors listed on the application, from the department prior to the beginning of the first class that is offered and annually thereafter. Behind-the-wheel instruction must be provided by a person who meets the instructor requirements in rule 761—634.6(321). Evidence of the approvals and certifications must be submitted to the department upon application for a license, upon renewal of a license, and upon reinstatement of a license following cancellation.

634.8(2) **Application and fees.** Application for license issuance or renewal shall be made to the department in a manner determined by the department. The fee for a license or the renewal of a license is $25. The fee must be paid by cash, money order or check, unless the department approves payment of the fee by electronic means. A money order or check must be for the exact amount and should be made payable to the Treasurer, State of Iowa, or the Department of Transportation.

634.8(3) **Issuance and renewal.** A license to teach driver education shall be issued for a calendar year or remainder of a calendar year. The license expires on December 31 but remains valid for an additional 30 days after the expiration date. The application for renewal shall be submitted to the department within 60 days of the expiration date, unless otherwise approved by the department.

634.8(4) **Cancellation.** A license to teach driver education shall be canceled if the course, teacher, or instructor is no longer approved or the person providing only behind-the-wheel instruction for driver education is no longer certified by the department and authorized by the Iowa board of educational examiners.

[ARC 4909C, IAB 2/12/20, effective 3/18/20]

761—634.9 and 634.10 **Reserved.**

761—634.11(321) **Driver education—teaching parent.** As an alternative to a driver education course offered by a course provider approved under rule 761—634.4(321), a teaching parent may instruct a student in an approved course of driver education.

634.11(1) **Definitions.** As used in this rule:

“**Approved course**” means a driver education curriculum approved by the department that meets the requirements of Iowa Code section 321.178A and is appropriate for teaching-parent-directed driver education and related behind-the-wheel instruction.

“**Clear driving record**” means the person currently and during the prior two-year period has not been identified as a candidate for suspension or revocation of a driver’s license under the habitual offender or habitual violator provisions of rule 761—615.9(321) or rule 761—615.13(321); is not subject to a driver’s license suspension, revocation, denial, cancellation, disqualification, or bar; and has no record of a conviction for a moving traffic violation determined to be the cause of a motor vehicle accident.

“**Course vendor**” means a third-party vendor that makes available commercially an approved course.

“**Student**” means a person between the ages of 14 and 21 years who is within the custody and control of the teaching parent and who holds a valid Iowa noncommercial instruction permit.

“**Teaching parent**” means the same as defined in Iowa Code section 321.178A.

634.11(2) **Reserved.**

634.11(3) **Instruction by a teaching parent.**

a. A teaching parent shall instruct the student using an approved course.

b. The teaching parent shall select the course to be used from the list of approved courses posted on the department’s website and shall purchase the course directly from the applicable course vendor.

c. No person shall provide driver education as a teaching parent unless the person meets the definition of a teaching parent, and the department shall not recognize driver education that was:

(1) Provided by a person who does not meet the definition of a teaching parent.

(2) Provided to a person who is not a student as defined in subrule 634.11(1).

(3) Offered under a course other than an approved course.

634.11(4) **Course completion—certificate of completion.**
a. Upon the student’s completion of an approved course, the teaching parent shall apply for a certificate of completion on behalf of the student. The teaching parent shall provide evidence showing the student’s completion of an approved course and substantial compliance with the requirements of Iowa Code section 321.178A, by affidavit signed by the teaching parent on a form provided by the department. The teaching parent shall include with the application all documentation, statements, certifications, and logs required by Iowa Code section 321.178A. The application and all required documentation, statements, certifications, and logs shall be submitted to the motor vehicle division.

b. The department shall review the application and evidence submitted and shall deny certification of completion if:
   (1) The course was not conducted by a person meeting the definition of a teaching parent for the student for whom certification is sought.
   (2) The application does not properly identify a student eligible to be instructed in driver education by the teaching parent.
   (3) The application and evidence do not demonstrate the student’s successful completion of an approved course.
   (4) The application and evidence do not include all documentation, statements, certifications, and logs required by Iowa Code section 321.178A in adequate and proper form and content.
   (5) The department has determined that the application should be rejected for any reason listed in Iowa Code section 321.13.

