

**MAGNETIC RESONANCE
IMAGING**

STATE HEALTH PLAN
CERTIFICATE OF NEED STANDARDS AND CRITERIA
FOR
MAGNETIC RESONANCE IMAGING SERVICES

The Health Services and Development Agency (HSDA) may consider the following standards and criteria for applications seeking to provide Magnetic Resonance Imaging (MRI) services. Existing providers of MRI services are not affected by these standards and criteria unless they take an action that requires a new certificate of need (CON) for MRI services.

These standards and criteria are effective immediately as of December 21, 2011, the date of approval and adoption by the Governor of the State Health Plan changes for 2011. Applications to provide MRI services that were deemed complete by HSDA prior to this date shall be considered under the Guidelines for Growth, 2000 Edition.

Definitions

Capacity: The measure of the maximum number of MRI procedures per MRI unit per year based upon the type of MRI equipment.

Dedicated Breast MRI Unit: An MRI unit that is configured to perform only breast MRI procedures and is not capable of performing other types of non-breast MRI procedures.

Dedicated Extremity MRI Unit: An MRI unit that is utilized for the imaging of extremities only and is of open design with a field of view no greater than 25 centimeters.

Magnetic Resonance Imaging (MRI): A noninvasive diagnostic modality in which electronic equipment is used to create tomographic images of body structure. The MRI scanner exposes the target area to nonionizing magnetic energy and radio frequency fields, focusing on the nuclei of atoms such as hydrogen in the body tissue. Response of selected nuclei to this stimulus is translated into images for evaluation by the physician.

MRI Procedure: A single, discrete MRI study performed on a single patient during a single visit. The Health Services and Development Agency (HSDA) shall be responsible for setting reporting requirements consistent with this definition, including the development of a selected set of CPT codes, which shall not include research-only CPT codes for purposes of determining capacity and need.

MRI Study: An MRI scan defined by a CPT procedure code.

MRI Unit: Medical imaging equipment (often referred to as a “scanner”) that uses nuclear magnetic resonance to create tomographic images of body structure. MRI units may be differentiated by magnetic field strength (“tesla” or “T”), and also by construction or orientation. A “closed” scanner typically uses a higher strength magnet and an “open” scanner typically uses a lower strength magnet. There are also “multi-position” or “stand-up” scanners (often used for spine and joint evaluation, where weight-bearing is required) and limited-use scanners, such as those designed only to scan the breast or extremities (e.g., elbows, wrists, toes, etc.).

Mobile MRI Unit: An MRI unit and transporting equipment that is moved or able to be moved to provide services at two or more host facilities, including facilities located in adjoining or contiguous states of the United States.

Mobile MRI Unit Capacity: Total capacity of a mobile MRI unit is 600 annual procedures per day of operation per week and is based upon a daily operating efficiency of 12 procedures per day x 50 weeks per year, multiplied by the number of days per week that the equipment is used. The optimal efficiency of a mobile MRI unit is based upon the number of days per week that it is in operation. For each day of operation per week, the optimal efficiency is 480 procedures per year, or 80 percent of total capacity.

Dedicated Multi-position MRI Unit: An MRI unit that permits the patient to be scanned in various positions, such as sitting, standing, bending, or leaning, as well as lying down, for the purpose of providing weight-bearing scans.

Service Area: The contiguous counties or portions thereof representing a reasonable area in which an applicant intends to provide MRI unit services and in which at least 75% of its service recipients reside. An MRI unit should be located at a site that allows reasonable access for residents of the service area.

Service Area Capacity: The estimate of the number of MRI units needed in a given service area. The estimate is based upon an optimal efficiency of 2,880 procedures per year for a stationary MRI unit and an optimal efficiency of 480 annual procedures per day of operation per week for a mobile MRI unit

Specialty MRI Unit: A Dedicated Breast, Extremity, or Multi-position MRI unit.

Stationary MRI Unit: A non-moveable MRI unit housed at a single permanent location.

