441—78.1 (249A) Physicians' services. Payment will be approved for all medically necessary services and supplies provided by the physician including services rendered in the physician's office or clinic, the home, in a hospital, nursing home or elsewhere.

Payment shall be made for all services rendered by a doctor of medicine or osteopathy within the scope of this practice and the limitations of state law subject to the following limitations and exclusions:

78.1(1) Payment will not be made for:

a. Drugs dispensed by a physician or other legally qualified practitioner (dentist, podiatrist, optometrist, physician assistant, or advanced registered nurse practitioner) unless it is established that there is no licensed retail pharmacy in the community in which the legally qualified practitioner's office is maintained. Rate of payment shall be established as in subrule 78.2(2), but no professional fee shall be paid. Payment will not be made for biological supplies and drugs provided free of charge to practitioners by the state department of public health.

- b. Routine physical examinations. Rescinded IAB 8/1/07, effective 8/1/07.
- c. Treatment of certain foot conditions as specified in 78.5(2) "a, " "b, " and "c. "
- d. Acupuncture treatments.
- e. Rescinded 9/6/78.

f. Unproven or experimental medical and surgical procedures. The criteria in effect in the Medicare program shall be utilized in determining when a given procedure is unproven or experimental in nature.

g. Charges for surgical procedures on the "Outpatient/Same Day Surgery List" produced by the Iowa Foundation for Medical Care or associated inpatient care charges when the procedure is performed in a hospital on an inpatient basis unless the physician has secured approval from the hospital's utilization review department prior to the patient's admittance to the hospital. Approval shall be granted only when inpatient care is deemed to be medically necessary based on the condition of the patient or when the surgical procedure is not performed as a routine, primary, independent procedure. The "Outpatient/Same Day Surgery List" shall be published by the department in the provider manuals for hospitals and physicians. The "Outpatient/Same Day Surgery List" shall be developed by the Iowa Foundation for Medical Care, and shall include procedures which can safely and effectively be performed in a doctor's office or on an outpatient basis in a hospital. The Iowa Foundation for Medical Care may add, delete, or modify entries on the "Outpatient/Same Day Surgery List."

h. Elective, non-medically necessary cesarean section (C-section) deliveries.

78.1(2) Drugs and supplies may be covered when prescribed by a legally qualified practitioner as provided in this rule.

a. Drugs are covered as provided by rule 441—78.2(249A).

b. Medical supplies are payable when ordered by a legally qualified practitioner for a specific rather than incidental use, subject to the conditions specified in rule 441—78.10(249A). When a member is receiving care in a nursing facility or residential care facility, payment will be approved only for the following supplies when prescribed by a legally qualified practitioner:

- (1) Colostomy and ileostomy appliances.
- (2) Colostomy and ileostomy care dressings, liquid adhesive and adhesive tape.
- (3) Disposable irrigation trays or sets.
- (4) Disposable catheterization trays or sets.
- (5) Indwelling Foley catheter.
- (6) Disposable saline enemas.

(7) Diabetic supplies including needles and syringes, blood glucose test strips, and diabetic urine test supplies.

c. Prescription records are required for all drugs as specified in Iowa Code sections 124.308, 155A.27 and 155A.29. For the purposes of the medical assistance program, prescriptions for medical supplies are required and shall be subject to the same provisions.

d. Rescinded IAB 1/30/08, effective 4/1/08.

e. In order to be paid for the administration of a vaccine covered under the Vaccines for Children (VFC) program, a physician must enroll in the VFC program. Payment for the vaccine will be approved only if the VFC program stock has been depleted.

f. Nonprescription drugs. Rescinded IAB 1/30/08, effective 4/1/08.

