# CHAPTER 2203
# STANDARDS FOR CERTIFICATE OF NEED REVIEW

[Prior to 7/29/87, Health Department[470] Ch 203]
[Prior to 9/4/24, see Public Health Department[641] Ch 203]

Chapter rescission date pursuant to Iowa Code section 17A.7: 6/5/29

**481—2203.1** Reserved.

**481—2203.2(10A) Cardiac catheterization and cardiovascular surgery standards.**

**2203.2(1)** *Purpose and scope.*

*a.* These standards are measures of some of those criteria found in Iowa Code sections 10A.714(1) *"a"* through *"q"* and 10A.714(3). Criteria that are measured by a standard are cited in parentheses following each standard.

*b.* Certificate of need applications that are to be evaluated against these cardiac catheterization and cardiovascular surgery standards include:

(1) Proposals to commence or expand capacity to perform cardiac catheterization.

(2) Proposals to add new or replace cardiovascular surgery services.

(3) Any other applications that relate to cardiac catheterization or cardiovascular surgery.

**2203.2(2)** *Definitions.*

*a.* Adult cardiac catheterization laboratory—a diagnostic facility exclusively for intracardiac or coronary artery catheterization on adults.

*b.* Pediatric cardiac catheterization laboratory—the same as adult cardiac catheterization laboratory, except exclusively for children and infants.

*c.* Cardiac catheterization—

(1) Intracardiac—a diagnostic study of the heart, pulmonary arteries, or both, in which a small catheter passes through a vein or artery in the neck, leg or arm and advances into the great vessels, the heart or the pulmonary arteries. Through this procedure one can measure pressure within the heart and in adjacent veins and arteries, collect blood samples for blood gas analysis and inject radiopaque material, and visualize cardiac and vessel anatomy. The procedure permits detection of congenital and acquired heart abnormalities, the study of ventricular function, the estimation of the orifice size, the placement of pacemakers, etc. Cardiac catheterization is incomplete without cineangiography, intracardiac pressure measurements, blood gas analysis and the ability to diagnose intracardiac shunts.

(2) Coronary artery catheterization—a diagnostic study of the coronary arteries, in which a small catheter passes through an artery in the leg, neck or arm into a coronary artery orifice. Intravascular pressure measurements are taken, and angiography of the coronary arteries is performed. Catheterization and cineangiocardiography of the left ventricle are an integral part of this procedure.

*d.* Angiography—

The photographic recording of X-ray or radiologic images of blood vessels, in any part of the body—the heart, the head, the great vessels, the kidney, etc. In the procedure blood vessels are injected with a radiopaque chemical. Immediately following injection, X-rays are employed to image the path of the injected chemical. These X-ray images are then photographically recorded.

*e.* Angiocardiography—

The recording of moving X-ray images (fluoroscopic images) of the heart and great vessels. After injection of radiopaque chemicals, moving X-rays of the chemical's flow are projected on a screen called a fluoroscope. Moving pictures (cineangiocardiography) or still pictures in sequence (serialography) may be recorded of the X-ray image.

*f.* Adult cardiovascular surgery—cardiovascular surgery exclusively for adults.

*g.* Pediatric cardiovascular surgery—cardiovascular surgery exclusively for infants and children.

*h.* Cardiovascular surgery—the services associated with and surgery performed for congenital or acquired diseases of the heart, great vessels, or pericardium, including the placement of travenous and epicardial pacemakers.

(1) Open heart surgery—cardiovascular surgery in which an incision of sufficient size is made to allow direct vision of the area. Open heart surgery requires temporary use of a heart-lung (cardiopulmonary bypass) machine, as blood flow through the heart is greatly reduced or stopped altogether.

(2) Coronary artery surgery—surgery to correct inadequate blood flow to the heart using revascularization techniques to bypass significantly obstructed coronary artery lesions.

*i.* Closed heart surgery—cardiovascular surgery in which a small incision and repairs are made without direct vision of the area.

**2203.2(3)** *Availability of services.*

*a.* Minimum utilization—cardiovascular surgery (Iowa Code section 10A.714(1)*"c,""g,""h"*).

(1) Adult cardiovascular surgical programs should project an annual minimum rate of over 200, or no approval will be granted. Higher case loads over 200 per annum are encouraged.

(2) Pediatric cardiovascular surgical units should project a minimum of 100 pediatric heart operations after the first year, at least 75 of which must be open heart procedures.

(3) Combined adult/pediatric cardiovascular surgery units should project the minimum projected annual rates for both adult and pediatric surgery.

(4) Applicants should project utilization of cardiovascular surgery, catheterization and cardiac care units based upon service area population demographics, current regional or national utilization rates of the service, disease incidence and prevalence rates, current cardiac care treatment modes, and in consideration those adult cardiovascular surgery units currently operating in Iowa, and bordering states within the project's service area.

*b.* Expansions—cardiovascular surgery (Iowa Code section 10A.714(1)*"c,""d,""e,""g,""h"*).

(1) There should be no additional adult cardiovascular surgery units initiated, unless each existing unit within the project's service area is operating at a minimum of 200 open heart surgery cases per year.

(2) There should be no additional pediatric cardiovascular surgery units initiated, unless each existing unit within the project's service area is operating at 100 surgeries per year. If one team serves more than one institution, the numbers for those institutions should be combined.

(3) If the annual utilization of the other cardiovascular surgery units within the area is below the levels noted above, future utilization above that current level must be reasonably projected or reasons for permanently utilizing the equipment below the level must be demonstrated.

(4) The applicant will demonstrate that an attempt was made to determine with the cooperation of existing providers whether such a reduction would occur. Existing providers of consequence are generally within two hours' surface travel time for adult services and within three for pediatric services.

*c.* Minimum utilization—cardiac catheterization (Iowa Code section 10A.714(1)*"c,""d,""g,""h"*).

(1) Adult cardiac catheterization laboratories should be projected to operate at a minimum of 300 catheterizations per annum.

(2) Pediatric catheterization laboratory units should project a minimum of 150 catheterizations annually.

(3) Combined units should meet each of the adult and pediatric standards.

