Regulatory Analysis

Notice of Intended Action to be published: 441—Chapters 123 and 124
"Certificate of Need"

Iowa Code section(s) or chapter(s) authorizing rulemaking: 135.61, 135.66, 135.69, 135.71, and 135.72, all as transferred by 2025 Iowa Acts, House File 972, division VIII

State or federal law(s) implemented by the rulemaking: Iowa Code sections 135.61 through 135.78, all as transferred by 2025 Iowa Acts, House File 972, division VIII

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

November 18, 2025 10 a.m.	Microsoft Teams Meeting ID: 224 106 109 665 1 Passcode: Pd9YP99Y

Public Comment

Any interested person may submit written or oral comments concerning this Regulatory Analysis, which must be received by the Department of Health and Human Services no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

Victoria L. Daniels
321 East 12th Street
Des Moines, Iowa 50319
Phone: 515.829.6021
Email: compliancerules@hhs.iowa.gov

Purpose and Summary

This proposed rulemaking implements, in part, 2025 Iowa Acts, House File 972, division VIII, which eliminates the Health Facilities Council and transfers the responsibility for approving Certificate of Need applications to the Department. It also transfers the existing Iowa Code sections governing the Certificate of Need process from Iowa Code chapter 10A to Iowa Code chapter 135 within Title IV, Public Health.

All references to Iowa Code sections 135.61 through 135.78 herein are to those sections as transferred by 2025 Iowa Acts, House File 972, division VIII.

Analysis of Impact

1. **Persons affected by the proposed rulemaking:**

- **Classes of persons that will bear the costs of the proposed rulemaking:**

Applicants for Certificates of Need must submit the fees detailed in this proposed rulemaking.

- **Classes of persons that will benefit from the proposed rulemaking:**

Applicants seeking Certificates of Need will benefit from the guidance in this proposed rulemaking.

2. **Impact of the proposed rulemaking, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred:**

- **Quantitative description of impact:**

Applicants for Certificates of Need must submit the fees enumerated in this proposed rulemaking.

- **Qualitative description of impact:**

Applicants for Certificates of Need will benefit from the guidance in this proposed rulemaking.

3. **Costs to the State:**

- **Implementation and enforcement costs borne by the agency or any other agency:**

The Department will incur personnel and other administrative costs to implement this proposed chapter.

- **Anticipated effect on State revenues:**

Because there is no increase in the fees already established, this proposed rulemaking has no effect on State revenues.

4. **Comparison of the costs and benefits of the proposed rulemaking to the costs and benefits of inaction:**

Rulemaking is required by Iowa Code section 135.71 as transferred by 2025 Iowa Acts, section 40.

5. **Determination whether less costly methods or less intrusive methods exist for achieving the purpose of the proposed rulemaking:**

Not applicable.

6. **Alternative methods considered by the agency:**

- **Description of any alternative methods that were seriously considered by the agency:**

Not applicable.

- **Reasons why alternative methods were rejected in favor of the proposed rulemaking:**

Not applicable.

Small Business Impact

If the rulemaking will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rulemaking on small business:

- Establish less stringent compliance or reporting requirements in the rulemaking for small business.
- Establish less stringent schedules or deadlines in the rulemaking for compliance or reporting requirements for small business.
- Consolidate or simplify the rulemaking's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rulemaking for small business.
- Exempt small business from any or all requirements of the rulemaking.

If legal and feasible, how does the rulemaking use a method discussed above to reduce the substantial impact on small business?

This proposed rulemaking has no impact on small business.

Text of Proposed Rulemaking

ITEM 1. Adopt the following **new** 441—Chapter 123:

CERTIFICATE OF NEED PROGRAM

CHAPTER 123
CERTIFICATE OF NEED PROGRAM

441—123.1(135) Definitions. For purposes of this chapter, the following definitions apply:

"Long-term (acute) care hospital" means a hospital that has been approved to participate in the Title XVIII (Medicare) program as a long-term care hospital-prospective payment system (LTCH-PPS) hospital in accordance with 42 CFR Part 412 as amended to August 1, 2025.