78.1(3) Payment will be approved for injections provided they are reasonable, necessary, and related to the diagnosis and treatment of an illness or injury. When billing for an injection, the legally qualified practitioner must specify the brand name of the drug and the manufacturer, the strength of the drug, the amount administered, and the charge of each injection. When the strength and dosage of the drug is not included, payment will be made based on the customary dosage. The following exclusions are applicable.

a. Payment will not be approved for injections when they are considered by standards of medical practice not to be specific or effective treatment for the particular condition for which they are administered.

b. Payment will not be approved for an injection when administered for a reason other than the treatment of a particular condition, illness, or injury. When injecting an amphetamine or legend vitamin, prior approval must be obtained as specified in 78.1(2) "*a*"(3).

c. Payment will not be approved when injection is not an indicated method of administration according to accepted standards of medical practice.

d. Allergenic extract materials provided the patient for self-administration shall not exceed a 90-day supply.

e. Payment will not be approved when an injection is determined to fall outside of what is medically reasonable or necessary based on basic standards of medical practice for the required level of care for a particular condition.

f. Payment for vaccines available through the Vaccines for Children (VFC) program will be approved only if the VFC program stock has been depleted.

g. Payment will not be approved for injections of "covered Part D drugs" as defined by 42 U.S.C. Section 1395w-102(e)(1)-(2) for any "Part D eligible individual" as defined in 42 U.S.C. Section 1395w-101(a)(3)(A), including an individual who is not enrolled in a Part D plan.

78.1(4) For the purposes of this program, cosmetic, reconstructive, or plastic surgery is surgery which can be expected primarily to improve physical appearance or which is performed primarily for psychological purposes or which restores form but which does not correct or materially improve the bodily functions. When a surgical procedure primarily restores bodily function, whether or not there is also a concomitant improvement in physical appearance, the surgical procedure does not fall within the provisions set forth in this subrule. Surgeries for the purpose of sex reassignment are not considered as restoring bodily function and are excluded from coverage.

a. Coverage under the program is generally not available for cosmetic, reconstructive, or plastic surgery. However, under certain limited circumstances payment for otherwise covered services and supplies may be provided in connection with cosmetic, reconstructive, or plastic surgery as follows:

(1) Correction of a congenital anomaly; or

(2) Restoration of body form following an accidental injury; or

(3) Revision of disfiguring and extensive scars resulting from neoplastic surgery.

(4) Generally, coverage is limited to those cosmetic, reconstructive, or plastic surgery procedures performed no later than 12 months subsequent to the related accidental injury or surgical trauma. However, special consideration for exception will be given to cases involving children who may require a growth period.

b. Cosmetic, reconstructive, or plastic surgery performed in connection with certain conditions is specifically excluded. These conditions are:

(1) Dental congenital anomalies, such as absent tooth buds, malocclusion, and similar conditions.

(2) Procedures related to transsexualism, hermaphroditism, gender identity disorders, or body dysmorphic disorders.

(3) Cosmetic, reconstructive, or plastic surgery procedures performed primarily for psychological reasons or as a result of the aging process.

(4) Breast augmentation mammoplasty, surgical insertion of prosthetic testicles, penile implant procedures, and surgeries for the purpose of sex reassignment.

c. When it is determined that a cosmetic, reconstructive, or plastic surgery procedure does not qualify for coverage under the program, all related services and supplies, including any institutional costs, are also excluded.

d. Following is a partial list of cosmetic, reconstructive, or plastic surgery procedures which are not covered under the program. This list is for example purposes only and is not considered all inclusive.

(1) Any procedure performed for personal reasons, to improve the appearance of an obvious feature or part of the body which would be considered by an average observer to be normal and acceptable for the patient's age or ethnic or racial background.

(2) Cosmetic, reconstructive, or plastic surgical procedures which are justified primarily on the basis of a psychological or psychiatric need.

(3) Augmentation mammoplasties.

(4) Face lifts and other procedures related to the aging process.

(5) Reduction mammoplasties, unless there is medical documentation of intractable pain not amenable to other forms of treatment as the result of increasingly large pendulous breasts.

(6) Panniculectomy and body sculpture procedures.

(7) Repair of sagging eyelids, unless there is demonstrated and medically documented significant impairment of vision.

(8) Rhinoplasties, unless there is evidence of accidental injury occurring within the past six months which resulted in significant obstruction of breathing.

(9) Chemical peeling for facial wrinkles.

(10) Dermabrasion of the face.

(11) Revision of scars resulting from surgery or a disease process, except disfiguring and extensive scars resulting from neoplastic surgery.

(12) Removal of tattoos.

(13) Hair transplants.

(14) Electrolysis.

(15) Sex reassignment.

(16) Penile implant procedures.