(4) Applicant should project utilization of cardiac catheterization units based upon service area population demographics, current regional or national utilization rates of the service, disease incidence and prevalence rates, current cardiac care treatment modes, and in consideration those adult cardiovascular surgery units currently operating in Iowa, and bordering states within the project's service area.

*d.* Expansions—cardiac catheterizations (Iowa Code section 10A.714(1)*"c,""d,""e,""g,""h"*).

(1) There should be no additional adult cardiac catheterization unit opened unless the number of studies per year in each existing unit within the project's service area is greater than 300. No additional pediatric unit should be opened unless the number of studies per year in each existing unit within the project's services area is greater than 150.

(2) If the annual utilization of the other cardiovascular surgery units within the area is below the levels noted above, future utilization above that current level must be reasonably projected or reasons for permanently utilizing the equipment below the level must be demonstrated.

(3) The applicant must demonstrate that an attempt was made to determine with the cooperation of existing providers whether such a reduction would occur. Existing providers of consequence are those within two hours' surface travel time for adults or three for pediatrics.

**2203.2(4)** *Costs.*

*a. Financial feasibility.* (Iowa Code section 10A.714(1)*"f,""i,""p"*) Cardiovascular surgery and catheterization equipment and associated remodeling or construction should be depreciated over a period consistent with generally accepted accounting standards.

*b. Cost-effectiveness.* Proposed new or replacement cardiac catheterization laboratories cost per catheterization and cardiovascular surgery services estimated costs per surgery should when compared to their peers demonstrate cost-effectiveness.

**2203.2(5)** *Accessibility.* (Iowa Code section 10A.714(1)*"c,""d"*)

*a.* Cardiovascular surgery units and cardiac catheterization labs should meet the needs of the communities that the units and labs are meant to serve.

*b.* Cardiac catheterization and cardiovascular surgery service should be provided regardless of ability to pay, in consideration of those programs available in the state that serve the medically indigent.

**2203.2(6)** *Quality.* (Iowa Code section 10A.714(1)*"i,""k"*)

*a.* Each surgery unit and cardiac catheterization lab shall demonstrate a reasonable set of criteria that are used in selecting appropriate candidates for surgery and catheterization.

*b.* Staffing minimums.

(1) The open heart surgery team should minimally consist of:

1. At least two certified or board-eligible cardiovascular surgeons for the first 75 to 130 pediatric open heart surgeries. If pediatric surgery is performed, one surgeon must have special training and experience in surgery for congenital cardiac defects.
2. Board-certified or board-eligible adult or pediatric cardiologist(s). The latter only if pediatric surgery is performed, the former only if adult surgery is performed.
3. Board-certified or board-eligible anesthesiologist with special training in the management of cardiovascular cases' respiratory care.
4. Radiologist trained in the cardiovascular field.
5. Pathologist familiar with cardiac problems.
6. Surgical nursing staff specially trained in heart disease.
7. Cardiopulmonary bypass pump technicians.
8. Other ancillary staff as needed.

(2) Each applicant will document that the proposed surgery unit can be so staffed when completed and operational.

*c.* Equipment and facilities. The applicant seeking to provide cardiovascular surgery should demonstrate that the following support services will be available:

(1) General X-ray diagnostic facilities and facilities for emergency X-rays on a 24-hour basis.

(2) A cardiac catheterization laboratory or angiography lab available on a 24-hour basis.

(3) A cardiographics laboratory, with facilities for recording the following tests: EKG, vector cardiogram, phonocardiogram, echocardiogram, and exercise stress testing.

(4) A supporting blood bank and hematology laboratory.

(5) A microbiology laboratory.

*d.* Cardiac catheterization labs serving infants and children should have biplane angiographic equipment, either cineangiocardiographic or cut film. Pediatric cardiac catheterization labs should be supervised by board-certified or board-eligible pediatric cardiologists; adult cardiac catheterization labs should be supervised by a board-certified or board-eligible adult cardiologist.

**2203.2(7)** *Continuity.* (Iowa Code section 10A.714(1)*"g,""h,""i,""k"*)

*a.* The applicant should demonstrate that an attempt was made to solicit letters of support from area hospitals and physicians to indicate a community need.

*b.* The applicant should provide documentation that emergency medical transport services will be available.

*c.* Institutions providing cardiovascular surgery services should include mechanisms for comprehensive medical followup including adequate medical records exchange.

**2203.2(8)** *Acceptability.* (Iowa Code section 10A.714(1)) Facilities with cardiovascular surgery and cardiac catheterization indicate a willingness to observe and respect the rights of patients.

[**ARC 7933C**, IAB 5/1/24, effective 6/5/24; Editorial change: IAC Supplement 9/4/24]

**481—2203.3(10A) Radiation therapy standards.**

**2203.3(1)** *Purpose and scope.*

*a.* These standards provide guidelines to assist the council in applying those criteria in Iowa Code sections 10A.714(1)*"a"* through *"r"* and 10A.714(3). Criteria that are measured by a standard are cited in parentheses following each standard.

*b.* Certificate of need applications that are to be evaluated against these radiation therapy standards include:

(1) Proposals to commence or expand the kind or capacity of megavoltage radiation therapy services.

(2) Proposals to replace a megavoltage radiation therapy unit.

(3) Any other applications that relate to megavoltage radiation therapy.

**2203.3(2)** *Definitions.*

*"Conjoint radiation oncology center"* or *"cancer center"* means a multi-institution, multidisciplinary network to provide radiation therapy for cancer patients. Integration of patient care management, common utilization of personnel and equipment, and a single system of records between center institutions ensures optimal care regardless of entry portal.

*"Dosimetrist"* means a staff member who calculates, verifies, and develops treatment plans for the radiation dose distributions that will be delivered to patients. The dosimetrist is an essential member of the treatment planning team and works closely with radiation oncologists and radiation physicists.

*"Megavoltage therapy"* means the use of ionizing radiation in excess of one million electron volts. Energies above one million electron volts cause considerably less skin damage, increase depth dose markedly, and result in much less scatter from the therapeutic beam. Megavoltage machines are classified as follows:

1. Electron accelerator. A machine such as a linear accelerator that uses a supply of electrons, which are accelerated into high energy beams. These electron beams are either caused to strike a target resulting in high energy X-ray production or are used themselves as the treatment beam. Electron accelerators generate over one million electron volts.