"Radiation therapy service applying ionizing radiation for the treatment of malignant disease using megavoltage external beam equipment," as the term applies to new or changed institutional health service in Iowa Code section 135.61(17)*"m"*(4), means the initiation or expansion of this service.

441—123.2(135) Letter of intent.

123.2(1) Before applying for a certificate of need, the sponsor of a proposed new institutional health service or changed institutional health service will electronically submit a letter of intent meeting the criteria noted in Iowa Code section 135.64(1).

123.2(2) The department will make available on the certificate of need website all criteria and standards pertinent to an application.

123.2(3) A letter of intent received by the department is valid for a period of one year from the date of receipt by the department. The sponsor may renew the validity of a letter of intent by providing written notification to the department prior to the one-year expiration date.

441—123.3(135) Determination of reviewability. A sponsor of a proposed project may submit a written request for a determination of reviewability as to whether the project requires a certificate of need.

123.3(1) If it is determined that a certificate of need is required, the department will notify the sponsor and the request for nonreviewability will be considered the letter of intent for purposes of subrule 123.2(2).

123.3(2) If it is determined that a certificate of need is not required, the department will notify the sponsor of the determination of nonreviewability.

441—123.4(135) Submission of application.

123.4(1) Application form.

a. A sponsor of a proposed project for a new or changed institutional health service will submit to the department an application for certificate of need using the appropriate application form found on the certificate of need website. All information requested in the application form is required in the absence of a waiver by the department.

b. An original application and all attachments shall be submitted electronically.

c. The department will establish and maintain electronic files on each application.

123.4(2) Application fee. The application fee specified in Iowa Code section 135.62(1) is based on the total cost of the project, including site costs, land improvements, facility costs, movable equipment, and financing costs.

a. The fee for leased or donated new institutional health services is calculated in the same manner as if the new institutional health services were purchased.

(1) The leased equipment fee is based on total value of the lease, plus sales tax, delivery and installation.

(2) The lease of space includes the cost of a one-year lease payment for the space, in addition to other costs associated with the project.

(3) Financing costs are not applicable on leases or cash purchases.

b. The application fee will be refunded by the department for any application that is voluntarily withdrawn from the review process in the amounts specified in Iowa Code section 135.62(1).

c. For purposes of this subrule and Iowa Code section 135.62(1), the term "submission" means the day the application is received by the department.

123.4(3) The notice of an accepted application issued pursuant to Iowa Code section 135.65(2) will inform the applicant and affected persons of the deadlines for the electronic submission to the department of written statements or other materials.

441—123.5(135) Organizational procedures.

123.5(1) The department will evaluate the application against the criteria specified in Iowa Code section 135.63.

123.5(2) Public comments on an application.

a. The department will receive written public comments on an application during a time frame prescribed by the department for each application. Oral comments will be received at a public hearing set by the department.

b. Public hearings conducted pursuant to Iowa Code section 135.65(3)*"b"* are not contested cases.

441—123.6(135) Summary review. Summary review may be utilized at the discretion of the department pursuant to Iowa Code section 135.66. An applicant requesting a summary review will abide by the following procedures:

123.6(1) An applicant will electronically submit a written request for summary review and a copy of the application and all attachments. An applicant is not required to submit a letter of intent pursuant to Iowa Code section 135.64 prior to submitting a written request for a summary review.

123.6(2) The eligibility of an application for summary review pursuant to Iowa Code section 135.66 does not mandate or require such review. The department will make the decision as to whether an application will be reviewed in the summary review process.

123.6(3) Upon receipt of a written request for summary review, an application, and the fee required by Iowa Code section 135.62(1), the department will notify the applicant in writing within 15 calendar days if the application is complete and if a summary review will be granted.

123.6(4) If an application is deemed incomplete, the department will state specifically in writing what information is needed to make the application complete.