Stationary MRI Unit Capacity: Total capacity of a stationary MRI unit is 3600 procedures per year and is based upon a daily operating efficiency of 1.20 procedures per hour, 12 hours per day x 5 days a week x 50 weeks of operation per year. The optimal efficiency for a stationary MRI unit is 80 percent of total capacity, or 2,880 procedures per year.

Standards and Criteria

1. Utilization Standards for non-Specialty MRI Units.
 - a. An applicant proposing a new non-Specialty stationary MRI service should project a minimum of at least 2160 MRI procedures in the first year of service, building to a minimum of 2520 procedures per year by the second year of service, and building to a minimum of 2880 procedures per year by the third year of service and for every year thereafter.
 - b. Providers proposing a new non-Specialty mobile MRI service should project a minimum of at least 360 mobile MRI procedures in the first year of service per day of operation per week, building to an annual minimum of 420 procedures per day of operation per week by the second year of service, and building to a minimum of 480 procedures per day of operation per week by the third year of service and for every year thereafter.
 - c. An exception to the standard number of procedures may occur as new or improved technology and equipment or new diagnostic applications for MRI units are developed. An applicant must demonstrate that the proposed unit offers a unique and necessary technology for the provision of health care services in the Service Area.
 - d. Mobile MRI units shall not be subject to the need standard in paragraph 1 b if fewer than 150 days of service per year are provided at a given location. However, the applicant must demonstrate that existing services in the applicant's Service Area are not adequate and/or that there are special circumstances that require these additional services.
 - e. Hybrid MRI Units. The HSDA may evaluate a CON application for an MRI "hybrid" Unit (an MRI Unit that is combined/utilized with another medical equipment such as a megavoltage radiation therapy unit or a positron emission tomography unit) based on the primary purposes of the Unit.
2. Access to MRI Units. All applicants for any proposed new MRI Unit should document that the proposed location is accessible to approximately 75% of the Service Area's population. Applications that include non-Tennessee counties in their proposed Service Areas should provide evidence of the number of existing MRI units that service the non-Tennessee counties and the impact on MRI unit utilization in the non-Tennessee counties, including the specific location of those units located in the non-Tennessee counties, their utilization rates, and their capacity (if that data are available).
3. Economic Efficiencies. All applicants for any proposed new MRI Unit should document that alternate shared services and lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.

4. Need Standard for non-Specialty MRI Units.

A need likely exists for one additional non-Specialty MRI unit in a Service Area when the combined average utilization of existing MRI service providers is at or above 80% of the total capacity of 3600 procedures, or 2880 procedures, during the most recent twelve-month period reflected in the provider medical equipment report maintained by the HSDA. The total capacity per MRI unit is based upon the following formula:

Stationary MRI Units: $1.20 \text{ procedures per hour} \times \text{twelve hours per day} \times 5 \text{ days per week} \times 50 \text{ weeks per year} = 3,600 \text{ procedures per year}$

Mobile MRI Units: Twelve (12) procedures per day x days per week in operation x 50 weeks per year. For each day of operation per week, the optimal efficiency is 480 procedures per year, or 80 percent of the total capacity of 600 procedures per year.

5. Need Standards for Specialty MRI Units.

- a. Dedicated fixed or mobile Breast MRI Unit. An applicant proposing to acquire a dedicated fixed or mobile breast MRI unit shall not receive a CON to use the MRI unit for non-dedicated purposes and shall demonstrate that annual utilization of the proposed MRI unit in the third year of operation is projected to be at least 1,600 MRI procedures (.80 times the total capacity of 1 procedure per hour times 40 hours per week times 50 weeks per year), and that:
 1. It has an existing and ongoing working relationship with a breast-imaging radiologist or radiology proactive group that has experience interpreting breast images provided by mammography, ultrasound, and MRI unit equipment, and that is trained to interpret images produced by an MRI unit configured exclusively for mammographic studies;
 2. Its existing mammography equipment, breast ultrasound equipment, and the proposed dedicated breast MRI unit are in compliance with the federal Mammography Quality Standards Act;
 3. It is part of or has a formal affiliation with an existing healthcare system that provides comprehensive cancer care, including radiation oncology, medical oncology, surgical oncology and an established breast cancer treatment program that is based in the proposed service area.
 4. It has an existing relationship with an established collaborative team for the treatment of breast cancer that includes radiologists, pathologists, radiation oncologists, hematologist/oncologists, surgeons, obstetricians/gynecologists, and primary care providers.