2. Heavy particle accelerator. A machine such as a cyclotron that produces beams of high energy particles such as protons, neutrons, pions, carbon ions, or other heavy ions with masses greater than that of an electron.

3. Isotope sources (gamma ray teletherapy units).

Cobalt 60 units—emit gamma rays of approximately 1.2 million electron volts.

*"Megavoltage therapy unit"* means a piece of megavoltage therapeutic radiologic equipment that provides megavoltage therapy.

*"New occurrence"* means a course of treatment for a new occurrence on a given patient at a given radiation therapy facility. First-time radiation therapy at a new facility is based on each round of treatment.

*"Radiation modality"* means the method of applying ionizing radiation in the treatment of patients with malignant disease using megavoltage external beam equipment.

*"Radiation oncologist"* means a physician authorized user trained in accordance with 641—subrule 41.3(5).

*"Radiation therapy facility"* or *"facility"* means the physical space that houses a megavoltage therapy unit and accompanying support equipment.

*"Radiation therapy physicist"* means an individual who works closely with radiation oncologists and is responsible for the safe and accurate delivery of radiation to patients. A radiation therapy physicist conducts quality control programs for the equipment and procedures, as well as calibrating the equipment. A radiation therapy physicist shall practice in accordance with 641—subrule 41.3(6).

*"Radiation therapy technologist"* means an individual who possesses an Iowa permit to practice as a radiation therapist in accordance with rule 641—42.7(136C).

*"Service area"* means the county in which the facility is located and any other counties from which the applicant expects to draw patients with a cancer diagnosis who need radiation therapy treatment.

*"Simulation"* means the precise mock-up of a patient treatment with an apparatus that uses planar X-rays, magnetic resonance imaging device, or computed tomography scanner, which is used in reproducing the two-dimensional or three-dimensional internal or external geometry to the patient, for use in treatment planning and delivery.

*"Superficial X-ray therapy"* means the use of a conventional X-ray machine, which generates X-rays of up to 150 kilovolts (150 kv), to treat superficial lesions, such as skin cancer.

*"Treatment"* means radiation fields applied in a single patient visit fraction or delivery session.

**2203.3(3)** *Availability.*

*a. Minimum utilization.* (Iowa Code section 10A.714(1)*"c,""g,""h"*)

(1) A megavoltage radiation therapy unit and cobalt units should treat at least 250 new occurrences annually within three years after initiation of the service.

(2) The expected number of new occurrences needing megavoltage radiation therapy annually in a service area should be calculated as follows:

1. Multiply the service area population times 0.00582 (5.82/1,000 population was the mean cancer incidence rate in 2017 in Iowa as filed by the Surveillance, Epidemiology, and End Results (SEER) Program).

2. Multiply this product times .5 (50 percent of all new occurrences receive radiation therapy).

(3) The expected volume of utilization sufficient to support the need for a new megavoltage therapy unit should be calculated as follows: each unit shall provide a minimum of 5,000 treatments per annum. Megavoltage treatments should be projected by multiplying the number of projected new occurrences needing megavoltage therapy times 20, which will result in no fewer than 5,000 treatments per annum.

(4) Applicants shall account for other providers of radiation therapy in the service area including, but not limited to, factors such as technological capability and quality. Applicants shall address in their application other providers and the impact on those providers in the service area and compare technological capability and quality.

(5) Applicants should provide a map of the expected service area.

(6) Institutions that form a conjoint oncology center should have at least 500 new occurrences annually.

*b. Simulator availability.* A simulator should be available within a radiation oncology department.

**2203.3(4)** *Accessibility.* (Iowa Code section 10A.714(1)*"c,""d"*) Radiation therapy services should be provided regardless of ability to pay, in consideration of those programs available in the state that serve the medically indigent.

**2203.3(5)** *Quality.* (Iowa Code section 10A.714(1)*"i,""k"*)

*a.* Minimum staffing requirements for radiation therapy facilities:

(1) Each facility will have the services of at least one radiation oncologist.

(2) Each facility will have the services of at least one radiation therapy physicist.

(3) Each facility will have the services of radiation therapy technologists that should be staffed at a level of two technologists per megavoltage unit.

(4) Each facility should have the services of nurses.

(5) Each facility should have the services of at least one dosimetrist.

(6) Each facility should have the services of one radiation therapist or radiation technologist competent to operate a CT simulator.

*b.* Each conjoint center will have at least two cancer biologists available.

*c.* Each conjoint center will have one radiation technologist available for each simulator.

*d.* The long-range plans for radiation therapy services shall be submitted to the Iowa department of health and human services.

*e.* Multidisciplinary tumor boards should be established in all institutions housing megavoltage machines.

*f.* A source of continuing education should exist within each conjoint center to reach participating community referral hospitals and physicians.

*g.* Each conjoint center should have a unified training program in radiation therapy for radiation oncologists.

*h.* Each radiation therapy facility should offer psychosocial counseling services and nutritional counseling.

**2203.3(6)** *Continuity.* (Iowa Code section 10A.714(1)*"g," "h," "i," "k"*) The applicant should demonstrate that an attempt was made to solicit letters and establish referral agreements from area hospitals and physicians to indicate their willingness to participate in a cooperative endeavor to refer to the proposed service.

[**ARC 7933C**, IAB 5/1/24, effective 6/5/24; Editorial change: IAC Supplement 9/4/24]

**481—2203.4(10A) Computerized tomography standards.**

**2203.4(1)** *Purpose and scope.*

*a.* These standards are measures of some of those criteria in Iowa Code section 10A.714(1)*"a"* through *"l."* Criteria that are measured by a standard are cited in parentheses following each standard.

*b.* Certificate of need applications that are to be evaluated against these computerized tomography standards include:

(1) Proposals to commence or expand the capacity of computerized tomography services.

(2) Any other applications that relate to computerized tomography services.