123.6(5) If the department notifies an applicant that a summary review will not be performed, this decision is binding on the applicant and the application will be entered into the formal review process on the date of written notice that such application will not be reviewed summarily.

123.6(6) A summary review of an application for a certificate of need will be completed within 60 calendar days of the acceptance of an application by the department. Summary review will follow the process outlined on the department's website.

123.6(7) At any time during the summary review process, an application may be withdrawn without prejudice from the process. An applicant may then submit the application for a formal 90-day review.

441—123.7(135) Extension of review time.

123.7(1) A formal review of an application for a certificate of need pursuant to Iowa Code section 135.65 may be extended by the department on the basis of any of the following criteria:

a. In order to review competing applications simultaneously;

b. In the case of technologically innovative equipment, to obtain additional information necessary to evaluate the proposal. The department will specify in writing such additional information as necessary;

c. At the request of an applicant;

d. At the request of the department in order to allow additional time for deliberation on all evidence present. The department will specify the time of the delay and the date on which the final decision will be rendered.

123.7(2) An extension by the department made pursuant to subrule 123.7(1) will in no case be more than 60 calendar days beyond the time a decision is required under Iowa Code section 135.68 unless the applicant and the department agree.

123.7(3) Where none of the provisions of subrule 123.7(1) are applicable and where an application will be automatically denied because of the expiration of time required by Iowa Code section 135.68 for the issuance of a written decision by the department, the department will notify the applicant of the likelihood of an automatic denial and will ask the applicant to request in writing an extension of the review time.

441—123.8(135) Rehearing of certificate of need decision.

123.8(1) An applicant or any affected person who has participated or sought unsuccessfully to participate in the formal review procedure prescribed in Iowa Code section 135.65 may, for good cause shown, file an application for rehearing in writing with the department stating the specific grounds therefor and the relief sought within 20 calendar days after the date of the issuance of the final decision on an application for certificate of need.

123.8(2) Grounds for rehearing include but are not limited to:

a. New significant, relevant information that was unavailable at the date of the hearing;

b. Significant changes in factors or circumstances relied upon by the department in reaching its decision;

c. Demonstration that the department has materially failed to follow its adopted procedures in reaching its decision; or

d. Such other bases as the department determines constitute good cause.

123.8(3) An application for rehearing is deemed to have been denied unless the department grants the application in writing within 20 calendar days after its filing.

123.8(4) If the application for rehearing is granted, the department may issue an order modifying the initial final order. At the department's discretion, public hearing may be granted on the application for rehearing and notice will be provided ten calendar days prior to the rehearing to the person applying for rehearing, the applicant and other affected persons upon request.

123.8(5) The department will issue the final decision on rehearing, stating the basis for its decision, within 60 calendar days after the application for rehearing was granted or 60 calendar days after public hearing or rehearing, whichever is later.

123.8(6) If a rehearing is not requested or an affected party remains dissatisfied after the request for rehearing, an appeal may be taken in the manner provided by Iowa Code chapter 17A. A request for rehearing is not required prior to appeal under Iowa Code section 17A.19.

441—123.9(135) Finality. The certificate of need application process is continuous beginning with submission of a letter of intent or request for waiver of a letter of intent through issuance of a final decision by the department subject to judicial review under Iowa Code chapter 17A.

123.9(1) The following stages of the process are intermediate and subject to judicial review only to the extent the stages meet criteria for intermediate review under Iowa Code section 17A.19:

a. A decision by the department pursuant to rule 441—123.3(135) that a proposed project does not require a certificate of need;

b. A decision by the department to waive submission of the letter of intent and substitute summary review; and

c. The rejection of an application by the department that fails to provide all information required under Iowa Code section 135.62(1).

123.9(2) The following stages of the process are final decisions subject to judicial review as final agency action under Iowa Code section 17A.19:

a. A decision by the department to disallow summary review;

b. A decision by the department that a proposed project does not require a certificate of need;

c. A decision by the department to approve or deny an application.

d. The department's final decision on an application for rehearing; and

e. A decision by the department to revoke a certificate of need pursuant to rule 441—123.10(135).