(17) Insertion of prosthetic testicles.

e. Coverage is available for otherwise covered services and supplies required in the treatment of complications resulting from a noncovered incident or treatment, but only when the subsequent complications represent a separate medical condition such as systemic infection, cardiac arrest, acute drug reaction, or similar conditions. Coverage shall not be extended for any subsequent care or procedure related to the complication that is essentially similar to the initial noncovered care. An example of a complication similar to the initial period of care would be repair of facial scarring resulting from dermabrasion for acne.

78.1(5) The legally qualified practitioner's prescription for medical equipment, appliances, or prosthetic devices shall include the patient's diagnosis and prognosis, the reason the item is required, and an estimate in months of the duration of the need. Payment will be made in accordance with rule 78.10(249A).

78.1(6) Payment will be approved for the examination to establish the need for orthopedic shoes in accordance with rule 441—78.15(249A).

78.1(7) No payment shall be made for the services of a private duty nurse.

78.1(8) Payment for mileage shall be the same as that in effect in part B of Medicare.

78.1(9) Payment will be approved for visits to patients in nursing facilities subject to the following conditions:

a. Payment will be approved for only one visit to the same patient in a calendar month. Payment for further visits will be made only when the need for the visits is adequately documented by the physician.

b. When only one patient is seen in a single visit the allowance shall be based on a follow-up home visit. When more than one patient is seen in a single visit, payment shall be based on a follow-up office visit. In the absence of information on the claim, the carrier will assume that more than one patient was seen, and payment approved on that basis.

c. Payment will be approved for mileage in connection with nursing home visits when:

- (1) It is necessary for the physician to travel outside the home community, and
- (2) There are not physicians in the community in which the nursing home is located.

d. Payment will be approved for tasks related to a resident receiving nursing facility care which are performed by a physician's employee who is a nurse practitioner, clinical nurse specialist, or physician assistant as specified in 441—paragraph 81.13(13)"*e.*" On-site supervision of the physician is not required for these services.

78.1(10) Payment will be approved in independent laboratory when it has been certified as eligible to participate in Medicare.

78.1(11) Rescinded, effective 8/1/87.

78.1(12) Payment will be made on the same basis as in Medicare for services associated with treatment of chronic renal disease including physician's services, hospital care, renal transplantation, and hemodialysis, whether performed on an inpatient or outpatient basis. Payment will be made for deductibles and coinsurance for those persons eligible for Medicare.

78.1(13) Payment will be made to the physician for services rendered by auxiliary personnel employed by the physician and working under the direct personal supervision of the physician, when such services are performed incident to the physician's professional service.

a. Auxiliary personnel are nurses, physician's assistants, psychologists, social workers, audiologists, occupational therapists and physical therapists.

b. An auxiliary person is considered to be an employee of the physician if the physician:

(1) Is able to control the manner in which the work is performed, i.e., is able to control when, where and how the work is done. This control need not be actually exercised by the physician.

- (2) Sets work standards.
- (3) Establishes job description.
- (4) Withholds taxes from the wages of the auxiliary personnel.

c. Direct personal supervision in the office setting means the physician must be present in the same office suite, not necessarily the same room, and be available to provide immediate assistance and direction.

Direct personal supervision outside the office setting, such as the member's home, hospital, emergency room, or nursing facility, means the physician must be present in the same room as the auxiliary person.

Advanced registered nurse practitioners certified under board of nursing rules 655—Chapter 7 performing services within their scope of practice are exempt from the direct personal supervision requirement for the purpose of reimbursement to the employing physicians. In these exempted circumstances, the employing physicians must still provide general supervision and be available to provide immediate needed assistance by telephone. Advanced registered nurse practitioners who prescribe drugs and medical devices are subject to the guidelines in effect for physicians as specified in rule 441—78.1(249A).

A physician assistant licensed under board of physician assistants' professional licensure rules in 645—Chapter 325 is exempt from the direct personal supervision requirement but the physician must still provide general supervision and be available to provide immediate needed assistance by telephone. Physician assistants who prescribe drugs and medical devices are subject to the guidelines in effect for physicians as specified in rule 441—78.1(249A).

d. Services incident to the professional services of the physician means the service provided by the auxiliary person must be related to the physician's professional service to the member. If the physician has not or will not perform a personal professional service to the member, the clinical records must document that the physician assigned treatment of the member to the auxiliary person.