**2203.4(2)** *Definitions.*

*a.* Computerized tomographic (CT) scanner—a diagnostic tool that rotates about and that sends X-ray beams through the body or brain. The X-ray beams that emerge from the body or brain are absorbed by a detector. Differences in the amount of X-rays absorbed by the detector indicate differences in tissue density. As the scanner rotates, it takes many images of a volume or cross-section. The images on the detector are transmitted to a computer that displays on a monitor a reconstructed cross-sectional slice or volume. Contrast media is often injected to alter absorption of the detector. If the scan is repeated, it is called enhancement. Studies of the heart, arteries and veins may be done with contrast only.

(1) Whole body scanner—one capable of imaging the entire body.

(2) Head scanner—one capable of imaging only the brain and structures adjacent to the head.

*b.* Enhanced scan—a scan performed on a patient who has been administered a contrast medium so that specific organs or areas of the body will be displayed more distinctly on the scan image.

*c.* Minimum shared-market area for a scanner (hereafter referred to as "area")—the smallest geographic area within which any scanner installation is judged to affect the utilization rate of any other scanner is the community (as defined by the U.S. Bureau of the Census) or a Standard Metropolitan Statistical Area (where an area is so designated).

*d.* Emergency medical service (EMS) level II trauma service—the level of various services and staffing that qualify a facility to be designated by the emergency medical service division of the Iowa department of health and human services, using the facilities categorization criteria of such services that is in effect on the date of the enactment of this standard.

*e.* Shared service agreements—a multi-institutional arrangement for coordination or consolidation of services or sharing of support services. Among the various types of arrangements are referred services, purchased or joint contract services, multisponsored services and regional services.

*f.* CT consortia—a cooperative venture in which two or more institutions form a separate entity that is created for the purpose of owning, leasing, planning for, and maintaining the use of the scanner. Each facility in the consortium maintains its autonomy for all other services.

*g.* Applicant—an applicant may be a facility or a consortium of facilities within an area, or a physician or group of physicians.

*h.* General imaging procedures—a radiological diagnostic procedure performed on an X-ray machine or similar radiological diagnostic instrument.

*i.* Active oncology service—full, multidisciplinary cancer care, provided by a medical team that would include: surgery, gynecology, medical oncology, radiation oncology, pathology, diagnostic radiology and nuclear medicine. The surgery specialties that might be available would include: thoracic, abdominal, genitourinary and gynecological. The active oncology staff would include those specialists with training in oncology, hematology, and pathology and who spend at least half of their time at the institution.

*j.* Radiotherapy service—the therapeutic application of megavoltage radiation, using a linear accelerator or cobalt unit. The availability of such service at a hospital would necessitate personnel trained in the therapeutic application of radiology.

*k.* Chemotherapy service—the treatment of cancer by chemical agents.

**2203.4(3)** *Determination of need.*

*a.* Applicants who do not have a scanner, or who have a scanner and seek a certificate for one or more additional scanners.

(1) Applicants in areas with no other scanners.

1. Applicants must have performed at least 30,000 general imaging procedures during the past calendar year or 12 months, or

2. Demonstrate that during the past calendar year or 12 months, the applicant performed diagnostic procedures equivalent to 1500 HECTs (head equivalent CTs), using the following:

100% of the number of patients referred to other facilities for CT diagnosis × 1.75 (in the case of head scans) and 2.75 (in the case of body scans)

(2) Applicants in areas with one or more scanners.

1. An applicant must meet the requirement of need, described in subparagraph 2203.4(3)*"a"*(1), and

2. The average level of utilization for scanners within the area was at least 3000 HECTs (plus or minus 10 percent) for the past calendar year or 12 months. The average level of utilization will be determined by adding the number of HECTs performed during the period at all area facilities divided by the number of facilities.

3. The University of Iowa Hospitals and Clinics is specifically exempted from consideration under numbered paragraph 2203.4(3)*"a"*(2)"2" because it has a service area that encompasses the entire state and adjoining states. The utilization statistics for the University Hospital will therefore neither affect nor be affected by Mercy Hospital, Iowa City. Additionally, the utilization statistics for scanners at the University of Nebraska Hospitals and Clinics and St. Joseph's Hospital (both in Omaha) will not affect the need for scanners at hospitals in Council Bluffs.

*b.* Replacement scanners—applicants who currently have a scanner.

(1) All applicants seeking to replace a scanner with another scanner, head or body.

1. The applicant must demonstrate that the applicant's use of the applicant's current scanner was at least at the operating capacity level during the last calendar year or 12 months, or

2. Below the operating capacity level, but above 1500 CT scan level, and the applicant must demonstrate reasons for permanently utilizing their scanner below operating capacity level and demonstrate that discontinuation of their scanner service would impair the applicant's ability to respond to the emergency needs of the area. Reasons for utilizing the scanner below the capacity should include a unique patient or procedure mix that would define the capacity level differently for this applicant.

(2) Reserved.

**2203.4(4)** *Costs and financial feasibility.* (Iowa Code section 10A.714(1)*"f," "i," "p"*) CT scanners should be depreciated over a period of not less than seven years. Remodeling shall be depreciated as appropriate by generally accepted accounting principles.

*a. Cost-effectiveness.* Applicants should demonstrate for themselves and the health care system that the most cost-effective method of providing CT services has been chosen. Proposed new and replacement CT scanner's cost per CT scan should, when compared to their peers, demonstrate cost-effectiveness.

*b.* Reserved.

**2203.4(5)** *Accessibility.* (Iowa Code section 10A.714(1)*"c," "d"*)

*a.* All scanners must be available to meet the needs of the communities the scanners are meant to serve.

*b.* Services should be provided to all patients regardless of the patient's ability to pay, taking into consideration the availability of those programs available in the state that serve the medically indigent.

*c.* Applicants will demonstrate a willingness to accept referrals for CT services from all area physicians.

**2203.4(6)** *Quality.* (Iowa Code section 10A.714(1)*"i," "k"*)

*a.* Data on use and costs of the CT scanners should be submitted to the Iowa department of health and human services as a condition of approval. (Iowa Code section 10A.714(1)*"a," "h"*)

*b.* All scanners.

(1) All applicants must demonstrate that they have on their staff or will acquire on their staff a full-time diagnostic radiologist, trained in the use of the CT scanner, or other physicians with comparable training and expertise.