441—123.10(135) Request for extension of certificate.

123.10(1) A request by an applicant for an extension of a certificate of need will be filed with the department using the form available on the certificate of need website no later than 30 days prior to the expiration of the certificate of need.

123.10(2) When an extension has been requested, the department will approve or deny the request prior to expiration of the certification. The certificate of need may be revoked by the department at the end of the certification period for insufficient progress in developing the project.

123.10(3) If an extension is denied, an applicant has the right to appeal under the provisions of Iowa Code section 135.69.

441—123.11(135) Application changes after approval.

123.11(1) Once a project has been approved by the department, no changes that vary from or alter the number of approved beds, the approved services or the approved cost by an amount indicated in subrule 123.11(2) may be made unless requested by the applicant and approved by the department. Requests should be made in writing and filed with the department electronically.

123.11(2) An increase in the actual cost of the project over and above that originally approved will automatically generate review by the department if the increase exceeds the originally approved amount by:

a. Fifteen percent for projects up to $999,999.99;

b. Twelve percent for projects from $1 million to $4,999,999.99;

c. Eight percent for projects $5 million and over.

An increase in the approved cost that falls below the above percentages will be reported to the department.

123.11(3) Failure to notify and receive permission of the department to change the project as originally approved may result in the imposition of sanctions as provided in Iowa Code section 135.72. The department may make a recommendation regarding the imposition of a sanction and the amount of the fine to be imposed.

441—123.12(135) Sanctions. Hearings to determine class I or class II violations pursuant to Iowa Code section 135.72 will be conducted in accordance with 441—Chapter 7.

These rules are intended to implement Iowa Code sections 135.61 through 135.78.

ITEM 2. Adopt the following **new** 441—Chapter 124:

CHAPTER 124
STANDARDS FOR CERTIFICATE OF NEED REVIEW

441—124.1(135) Cardiac catheterization and cardiovascular surgery standards.

124.1(1) *Purpose and scope.*

a. These standards are measures of some of those criteria found in Iowa Code section 135.63(1)*"a"* through *"q"* and 135.63(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.

124.1(2) *Definitions.* The following definitions apply to the terms used in this rule:

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

"Adult cardiovascular surgery" means cardiovascular surgery exclusively for adults.

"Angiocardiography" means 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.

"Angiography" means 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.

"Cardiovascular surgery" means 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.

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

"Coronary artery catheterization" means 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.

"Coronary artery surgery" means surgery to correct inadequate blood flow to the heart using revascularization techniques to bypass significantly obstructed coronary artery lesions.

"Intracardiac" means 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.

"Open heart surgery" means 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 since blood flow through the heart is greatly reduced or stopped altogether.

"Pediatric cardiac catheterization laboratory" means the same as adult cardiac catheterization laboratory, except exclusively for children and infants.

"Pediatric cardiovascular surgery" means cardiovascular surgery exclusively for infants and children.

124.1(3) *Availability of services.*

a. Minimum utilization—cardiovascular surgery (Iowa Code section 135.63(1)*"c," "g,"* and *"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 and pediatric cardiovascular surgery units should project the minimum projected annual rates for both adult and pediatric surgery.

(4) An applicant 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 of 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 135.63(1)*"c," "d," "e," "g,"* and *"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) An 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 hours' surface travel time for pediatric services.

c. Minimum utilization—cardiac catheterization (Iowa Code section 135.63(1)*"c," "d," "g,"* and *"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 per annum.

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

(4) An 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 of 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 135.63(1)*"c," "d," "e," "g,"* and *"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) An 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 hours' surface travel time for pediatrics.

124.1(4) *Costs.*

a. Financial feasibility. (Iowa Code section 135.63(1)*"f," "i,"* and *"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.

124.1(5) *Accessibility.* (Iowa Code section 135.63(1)*"c"* and *"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.

124.1(6) *Quality.* (Iowa Code section 135.63(1)*"i"* and *"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. An 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.