c. If the application is denied, the department shall issue a letter of denial to the teaching parent explaining the reason or reasons for the denial.

d. If the application is approved, the department shall issue a certificate of completion to the student identified in the application. A certification of completion issued by the department under this subrule shall constitute proof of successful completion of an Iowa-approved course in driver education but shall not be grounds for waiver of a driving test under 761—subrule 604.31(2).

634.11(5) Course approval.

a. For a course to become an approved course under Iowa Code section 321.178A, a vendor of a driver education curriculum shall submit an application on a form provided by the department to the motor vehicle division, along with a copy of all proposed curriculum materials. A vendor offering an electronic curriculum may provide a uniform resource locator (URL) for the proposed electronic materials.

b. To be designated as an approved course, the curriculum submitted must, at a minimum, meet the requirements of Iowa Code section 321.178A, be appropriate for teaching-parent-directed driver education and related street or highway instruction, and meet or exceed the required content set forth in the Appendix to this rule.

c. The department shall review the application and proposed curriculum and shall issue a letter of denial to the course vendor explaining the reason or reasons for denial if the proposed curriculum does not meet the requirements for an approved course.

d. If the proposed curriculum is approved, the department shall issue a certificate of approval to the vendor designating the curriculum as an approved course and shall list the approved course on the department’s website. Course approval will be issued for one calendar year or for the remainder of a calendar year. The approval expires on December 31 and must be renewed annually by the submission of an application on a form provided by the department and all required materials as set forth in this subrule at least 60 days prior to the expiration date, unless otherwise approved by the department.

These rules are intended to implement Iowa Code sections 321.178, 321.178A, 321.180B and 321.194.

[Filed 3/10/04, Notice 2/4/04—published 3/31/04, effective 5/5/04]
[Filed 10/11/06, Notice 8/30/06—published 11/8/06, effective 12/13/06]
[Filed 12/12/07, Notice 11/7/07—published 1/2/08, effective 2/6/08]
[Filed ARC 1612C (Notice ARC 1526C, IAB 7/9/14), IAB 9/3/14, effective 10/8/14]
[Filed ARC 4909C (Notice ARC 4771C, IAB 11/20/19), IAB 2/12/20, effective 3/18/20]
[Filed ARC 6062C (Notice ARC 5922C, IAB 9/22/21), IAB 12/1/21, effective 1/5/22]
[Filed ARC 6337C (Notice ARC 6278C, IAB 4/6/22), IAB 6/1/22, effective 7/6/22]
Appendix to Rule 761—634.11(321)

To be designated as an approved course, a curriculum must, at a minimum, meet the requirements of Iowa Code section 321.178A, be appropriate for teaching-parent-directed driver education and related street or highway instruction, and meet or exceed the required content listed below:

1. Duration and required content. The course must provide for both classroom and behind-the-wheel instruction. As used in this rule, “classroom instruction” means instruction provided by a teaching parent in a private setting using printed or electronic course materials, and “behind-the-wheel instruction” means street or highway driving instruction provided by a teaching parent or a person who is qualified to provide street or highway driving instruction pursuant to Iowa Code section 321.178 in a motor vehicle operated by the student.
   a. Classroom instruction shall include all of the following:
      i. Instruction concerning distracted driving and substance abuse.
      ii. Instruction concerning railroad crossing safety.
      iii. Instruction relating to becoming an organ donor under the revised uniform anatomical gift Act as provided in Iowa Code chapter 142C.
      iv. Instruction providing awareness about sharing the road with pedestrians, bicycles and motorcycles.
   b. Behind-the-wheel instruction shall consist of at least 40 hours of street or highway driving including 4 hours of driving after sunset and before sunrise while accompanied by the teaching parent or a person who is qualified to provide street or highway driving instruction pursuant to Iowa Code section 321.178.