(2) All applicants must document that they have on their medical staff individuals who are qualified to operate a scanner and interpret and act upon the diagnostic results. Such documentation may include reference to board certification, apprenticeship, academic credentials or such other qualifications that would prompt a medical staff to accept the responsibility for offering this new service. Applicants who intend to acquire staff with the desired expertise should provide signed letters of intent from the incoming medical personnel. Applicants who intend to upgrade the specialty skills of their staff should document a plan for training their current staff in the use of CT scanners.

(3) All applicants should have a complement of other diagnostic modalities available. Applicants seeking body scanners should also have available ultrasound and conventional X-ray services.

(4) All applicants should have the facilities for treating the conditions diagnosed by imaging with the scanner or should demonstrate referral agreements with treatment facilities, in the event that the scanner will be used as a screening device.

(5) All applicants should have on their staff or available on a consultative basis the services of a biomedical engineer or medical physicist, with special training in CT applications. These functions may also be provided by contract with the scanner manufacturer.

**2203.4(7)** *Continuity.* (Iowa Code section 10A.714(1)*"g," "h," "i," "k"*)

*a.* The applicant should demonstrate that an attempt was made to solicit letters of support from area hospitals and physicians to indicate a community need for the proposed service.

*b.* The applicant should provide documentation that emergency medical transport services will be available.

*c.* The applicant should demonstrate an emphasis on the availability of outpatient CT procedures and that an appropriate percentage of all CT procedures will be done on an outpatient basis.

**2203.4(8)** *Acceptability.* (Iowa Code section 10A.714(1)*"k"*) Providers of CT services should indicate a willingness to observe the rights of patients.

[**ARC 7933C**, IAB 5/1/24, effective 6/5/24; Editorial change: IAC Supplement 9/4/24]

**481—2203.5(10A) Long-term care.**

**2203.5(1)** *Purpose and scope.*

*a.* These standards are measures of criteria found in Iowa Code section 10A.714(1)*"a"* through *"g."* Criteria that are measured by a standard are cited in parentheses following each standard.

*b.* Certificate of need applications that are to be evaluated against these standards include applications to:

(1) Construct, develop, offer new, modernize, replace, renovate, or relocate intermediate care or skilled nursing care beds in nursing homes or hospitals.

(2) Expand bed capacity in intermediate care or skilled nursing care facilities or designated units in hospitals.

**2203.5(2)** *Definitions.*

*"Intermediate care facility"* or *"ICF"* means any institution, place, building, or agency providing for a period exceeding 24 consecutive hours accommodation, board, and nursing services, the need for which is certified by a physician, to three or more individuals, not related to the administrator or owner thereof within the third degree of consanguinity, who by reason of illness, disease, or physical or mental infirmity require nursing services that can be provided only under the direction of a registered nurse or a licensed practical nurse.

*"Rural counties"* means all counties not designated by the U.S. Census as SMA (Standard Metropolitan Area) counties.

*"Skilled nursing facility"* or *"SNF"* means any institution, place, building, or agency providing for a period exceeding 24 consecutive hours accommodation, board, and nursing services, the need for which is

certified by a physician, to three or more individuals not related to the administrator or owner thereof within the third degree of consanguinity who by reason of illness, disease, or physical or mental infirmity require continuous nursing care services and related medical services, but do not require hospital care. The nursing care services provided must be under the direction of a registered nurse on a 24-hour-per-day basis.

*"Urban counties"* means those counties designated by the U.S. Census as SMA (Standard Metropolitan Area) counties.

**2203.5(3)** *Availability and need.* (Iowa Code section 10A.714(1)*"c," "d," "e," "g," "h"*)

*a.* The following formula shall be used as a means of projecting the approximate number of intermediate and skilled nursing care beds needed to serve the projected population five years into the future:

(1) Rural counties:

[.09(65 + population) + .0015 (64 – population)] × 110% equals total long-term care bed need
Combined SNF and ICF bed need equals 2/3 (total long-term care bed need)
Assumed RCF bed need equals 1/3 (total long-term care bed need).

(2) Urban counties:

[.07(65 + population) + .0015 (64 – population)] × 110% equals total long-term care bed need
Combined SNF and ICF bed need equals 2/3 (total long-term care bed need)
Assumed RCF bed need equals 1/3 (total long-term care bed need).

(3) Economic development authority population projections are adopted for use in the determination of long-term care bed need.

(4) The department of inspections, appeals, and licensing will calculate long-term care bed need figures annually, using population projections five years into the future.

*b.* For purposes of comparing "need" to "existing" beds in a given county, the following shall be considered in the calculation of "existing" beds:

(1) ICF and SNF beds licensed at freestanding facilities in the county.

(2) Additional ICF and SNF beds previously approved through certificate of need but not yet licensed.

(3) ICF and SNF beds in designated units in hospitals in the county.

*c.* The statistical calculation of bed need shall serve as a guideline for the health facilities council in reviewing need for the proposed long-term care beds. Other factors that may be considered by the council include, but are not limited to:

(1) The availability and utilization of other ICF and SNF services in the county, or within the applicant's service area.

(2) The availability and utilization of other long-term care services in nearby hospitals, such as skilled care available through the swing bed program.

(3) The availability of supportive living arrangements that may or may not be licensed as residential care facilities (RCF).

(4) The availability of home health and other in-home services.

(5) The availability of other services to the elderly.

(6) The availability of ICF and SNF services in neighboring counties.

(7) Utilization by out-of-state residents of facilities in counties bordering other states, where the applicant provides evidence that in-migration of long-term care patients exceeds out-migration to the bordering state.

(8) Programs and services directed at special populations whose needs cannot otherwise be met, or whose needs cannot be met cost-effectively at other facilities.

*d.* In documenting need for a project, the applicant shall identify the service area and target population, including a description of the methodology used by the applicant in determining need for the requested beds and the expected sources of referrals. The applicant shall document that the number of beds requested is appropriate to address the identified need. The applicant shall also identify how the target population is currently being cared for, and what hardship is being experienced by the absence of the proposed beds.