124.1(7) *Continuity.* (Iowa Code section 135.63(1)*"g," "h," "i,"* and *"k"*)

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

b. An 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.

124.1(8) *Acceptability.* (Iowa Code section 135.63(1)) Facilities with cardiovascular surgery and cardiac catheterization indicate a willingness to observe and respect the rights of patients.

441—124.2(135) Radiation therapy standards.

124.2(1) *Purpose and scope.*

a. These standards provide guidelines to assist the department in applying those criteria in Iowa Code section 135.63(1)*"a"* through *"r"* and 135.63(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.

124.2(2) *Definitions.* The following definitions apply to the terms used in this rule:

"Computed tomography" or *"CT"* 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.

"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 1 million electron volts. Energies above 1 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 1 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 rule 641—42.5(136C).

"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 and calibrates the equipment. A radiation therapy physicist shall practice in accordance with rule 641—42.6(136C).

"Radiation therapy technologist" means an individual who possesses an Iowa permit to practice as a radiation therapist in accordance with rule 641—38.4(136C).

"Service area" means the county in which the facility is located and any other counties from which an 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, a magnetic resonance imaging device, or a 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.

124.2(3) *Availability.*

a. Minimum utilization. (Iowa Code section 135.63(1)*"c," "g,"* and *"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 by 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 by 0.5 (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 by 20, which will result in no fewer than 5,000 treatments per annum.

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

(5) An applicant 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.

124.2(4) *Accessibility.* (Iowa Code section 135.63(1)*"c"* and *"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.

124.2(5) *Quality.* (Iowa Code section 135.63(1)*"i"* and *"k"*)

a. Minimum staffing requirements for radiation therapy facilities. Each facility:

(1) Will have the services of at least one radiation oncologist.

(2) Will have the services of at least one radiation therapy physicist.

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

(4) Should have the services of nurses.

(5) Should have the services of at least one dosimetrist.

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

(7) Should offer psychosocial counseling services and nutritional counseling.

b. Minimum staffing requirements for conjoint centers. Each center:

(1) Will have at least two cancer biologists available.

(2) Will have one radiation technologist available for each simulator.

(3) Should have a source of continuing education to reach participating community referral hospitals and physicians.

(4) Should have a unified training program in radiation therapy for radiation oncologists.

c. The long-range plans for radiation therapy services shall be submitted to the department.

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

124.2(6) *Continuity.* (Iowa Code section 135.63(1)*"g," "h," "i,"* and *"k"*) An 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.

441—124.3(135) Computerized tomography standards.

124.3(1) *Purpose and scope.*

a. These standards are measures of some of those criteria in Iowa Code section 135.63(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.

124.3(2) *Definitions.* The following definitions apply to the terms used in this rule:

"Active oncology service" means 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.

"Applicant" means a facility or a consortium of facilities within an area or a physician or group of physicians.

"Chemotherapy service" means the treatment of cancer by chemical agents.

"Computerized tomographic (CT) scanner" means a diagnostic tool that rotates around the body 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.

"CT consortia" means 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.

"Emergency medical service (EMS) level II trauma service" means the level of various services and staffing that qualify a facility to be designated by the department, using the facilities categorization criteria of such services that is in effect on the date of the enactment of this standard.

"Enhanced scan" means 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.

"General imaging procedures" means a radiological diagnostic procedure performed on an X-ray machine or similar radiological diagnostic instrument.

"Head scanner" means a scanner capable of imaging only the brain and structures adjacent to the head.

"Minimum shared-market area for a scanner" (hereafter referred to as "area") means the smallest geographic area within which any scanner installation is judged to affect the utilization rate of any other scanner in the community (as defined by the U.S. Bureau of the Census) or a standard metropolitan statistical area (where an area is so designated).

"Radiotherapy service" means 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.

"Shared service agreement" means 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.

"Whole body scanner" means a scanner capable of imaging the entire body.

124.3(3) *Determination of need.*

a. An applicant who does not have a scanner or an applicant who has a scanner and seeks a certificate for one or more additional scanners.

