

**641—203.12 (135) Magnetic resonance imaging services standards.****203.12(1) Purpose and scope.**

*a.* These standards are measures of some of those criteria in Iowa Code sections 135.64(1) “a” to “q.” Criteria which are measured by a standard are cited in parentheses following each standard.

*b.* Certificate of need applications which 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 which relate to magnetic resonance imaging.

**203.12(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 which 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.

**203.12(3) Availability and need.** (Iowa Code sections 135.64(1) “c,” “d,” “e,” “g,” “h”)

*a.* Applicants in areas with no other MRI units. Applicant must document a CT procedure volume of at least 4,500 CT procedures during the most recent calendar or fiscal year period. For purposes of calculating the volumes required, the applicant may use the combined total of more than one facility if the application involves joint ownership of the equipment, or the applicant provides evidence of referral arrangements for the proposed MRI service from the facilities whose procedure or patient volumes are included in the calculations.

*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 203.12(3) “a” and
- (2) The other MRI unit(s) within the area must have been operating at a minimum of 3,000 MRI procedures annually (or 750 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 3,000 procedures, future utilization above that current level must be reasonably projected or reasons for permanently utilizing the equipment below the 3,000 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 3,000 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 3,500 procedures annually.

*e.* The provisions of subrule 203.12(3) shall be effective until June 30, 1995. Prior to that time the Iowa department of public health shall reconvene a task force to recommend continuing use of the need methodology outlined or develop a new or revised methodology to use in projecting future MRI needs. The department shall promulgate a new subrule 203.12(3) accordingly.

**203.12(4) *Quality and continuity.*** (Iowa Code sections 135.64(1) “g,” “h,” “i,” “k” )

*a.* The proposed MRI unit must 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 — whole body unit
- (3) Angiography
- (4) Nuclear medicine
- (5) Conventional radiography

*b.* The proposed MRI unit must be located in a facility which 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 an institutional review board whose membership is consistent with U.S. Department of Health and Human Services regulations.

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

1. A full-time board eligible or board certified radiologist or nuclear medicine imaging physician 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.

**203.12(5) *Accessibility and acceptability.*** (Iowa Code sections 135.64(1) “c,” “d” )

*a.* MRI facilities should have adequate scheduled hours to avoid an excessive backlog of cases and MRI shall be available 24 hours a day, seven days a week on an emergency (on-call) basis.

*b.* Selection of patients for clinical MRI studies must 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 MRI procedures shall accept appropriate referrals from other local providers. These patients shall 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.

**203.12(6) *Costs and financial feasibility.*** (Iowa Code sections 135.64(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.

*e.* To provide a data base for evaluation of subsequent MRI applications by the health facilities council, applicants granted a certificate of need shall provide to the certificate of need office the following data upon request of the Iowa department of public health. The department will request the following data on an annual basis.

1. Total number of procedures performed;
2. Total number of inpatient procedures;
3. Total number of outpatient procedures;
4. Average charge per procedure;
5. Hours of operation of the MRI unit;
6. Total revenues and expenses for the MRI unit for the year.

This rule is intended to implement Iowa Code section 135.64.