441—124.3(135) MRI services 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 *"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.

124.3(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.

124.3(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 124.3(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.

124.3(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.

124.3(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.

124.3(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.

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