78.1(14) Payment will be made for persons aged 20 and under for nutritional counseling provided by a licensed dietitian employed by or under contract with a physician for a nutritional problem or condition of a degree of severity that nutritional counseling beyond that normally expected as part of the standard medical management is warranted. For persons eligible for the WIC program, a WIC referral is required. Medical necessity for nutritional counseling services exceeding those available through WIC shall be documented.

78.1(15) The certification of inpatient hospital care shall be the same as that in effect in part A of Medicare. The hospital admittance record is sufficient for the original certification.

78.1(16) No payment will be made for sterilization of an individual under the age of 21 or who is mentally incompetent or institutionalized. Payment will be made for sterilization performed on an individual who is aged 21 or older at the time the informed consent is obtained and who is mentally competent and not institutionalized when all the conditions in this subrule are met.

a. The following definitions are pertinent to this subrule:

(1) Sterilization means any medical procedure, treatment, or operation performed for the purpose of rendering an individual permanently incapable of reproducing and which is not a necessary part of the treatment of an existing illness or medically indicated as an accompaniment of an operation on the genital urinary tract. Mental illness or retardation is not considered an illness or injury.

(2) Hysterectomy means a medical procedure or operation to remove the uterus.

(3) Mentally incompetent individual means a person who has been declared mentally incompetent by a federal, state or local court of jurisdiction for any purpose, unless the individual has been declared competent for purposes which include the ability to consent to sterilization.

(4) Institutionalized individual means an individual who is involuntarily confined or detained, under a civil or criminal statute, in a correctional or rehabilitative facility, including a mental hospital or other facility for the care and treatment of mental illness, or an individual who is confined under a voluntary commitment in a mental hospital or other facility for the care and treatment of mental illness.

b. The sterilization shall be performed as the result of a voluntary request for the services made by the person on whom the sterilization is performed. The person's consent for sterilization shall be documented on:

(1) Form 470-0835 or 470-0835(S), Consent Form, or

(2) An official sterilization consent form from another state's Medicaid program that contains all information found on the Iowa form and complies with all applicable federal regulations.

c. The person shall be advised prior to the receipt of consent that no benefits provided under the medical assistance program or other programs administered by the department may be withdrawn or withheld by reason of a decision not to be sterilized.

d. The person shall be informed that the consent can be withheld or withdrawn any time prior to the sterilization without prejudicing future care and without loss of other project or program benefits.

e. The person shall be given a complete explanation of the sterilization. The explanation shall include:

(1) A description of available alternative methods and the effect and impact of the proposed sterilization including the fact that it must be considered to be an irreversible procedure.

(2) A thorough description of the specific sterilization procedure to be performed and benefits expected.

(3) A description of the attendant discomforts and risks including the type and possible effects of any anesthetic to be used.

(4) An offer to answer any inquiries the person to be sterilized may have concerning the procedure to be performed. The individual shall be provided a copy of the informed consent form in addition to the oral presentation.

f. At least 30 days and not more than 180 days shall have elapsed following the signing of the informed consent except in the case of premature delivery or emergency abdominal surgery which occurs not less than 72 hours after the informed consent was signed. The informed consent shall have been signed at least 30 days before the expected delivery date for premature deliveries.

g. The information in paragraphs "b" through "f" shall be effectively presented to a blind, deaf, or otherwise handicapped individual and an interpreter shall be provided when the individual to be sterilized does not understand the language used on the consent form or used by the person obtaining consent. The individual to be sterilized may have a witness of the individual's choice present when consent is obtained.

h. The consent form described in paragraph 78.1(16) "b" shall be attached to the claim for payment and shall be signed by:

- (1) The person to be sterilized,
- (2) The interpreter, when one was necessary,
- (3) The physician, and
- (4) The person who provided the required information.
- *i.* Informed consent shall not be obtained while the individual to be sterilized is:
- (1) In labor or childbirth, or
- (2) Seeking to obtain or obtaining an abortion, or
- (3) Under the influence of alcohol or other substance that affects the individual's state of awareness.

j. Payment will be made for a medically necessary hysterectomy only when it is performed for a purpose other than sterilization and only when one or more of the following conditions is met:

(1) The individual or representative has signed an acknowledgment that she has been informed orally and in writing from the person authorized to perform the hysterectomy that the hysterectomy will make the individual permanently incapable of reproducing, or

(2) The individual was already sterile before the hysterectomy, the physician has certified in writing that the individual was already sterile at the time of the hysterectomy and has stated the cause of the sterility, or

(3) The hysterectomy was performed as a result of a life-threatening emergency situation in which the physician determined that prior acknowledgment was not possible and the physician includes a description of the nature of the emergency.