**2203.5(4)** *Quality.* (Iowa Code section 10A.714(1)*"i," "k"*) The applicant shall document that the applicant has contacted the health and safety division of the department of inspections, appeals, and

licensing to conform with physical standards, staffing requirements, and other licensing requirements to assess the potential for provision of quality care at the facility. When necessary, the applicant shall attempt to arrange an on-site visit to the facility to determine compliance with physical requirements, and shall provide documentation of this site visit or attempts to arrange such a site visit.

**2203.5(5)** *Continuity.* (Iowa Code section 10A.714(1)*"g," "h," "k"*)

*a.* The applicant shall document the relationship of the facility's proposed services to other health and long-term care services in the community such as physician and hospital services, habilitation, rehabilitation, transportation or other services. The facility should be capable of providing or arranging for the provision of a continuum of long-term care services.

*b.* The facility should be capable of providing or arranging for the provision of a comprehensive program of coordinated patient services. The applicant shall provide evidence of contracts for services, appropriate staffing patterns and ratios, and licensure of personnel as necessary.

**2203.5(6)** *Accessibility and acceptability.* (Iowa Code section 10A.714(1)*"c," "d"*)

*a.* Population subgroups that have traditionally been underserved, such as adolescents, the elderly, women, racial minorities, mentally ill, intellectually disabled, and developmentally disabled should be considered when planning for or reviewing long-term care facilities.

*b.* The applicant shall document to what extent Medicaid patients will be served by the proposed beds, using past Medicaid utilization as an indicator or, in the case of a new facility, projecting anticipated Medicaid utilization.

**2203.5(7)** *Costs and financial feasibility.* (Iowa Code section 10A.714(1)*"e," "f," "i," "p"*)

*a.* The applicant shall identify capital and operating costs associated with the project, identify sources of funding to cover those costs, and demonstrate that the project is financially feasible.

*b.* Construction costs shall be in line with construction costs of other similar projects.

*c.* The applicant shall provide budgets for the first three years of operation, including documentation of all assumptions used. The budget shall include anticipated sources of revenue, including the percentage of revenue from private pay, Medicaid, Medicare and other patient revenues.

*d.* Proposed charges per patient day should be justifiable when compared to current charges of other similarly licensed facilities in the applicant's service area, or other similar facilities elsewhere in the state. If charges are significantly higher or lower, the applicant shall provide a description of proposed programs or services that explain the difference in charges.

[**ARC 7933C**, IAB 5/1/24, effective 6/5/24; Editorial change: IAC Supplement 9/4/24]

These rules are intended to implement Iowa Code section 10A.722.

**481—2203.6** to **2203.11** Reserved.

**481—2203.12(10A) Magnetic resonance imaging services standards.**

**2203.12(1)** *Purpose and scope.*

*a.* These standards are measures of some of those criteria in Iowa Code section 10A.714(1)*"a"* through *"q."* Criteria that are measured by a standard are cited in parentheses following each standard.

*b.* Certificate of need applications that are to be evaluated against these standards include:

(1) Proposals to commence or expand the capacity of magnetic resonance imaging services.

(2) Proposals to replace a magnetic resonance imaging unit.

(3) Any other applications that relate to magnetic resonance imaging.

**2203.12(2)** *Definitions.*

*"Area"* means the community or a metropolitan statistical area (as defined by the U.S. Office of Management and Budget and used by the U.S. Census Bureau).

*"CT (computed tomography) procedure"* means a CT study of a single site of anatomic interest during an individual patient visit.

*"Magnetic resonance imaging (MRI)"* means a diagnostic modality that employs a combination of magnetic and radio frequency fields and computers to produce images of body organs and tissues.

*"MRI procedure"* means each discrete MRI study of one patient.

*"MRI unit"* means the essential equipment and facility necessary to operate one MRI system.

**2203.12(3)** *Availability and need.* (Iowa Code section 10A.714(1)*"c," "d," "e," "g," "h"*)

*a.* Applicants in areas with no other MRI units. Applicant must document a future utilization of reasonably projected MRI procedure volume for the fiscal year period after projected installation.

*b.* Applicants in areas with one or more MRI units currently in operation or approved by certificate of need for operation.

(1) Applicant must meet the requirement of need described in paragraph 2203.12(3)*"a,"* and

(2) The other MRI unit(s) within the area must have been operating at a minimum of 2,000 MRI procedures annually (or 500 in three months), or proportionately more if the MRI unit runs more than one ten-hour shift.

(3) If the annual utilization of the other MRI unit(s) within the area has been below 2,000 procedures, future utilization above that current level must be reasonably projected or reasons for permanently utilizing the equipment below the 2,000 procedure level must be demonstrated.

*c.* Applicants seeking to replace an MRI unit.

(1) The applicant must demonstrate that the existing MRI unit has been operating at the level of at least 3,000 procedures during the most recent annual period.

(2) If the applicant's annual utilization has been below 2,000 procedures, the applicant must reasonably project future utilization above that level or demonstrate reasons for permanently utilizing the equipment below that level.

*d.* Applicants seeking to add an additional MRI unit.

(1) The applicant must demonstrate that the existing MRI unit(s) has been operating at the level of at least 3,500 procedures during the most recent annual period.

(2) The applicant must demonstrate that the demand significantly exceeds the 2,000 procedures annually.

(3) If the applicant's annual utilization has been below 2,000 procedures, the applicant must reasonably project future utilization above that level or demonstrate reasons for permanently utilizing the equipment below that level.

**2203.12(4)** *Quality and continuity.* (Iowa Code section 10A.714(1)*"g," "h," "i," "k"*)

*a.* The proposed MRI unit should function as a component of a comprehensive inpatient or outpatient diagnostic service. The proposed MRI unit must have the following modalities on-site or through referral arrangements:

(1) Ultrasound.

(2) Computed tomography.

(3) Angiography.

(4) Nuclear medicine.

(5) Conventional radiography.

*b.* The proposed MRI unit must be located in a facility that has, either in-house or through referral arrangement, the resources necessary to treat most of the conditions diagnosed or confirmed by MRI. The following medical specialties must be available during MRI service hours on-site or by referral arrangements: neurology or neurosurgery, oncology and cardiology.