(1) An applicant in areas with no other scanners.

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

2. An applicant must demonstrate that during the past calendar year or 12 months, the applicant has performed diagnostic procedures equivalent to 1,500 head equivalent CTs (HECTs), using the following: 100 percent 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) An applicant in an area with one or more scanners.

1. An applicant must meet the requirement of need described in subparagraph 124.4(3)*"a"*(1), and

2. The average level of utilization for scanners within the area was at least 3,000 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. University of Iowa Health Care is specifically exempted from consideration under numbered paragraph 124.3(3)*"a"*(2)"2" because it has a service area that encompasses the entire state and adjoining states. The utilization statistics for scanners at the University of Nebraska Medical Center and Creighton University Medical Center – Bergan Mercy (both in Omaha) will not affect the need for scanners at hospitals in Council Bluffs.

b. Replacement scanners—applicant who currently has a scanner.

(1) An applicant seeking to replace a scanner with another scanner, head or body.

1. An 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. An applicant must demonstrate that the applicant's use of the applicant's current scanner was at least below the operating capacity level, but above the 1,500 CT scan level, and the applicant must demonstrate reasons for permanently utilizing the applicant's scanner below operating capacity level and demonstrate that discontinuation of the applicant's 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 the applicant.

(2) Reserved.

124.3(4) *Costs and financial feasibility.* (Iowa Code section 135.63(1)*"f," "i,"* and *"p"*)

a. 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.

b. Cost-effectiveness. An applicant should demonstrate for the applicant and the health care system that the most cost-effective method of providing CT services has been chosen. A proposed new and replacement CT scanner's cost per CT scan should, when compared to the applicant's peers, demonstrate cost-effectiveness.

124.3(5) *Accessibility.* (Iowa Code section 135.63(1)*"c"* and *"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. An applicant will demonstrate a willingness to accept referrals for CT services from all area physicians.

124.3(6) *Quality.* (Iowa Code section 135.63(1)*"i"* and *"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 135.63(1)*"a"* and *"h"*)

b. All scanners.

(1) An applicant must demonstrate that the applicant has on its staff or will acquire on its staff a full-time diagnostic radiologist trained in the use of the CT scanner or other physicians with comparable training and expertise.

(2) An applicant must document that the applicant has on its 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. An applicant that intends to acquire staff with the desired expertise should provide signed letters of intent from the incoming medical personnel. An applicant that intends to upgrade the specialty skills of its staff should document a plan for training its current staff in the use of CT scanners.

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

(4) An applicant 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) An applicant should have on its 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.

124.3(7) *Continuity.* (Iowa Code section 135.63(1)*"g," "h," "i,"* and *"k"*)

a. An 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. An applicant should provide documentation that emergency medical transport services will be available.

c. An 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.

124.3(8) *Acceptability.* (Iowa Code section 135.63(1)*"k"*) Providers of CT services should indicate a willingness to observe the rights of patients.

441—124.4(135) Long-term care.

124.4(1) *Purpose and scope.*

a. These standards are measures of criteria found in Iowa Code section 135.63(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.

124.4(2) *Definitions.* The following definitions apply to the terms used in this rule:

"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 standard metropolitan area (SMA) 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 counties.

124.4(3) *Availability and need.* (Iowa Code section 135.63(1)*"c," "d," "e," "g,"* and *"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 percent 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 percent 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 department in reviewing need for the proposed long-term care beds. Other factors that may be considered by the department include but are not limited to:

(1) The availability and utilization of other ICF and SNF services in the county or within an 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 an 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 an 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, an 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.

124.4(4) *Quality.* (Iowa Code section 135.63(1)*"i"* and *"k"*) An 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.

124.4(5) *Continuity.* (Iowa Code section 135.63(1)*"g," "h,"* and *"k"*)

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

124.4(6) *Accessibility and acceptability.* (Iowa Code section 135.63(1)*"c"* and *"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. An 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.