2. Required topics. The course may follow any format the vendor determines, provided all of the following topics are properly and adequately covered, as detailed in the course application form provided by the department:
   a. Traffic law – classroom instruction
      i. Introduction to driver education and driving laws and privileges.
      ii. Understanding your license to drive.
      iii. Right-of-way.
      iv. Traffic control devices.
      v. Controlling traffic flow.
      vi. Alcohol and other drugs.
      vii. Cooperating with other roadway users.
   b. Driver preparation – classroom and behind-the-wheel instruction
      i. Pre-drive tasks.
      ii. Occupant protection.
      iii. Symbols and devices.
      iv. Starting tasks.
      v. Vehicle operation and control tasks.
      vi. Post-drive tasks.
      vii. In-car progress assessment.
      viii. Driving plan (classroom instruction).
   c. Vehicle movements – classroom and behind-the-wheel instruction
      i. Visual attention, mental attention and communication.
      ii. Reference points.
iii. Vehicle balance.
iv. Vehicle maneuvers.

v. In-car progress assessment *(behind-the-wheel instruction)*.

d. Driver readiness – *classroom and behind-the-wheel instruction*

i. Driving practices.

ii. Fatigue.

iii. Aggressive driving.

iv. In-car progress assessment *(behind-the-wheel instruction)*.

e. Risk reduction – *classroom and behind-the-wheel instruction*

i. Risk factors.

ii. Space management.

iii. In-car progress assessment *(behind-the-wheel instruction)*.

f. Environmental factors – *classroom and behind-the-wheel instruction*

i. Environmental characteristics.

ii. Environmental risk factors.

iii. In-car progress assessment *(behind-the-wheel instruction)*.

g. Distractions – *classroom and behind-the-wheel instruction*

i. Distractions.

ii. Multi-task performances.

iii. In-car progress assessment *(behind-the-wheel instruction)*.

h. Alcohol and other drugs – *classroom instruction*

i. Introduction of alcohol and other drug problems.


iii. Physiological effects of alcohol.

iv. Psychological effects of alcohol.

v. Other drug effects on the driving task.

vi. Zero-tolerance in the driving environment.

i. Vehicle movement and reference points – *(behind-the-wheel instruction)*

i. Vehicle movements and reference points (entering and exiting traffic and parking).

ii. In-car progress assessment *(behind-the-wheel instruction)*.

j. Adverse conditions – *classroom instruction*

i. Adverse weather and reduced visibility conditions.

ii. Traction loss.

iii. Emergencies.

k. Vehicle requirements – *classroom and behind-the-wheel instruction*

i. Vehicle malfunctions *(classroom instruction)*.

ii. Vehicle maintenance *(classroom instruction)*.

iii. Trip planning *(classroom instruction)*.

iv. Adverse conditions and vehicle requirements – off-street simulated practice *(behind-the-wheel instruction)*.

v. In-car progress assessments *(behind-the-wheel instruction)*.

l. Consumer responsibility – *classroom and behind-the-wheel instruction*
i. Vehicle use and ownership (*classroom instruction*).

ii. Vehicle insurance (*classroom instruction*).

iii. Environmental protection and litter prevention (*classroom instruction*).

iv. Anatomical gift Act – organ donor (*classroom instruction*).

v. Trip planning (*behind-the-wheel instruction*).

vi. In-car progress assessment (*behind-the-wheel instruction*).

m. Personal responsibility (*classroom and behind-the-wheel instruction*).

i. Comprehensive classroom progress assessment (testing) (*classroom instruction*).

ii. Driver licensing (*classroom instruction*).

iii. In-car progress assessment (*behind-the-wheel instruction*).

[ARC 1612C, IAB 9/3/14, effective 10/8/14; ARC 6062C, IAB 12/1/21, effective 1/5/22]