*c.* A proposal to provide new or expanded MRI must include satisfactory assurances that the services will be offered in a physical environment that conforms to federal standards, manufacturer's specifications, and licensing agencies' requirements.

*d.* The applicant must provide evidence that the proposed MRI equipment has been certified for clinical use by the U.S. Food and Drug Administration or will be operated under the approval and authority of an institutional review board whose membership is consistent with U.S. Department of Health and Human Services regulations.

*e.* Applicants for MRI should document that the necessary qualified staff are available to operate the proposed unit. The following minimum staff will be available to the MRI unit:

(1) A board-eligible or board-certified radiologist or any other board-eligible or board-certified licensed physician whose exclusive responsibility for at least a two-year period prior to submission of a certificate of need request has been in the acquisition and interpretation of clinical images. This individual shall have a knowledge of MRI through training, experience, or documented postgraduate education. The individual shall also have training with a functional MRI facility.

(2) Qualified engineering personnel, available to the institution during MRI service hours, with training and experience in the operation and maintenance of the MRI equipment.

(3) Diagnostic radiologic technologists or other certified technologists with expertise in computed tomography or other cross-sectional imaging methods, at a staffing level consistent with the hospital's expected MRI service volume.

(4) Other appropriate physicians shall be available during MRI service hours in clinical specialties such as neurology or neurosurgery, oncology and cardiology.

*f.* The applicant shall demonstrate how emergencies within the MRI unit will be managed in conformity with accepted medical practice.

**2203.12(5)** *Accessibility and acceptability.* (Iowa Code section 10A.714(1)*"c," "d"*)

*a.* MRI facilities should have adequate scheduled hours to avoid an excessive backlog of cases and to meet the needs of the communities the scanners are meant to serve.

*b.* Selection of patients for clinical MRI studies must guarantee equal access to all persons regardless of insurance coverage or ability to pay.

**2203.12(6)** *Costs and financial feasibility.* (Iowa Code section 10A.714(1)*"e," "f," "i," "p"*)

*a.* The applicant shall identify capital and operating costs associated with the proposed MRI unit, identify sources of funding to cover those costs, and demonstrate that the project is financially feasible.

*b.* The applicant shall provide budgets for the first three years of operation, including documentation and justification of all assumptions used.

*c.* The applicant must document its projected average cost per procedure and charge per procedure for the first three years. Charges for MRI should be reasonably related to service cost, and comparable to MRI charges at other facilities in the state.

*d.* The applicant shall demonstrate that alternatives were considered and the proposed application is the most cost-effective and will accomplish the goals of the project.

[**ARC 7933C**, IAB 5/1/24, effective 6/5/24; Editorial change: IAC Supplement 9/4/24]

**481—2203.13(10A) Positron emission tomography services standards.**

**2203.13(1)** *Purpose and scope.*

*a.* These standards are measures of some of those criteria in Iowa Code section 10A.714(1)*"a"* through *"q."* Criteria that are measured by a standard are cited in parentheses following each standard.

*b.* Certificate of need applications that are to be evaluated against these standards include:

(1) Proposals to commence or expand the capacity of positron emission tomography services.

(2) Proposals to replace a positron emission tomography unit.

(3) Any other applications that relate to positron emission tomography.

**2203.13(2)** *Definitions.*

*"Area"* means the community or a metropolitan statistical area (as defined by the U.S. Office of Management and Budget and used by the U.S. Census Bureau).

*"CT (computed tomography)"* means an imaging method in which a cross-sectional image of the structures in a body plane is reconstructed by a computer program from the X-ray absorption of beams projected through the body in the image plane.

*"Cyclotron"* means an apparatus for accelerating protons or neutrons to high energies by means of a constant magnet and an oscillating electric field.

*"MRI (magnetic resonance imaging)"* means a diagnostic modality that employs a combination of magnetic and radio frequency fields and computers to produce images of body organs and tissues.

*"Radiopharmaceutical"* means a radioactive pharmaceutical used for diagnostic or therapeutic purposes.

*"PET procedure"* means an image-scanning sequence derived from a single administration of PET, equated with a single injection of the tracer.

*"Positron emission tomography (PET)"* means an imaging method in which positron-emitting radionuclides, which are produced either by a cyclotron or generator, and a nuclear camera are used to create pictures of organ function rather than structure.

*"SPECT (single photon emission computed tomography)"* means a camera-based imaging system using the radionuclides in the routine practice of nuclear medicine.

**2203.13(3)** *Availability and need.* (Iowa Code section 10A.714(1)*"c," "d," "e," "g," "h"*)

*a.* Applicants in areas with no other PET units.

(1) Applicants should demonstrate a reasonable potential utilization of a PET unit based on diversified inpatient and outpatient case mix thresholds including:

1. Intracranial cases.

- Primary brain tumors 50/year
- Metastasis 100/year
- Cerebral vascular disease 200/year
- Organic brain disease and dementia/psychiatric diagnoses (including epilepsy-seizure disorders) 500/year
- Spinal 100/year

2. Cardiovascular cases.

- Ischemic heart disease (including acute and chronic infarction) 1200/year

3. Neoplasms (head, neck, thorax (excluding heart), abdomen, pelvic, prostate and musculoskeletal 1300/year.

(2) Applicants should have other diagnostic capabilities, on-site or through referral arrangements, with appropriate volumes including:

| | Proposed Threshold |
|---|---|
| Nuclear medicine imaging services | 5,600 |
| Single photon emission computed tomography (including brain, bone, liver, Gallium and Thallium stress) | 1,600 |
| CT | 8,000 |
| MRI | 2,400 |

(3) Applicants should demonstrate secondary and tertiary service capability, on-site or through referral arrangements, including cardiac surgery, cardiology, internal medicine, general surgery, hematology/oncology, neurology, pathology, thoracic surgery and psychiatry.

*b.* Applicants in areas with one or more PET units currently in operation or approved by the certificate of need program for operation.

Existing PET units within the area (whether basic or enhanced) should have been operating at a minimum of 1000 PET procedures during the most recent annual period as reported to the certificate of need program according to paragraph 2203.13(6)*"e."*

**2203.13(4)** *Quality and continuity.* (Iowa Code section 10A.714(1)*"g," "h," "i," "k"*)

*a.* The proposed PET unit should function as a component of a comprehensive inpatient or outpatient diagnostic service. The proposed PET unit should have the following modalities (and capabilities) on-site or through referral arrangements:

(1) Computed tomography.