78.1(17) Abortions. Payment for an abortion or related service is made when Form 470-0836 is completed for the applicable circumstances and is attached to each claim for services. Payment for an abortion is made under one of the following circumstances:

a. The physician certifies that the pregnant woman's life would be endangered if the fetus were carried to term.

b. The physician certifies that the fetus is physically deformed, mentally deficient or afflicted with a congenital illness and the physician states the medical indication for determining the fetal condition.

c. The pregnancy was the result of rape reported to a law enforcement agency or public or private health agency which may include a family physician within 45 days of the date of occurrence of the incident. The report shall include the name, address, and signature of the person making the report. Form 470-0836 shall be signed by the person receiving the report of the rape.

d. The pregnancy was the result of incest reported to a law enforcement agency or public or private health agency including a family physician no later than 150 days after the date of occurrence. The report shall include the name, address, and signature of the person making the report. Form 470-0836 shall be signed by the person receiving the report of incest.

78.1(18) Payment and procedure for obtaining eyeglasses, contact lenses, and visual aids, shall be the same as described in 441—78.6(249A). (Cross-reference 78.28(3))

78.1(19) Preprocedure review by the Iowa Foundation for Medical Care (IFMC) will be required if payment under Medicaid is to be made for certain frequently performed surgical procedures which have a wide variation in the relative frequency the procedures are performed. Preprocedure surgical review applies to surgeries performed in hospitals (outpatient and inpatient) and ambulatory surgical centers. Approval by the IFMC will be granted only if the procedures are determined to be necessary based on the condition of the patient and the published criteria established by the IFMC and the department. If not so approved by the IFMC, payment will not be made under the program to the physician or to the facility in which the surgery is performed. The criteria are available from IFMC, 6000 Westown Parkway, Suite 350E, West Des Moines, Iowa 50265-7771, or in local hospital utilization review offices.

The "Preprocedure Surgical Review List" shall be published by the department in the provider manuals for physicians, hospitals, and ambulatory surgical centers. The "Preprocedure Surgical Review List" shall be developed by the department with advice and consultation from the IFMC and appropriate professional organizations and will list the procedures for which prior review is required and the steps that must be followed in requesting such review. The department shall update the "Preprocedure Surgical Review List" annually. (Cross-reference 78.28(1)"e.")

78.1(20) Transplants.

- a. Payment will be made only for the following organ and tissue transplant services:
- (1) Kidney, cornea, skin, and bone transplants.

(2) Allogeneic bone marrow transplants for the treatment of aplastic anemia, severe combined immunodeficiency disease, Wiskott-Aldrich syndrome, or the following types of leukemia: acute myelocytic leukemia in relapse or remission, chronic myelogenous leukemia, and acute lemphocytic leukemia in remission.

(3) Autologous bone marrow transplants for treatment of the following conditions: acute leukemia in remission with a high probability of relapse when there is no matched donor; resistant non-Hodgkin's lymphomas; lymphomas presenting poor prognostic features; recurrent or refractory neuroblastoma; or advanced Hodgkin's disease when conventional therapy has failed and there is no matched donor.

(4) Liver transplants for persons with extrahepatic biliary artesia or any other form of end-stage liver disease, except that coverage is not provided for persons with a malignancy extending beyond the margins of the liver.

Liver transplants require preprocedure review by the Iowa Foundation for Medical Care. (Cross-reference 78.1(19) and 78.28(1) "f.")

Covered liver transplants are payable only when performed in a facility that meets the requirements of 78.3(10).

(5) Heart transplants. Artificial hearts and ventricular assist devices, either as a permanent replacement for a human heart or as a temporary life-support system until a human heart becomes available for transplants, are not covered. Heart-lung transplants are covered where bilateral or unilateral lung transplantation with repair of a congenital cardiac defect is contraindicated.

Heart transplants and heart-lung transplants described above require preprocedure review by the Iowa Foundation for Medical Care. (Cross-reference 78.1(19) and 78.28(1) "f.") Covered heart transplants are payable only when performed in a facility that meets the requirements of 78.3(10).