124.4(7) *Costs and financial feasibility.* (Iowa Code section 135.63(1)*"e," "f," "i,"* and *"p"*)

a. An 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. An 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 an 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.

These rules are intended to implement Iowa Code section 135.71.

441—124.5(135) MRI services standards.

124.5(1) *Purpose and scope.*

a. These standards are measures of some of those criteria in Iowa Code section 135.63(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.

124.5(2) *Definitions.* The following definitions apply to the terms used in this rule:

"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).

"Computed tomography" or *"CT"* 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.

"CT procedure" means a CT study of a single site of anatomic interest during an individual patient visit.

"Magnetic resonance imaging" or *"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.

124.5(3) *Availability and need.* (Iowa Code section 135.63(1)*"c," "d," "e," "g,"* and *"h"*)

a. An applicant in an area with no other MRI units. The applicant must document a future utilization of reasonably projected MRI procedure volume for the fiscal year period after projected installation.

b. An applicant in an area with one or more MRI units currently in operation or approved by certificate of need for operation.

(1) An applicant must meet the requirement of need described in paragraph 124.5(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. An applicant seeking to replace an MRI unit.

(1) An 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 an 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. An applicant seeking to add an additional MRI unit.

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

(3) If an 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.

124.5(4) *Quality and continuity.* (Iowa Code section 135.63(1)*"g," "h," "i,"* and *"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 a new or an 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. An 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. An applicant 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 CT 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. An applicant shall demonstrate how emergencies within the MRI unit will be managed in conformity with accepted medical practice.

124.5(5) *Accessibility and acceptability.* (Iowa Code section 135.63(1)*"c"* and *"d"*)

a. An MRI facility 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.

124.5(6) *Costs and financial feasibility.* (Iowa Code section 135.63(1)*"e," "f," "i,"* and *"p"*)

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

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

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

441—124.6(135) PET services standards.

124.6(1) *Purpose and scope.*

a. These standards are measures of some of those criteria in Iowa Code section 135.63(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.

124.6(2) *Definitions.* The following definitions apply to the terms used in this rule:

"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).

"Computed tomography" or *"CT"* 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.

"Magnetic resonance imaging" or *"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.

"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" or *"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.

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

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

124.6(3) *Availability and need.* (Iowa Code section 135.63(1)*"c," "d," "e," "g,"* and *"h"*)

a. An applicant in an area with no other PET units.

(1) An applicant 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 per year.
- Metastasis: 100 per year.
- Cerebral vascular disease: 200 per year.
- Organic brain disease and dementia/psychiatric diagnoses (including epilepsy-seizure disorders): 500 per year.
- Spinal: 100 per year.

2. Cardiovascular cases.

- Ischemic heart disease (including acute and chronic infarction): 1,200 per year.

3. Neoplasms (head, neck, thorax (excluding heart), abdomen, pelvic, prostate and musculoskeletal): 1,300 per year.

(2) An applicant 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) An applicant 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. An applicant in an area 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 1,000 PET procedures during the most recent annual period as reported to the certificate of need program according to paragraph 124.6(4)*"e."*

124.6(4) *Quality and continuity.* (Iowa Code section 135.63(1)*"g," "h," "i,"* and *"k"*)

a. A 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) CT.

(2) MRI.

(3) Nuclear medicine—cardiac, SPECT.

(4) Conventional radiography.

b. A 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. An 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. An applicant for PET will document that the necessary qualified staff are available to operate the proposed unit. The applicant 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. An applicant will demonstrate how emergencies within the PET unit will be managed in conformity with accepted medical practice.

124.6(5) *Accessibility and acceptability.* (Iowa Code section 135.63(1)*"c"* and *"d"*)

a. A PET facility 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, a facility 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.

124.6(6) *Costs and financial feasibility.* (Iowa Code section 135.63(1)*"e," "f," "i,"* and *"p"*)

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

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

c. An 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. An applicant should verify whether the service is eligible for reimbursement by public and private third-party payers.

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

These rules are intended to implement Iowa Code sections 135.61 through 135.78.