(2) Magnetic resonance imaging.

(3) Nuclear medicine — (cardiac, SPECT).

(4) Conventional radiography.

*b.* The proposed PET unit should be located in a facility that has, either in-house or through referral arrangement, the resources necessary to treat most of the conditions diagnosed or confirmed by PET. The following medical specialties should be available during PET service hours on-site or by referral arrangements: cardiology, neurology, neurosurgery, oncology, and psychiatry.

*c.* A proposal to provide new or expanded PET must include satisfactory assurances that services will be offered in a physical environment that conforms to federal standards, manufacturer's specifications, and licensing agencies' requirements. The following areas are to be addressed:

(1) Quality control and assurance of radiopharmaceutical production of generator or cyclotron-produced agents;

(2) Quality control and assurance of PET tomograph and associated instrumentation;

(3) Radiation protection and shielding;

(4) Radioactive emissions to the environment.

*d.* The applicant will provide evidence that the proposed PET equipment has been certified for clinical use by the U.S. Food and Drug Administration or will be operated under the approval and authority of an institutional review board whose membership is consistent with U.S. Department of Health and Human Services regulations.

*e.* Applicants for PET will document that the necessary qualified staff are available to operate the proposed unit. The applicants will document the PET training and experience of the staff. The following minimum staff will be available to the PET unit:

(1) One or more nuclear medicine imaging physician(s) available to the PET unit who have been licensed by the state for the handling of medical radionuclides and whose primary responsibility for at least a one-year period prior to submission of the certificate of need application has been in acquisition and interpretation of tomographic images. This individual shall have knowledge of PET through training, experience, or documented postgraduate education. The individual shall also have training with a functional PET facility.

(2) Qualified PET radiochemist or radiopharmacist personnel, available to the facility during PET service hours, with at least one year of training. The individual(s) will demonstrate experience in the testing of chemical, radiochemical, and radionuclidic purity of PET radiopharmaceutical syntheses.

(3) Qualified engineering and physics personnel, available to the facility during PET service hours, with training and experience in the operation and maintenance of the PET equipment.

(4) Qualified radiation safety personnel, available to the facility at all times, with training and experience in the handling of short-lived positron-emitting nuclides.

(5) Certified nuclear medicine technologists with expertise in computed tomographic nuclear medicine imaging procedures, at a staffing level consistent with the proposed center's expected PET service volume.

(6) Other appropriate personnel should be available during PET service hours, which may include certified nuclear medicine technologists, computer programmers, nurses, and radiochemistry technicians.

*f.* The applicant will demonstrate how emergencies within the PET unit will be managed in conformity with accepted medical practice.

**2203.13(5)** *Accessibility and acceptability.* (Iowa Code section 10A.714(1)*"c," "d"*)

*a.* PET facilities should have adequate scheduled hours to avoid an excessive backlog of cases.

*b.* Selection of patients for clinical PET studies will guarantee equal access to all persons regardless of insurance coverage or ability to pay.

*c.* In addition to accepting patients from participating institutions, facilities performing clinical PET procedures should accept appropriate referrals from other local providers. These patients will be accommodated to the extent possible by extending the hours of service and by prioritizing patients according to standards of need and appropriateness rather than source of referral.

**2203.13(6)** *Costs and financial feasibility.* (Iowa Code section 10A.714(1)*"e," "f," "i," "p"*)

*a.* The applicant will identify capital and operating costs associated with the proposed PET unit, identify sources of funding to cover those costs, and demonstrate that the project is financially feasible.

*b.* The applicant will provide budgets for the first three years of operation, including documentation and justification of all assumptions used.

*c.* The applicant will document its projected average cost per procedure and charge per procedure for the first three years. Charges for PET should be reasonably related to service cost and comparable to PET charges at other facilities in the state.

*d.* The applicant should verify whether the service is eligible for reimbursement by public and private third-party payers.

*e.* The applicant should demonstrate that alternatives were considered and the proposed application is the most cost-effective and should accomplish the goals of the project.

[**ARC 7933C**, IAB 5/1/24, effective 6/5/24; Editorial change: IAC Supplement 9/4/24]

These rules are intended to implement Iowa Code sections 10A.711 through 10A.729.

[Filed emergency 7/26/78—published 8/23/78, effective 7/26/78]
[Filed 2/1/80, Notice 8/8/79—published 2/20/80, effective 3/26/80]
[Filed 6/6/80, Notice 2/6/80—published 6/25/80, effective 7/30/80]

[Filed emergency 9/10/80—published 10/1/80, effective 9/10/80]
[Filed emergency 11/7/80—published 11/26/80, effective 11/7/80]
[Filed 12/5/80, Notice 10/15/80—published 12/24/80, effective 1/28/81]
[Filed emergency 4/9/81—published 4/29/81, effective 4/10/81]
[Filed 6/2/81, Notice 4/15/81—published 6/24/81, effective 8/1/81]
[Filed 3/22/84, Notice 12/7/83—published 4/11/84, effective 5/16/84]
[Filed 11/14/85, Notice 9/25/85—published 12/4/85, effective 1/8/86]
[Filed 3/20/86, Notice 1/29/86—published 4/9/86, effective 5/16/86]
[Filed 5/15/87, Notice 3/11/87—published 6/3/87, effective 7/8/87]
[Filed emergency 7/10/87—published 7/29/87, effective 7/10/87]
[Filed 5/11/90, Notice 3/7/90—published 5/30/90, effective 7/4/90]
[Filed ARC 2297C (Notice ARC 2177C, IAB 9/30/15), IAB 12/9/15, effective 1/13/16]
[Filed ARC 5931C (Notice ARC 5633C, IAB 5/19/21), IAB 10/6/21, effective 11/10/21]
[Filed ARC 7933C (Notice ARC 7380C, IAB 1/10/24), IAB 5/1/24, effective 6/5/24]
[Editorial change: IAC Supplement 9/4/24]