(6) Lung transplants. Lung transplants for persons having end-stage pulmonary disease. Lung transplants require preprocedure review by the Iowa Foundation for Medical Care. (Cross-reference 78.1(19) and 78.28(1) "f.") Covered transplants are payable only when performed in a facility that meets the requirements of 78.3(10). Heart-lung transplants are covered consistent with criteria in subparagraph (5) above.

(7) Pancreas transplants for persons with type I diabetes mellitus, as follows:

1. Simultaneous pancreas-kidney transplants and pancreas after kidney transplants are covered.

2. Pancreas transplants alone are covered for persons exhibiting any of the following:

• A history of frequent, acute, and severe metabolic complications (e.g., hypoglycemia, hyperglycemia, or ketoacidosis) requiring medical attention.

• Clinical problems with exogenous insulin therapy that are so severe as to be incapacitating.

• Consistent failure of insulin-based management to prevent acute complications.

The pancreas transplants listed under this subparagraph require preprocedure review by the Iowa Foundation for Medical Care. (Cross-reference 78.1(19) and 78.28(1) "f.")

Covered transplants are payable only when performed in a facility that meets the requirements of 78.3(10).

Transplantation of islet cells or partial pancreatic tissue is not covered.

b. Donor expenses incurred directly in connection with a covered transplant are payable. Expenses incurred for complications that arise with respect to the donor are covered only if they are directly and immediately attributed to surgery. Expenses of searching for a donor are not covered.

c. All transplants must be medically necessary and meet other general requirements of this chapter for physician and hospital services.

d. Payment will not be made for any transplant not specifically listed in paragraph "a."

78.1(21) Utilization review. Utilization review shall be conducted of Medicaid members who access more than 24 outpatient visits in any 12-month period from physicians, advanced registered nurse practitioners, federally qualified health centers, other clinics, and emergency rooms. For the purposes of utilization review, the term "physician" does not include a psychiatrist. Refer to rule 441-76.9(249A) for further information concerning the member lock-in program.

78.1(22) Risk assessment. Risk assessment, using Form 470-2942, Medicaid Prenatal Risk Assessment, shall be completed at the initial visit during a Medicaid member's pregnancy.

a. If the risk assessment reflects a low-risk pregnancy, the assessment shall be completed again at approximately the twenty-eighth week of pregnancy.

b. If the risk assessment reflects a high-risk pregnancy, referral shall be made for enhanced services. Enhanced services include health education, social services, nutrition education, and a postpartum home visit. Additional reimbursement shall be provided for obstetrical services related to a high-risk pregnancy. (See description of enhanced services at subrule 78.25(3).)

78.1(23) EPSDT care coordination. Rescinded IAB 12/3/08, effective 2/1/09.

78.1(24) Topical fluoride varnish. Payment shall be made for application of an FDA-approved topical fluoride varnish, as defined by the Current Dental Terminology, Third Edition (CDT-3), for the purpose of preventing the worsening of early childhood caries in children aged 0 to 36 months of age, when rendered by physicians acting within the scope of their practice, licensure, and other applicable state law, subject to the following provisions and limitations:

a. Application of topical fluoride varnish must be provided in conjunction with an early and periodic screening, diagnosis, and treatment (EPSDT) examination which includes a limited oral screening.

b. Separate payment shall be available only for application of topical fluoride varnish, which shall be at the same rate of reimbursement paid to dentists for providing this service. Separate payment for the limited oral screening shall not be available, as this service is already part of and paid under the EPSDT screening examination.

c. Parents, legal guardians, or other authorized caregivers of children receiving application of topical fluoride varnish as part of an EPSDT screening examination shall be informed by the physician or auxiliary staff employed by and under the physician's supervision that this application is not a substitute for comprehensive dental care.

d. Physicians rendering the services under this subrule shall make every reasonable effort to refer or facilitate referral of these children for comprehensive dental care rendered by a dental professional.

This rule is intended to implement Iowa Code section 249A.4.

[ARC 8714B, IAB 5/5/10, effective 5/1/10; ARC 0065C, IAB 4/4/12, effective 6/1/12; ARC 0305C, IAB 9/5/12, effective 11/1/12; ARC 0846C, IAB 7/24/13, effective 7/1/13; ARC 1052C, IAB 10/2/13, effective 11/6/13]