- c. The applicant should demonstrate how emergencies within the MRI Unit facility will be managed in conformity with accepted medical practice.
 - d. The applicant should establish protocols that assure that all MRI Procedures performed are medically necessary and will not unnecessarily duplicate other services.
 - e. An applicant proposing to acquire any MRI Unit or institute any MRI service, including Dedicated Breast and Extremity MRI Units, shall demonstrate that it meets or is prepared to meet the staffing recommendations and requirements set forth by the American College of Radiology, including staff education and training programs.
 - f. All applicants shall commit to obtain accreditation from the Joint Commission, the American College of Radiology, or a comparable accreditation authority for MRI within two years following operation of the proposed MRI Unit.
 - g. All applicants should seek and document emergency transfer agreements with local area hospitals, as appropriate. An applicant's arrangements with its physician medical director must specify that said physician be an active member of the subject transfer agreement hospital medical staff.
8. The applicant should provide assurances that it will submit data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.
 9. In light of Rule 0720-11.01, which lists the factors concerning need on which an application may be evaluated, and Principle No. 2 in the State Health Plan, "Every citizen should have reasonable access to health care," the HSDA may decide to give special consideration to an applicant:
 - a. Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;
 - b. Who is a "safety net hospital" or a "children's hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program; or
 - c. Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program; or
 - d. Who is proposing to use the MRI unit for patients that typically require longer preparation and scanning times (e.g., pediatric, special needs, sedated, and contrast agent use patients). The applicant shall provide in its application information supporting the additional time required per scan and the impact on the need standard.

Rationale for Revised and Updated Standards and Criteria for Magnetic Resonance Imaging Services

Definitions

Specialty MRI Units. The Office of Health Planning recognizes that certain MRI Units dedicated for breast, extremity, and multi-position purposes do not reach the level of utilization that standard MRI Units do. Consequently, definitions for these Specialty Units have been created and specific standards for each have been developed.

MRI Procedure. To provide for uniform procedure reporting, the Health Services and Development Agency is responsible for setting CPT code reporting requirements consistent with the definition of MRI Procedure. Research CPT codes are excluded from capacity and need calculations.

Capacity. The Office solicited operating schedule information from owners/operators of MRI Units. From this information, while total capacity of a non-Specialty MRI Unit could conceivably be based on an operating schedule of 24 hours per day, 7 days per week, usual practice does not cover such extended hours of operation. It appears that physician offices and outpatient diagnostic centers more usually operate their MRI Units Monday-Friday; inpatient facilities typically operate Monday-Friday, with the potential to operate on Saturdays as needed. There are exceptions, however, with both outpatient and inpatient MRI Units operating more than five days a week. Hours of operation vary and seem to not be dependent upon outpatient or inpatient use, usually from 12 to 16 hours per day. Utilization and operating practices can and do vary widely.

Additionally, from the information received, the length of time per scan varies depending on a variety of circumstances, including protocols in place, whether a patient is sedated or needs longer time to be placed in the unit, whether the scan is with or without contrast, etc. A scan may take as little as 30 minutes or as long as 80 (or more) minutes. Typically, due to sedation and/or contrast requirements, an inpatient facility will take longer to perform its scans. However, Tennessee does not collect sufficient data on these scans in order to develop a total capacity formula based on them.

We are basing a total non-Specialty MRI unit capacity number on the performance of 1.20 scans per hour, Monday through Friday utilization, 12 hours a day, 50 weeks a year, for a total capacity number of 3,600. Using an 80% optimal efficiency number, we arrive at 2,880 as the number of scans a year that a typical stationary non-Specialty MRI Unit should be able to perform.

Standards and Criteria Regarding Certificate of Need Applications for Magnetic Resonance Imaging Services

1. **Exceptions to Utilization Standards:** Exceptions to the standard number of procedures has been retained for new or improved technology and diagnostic applications, and for mobile MRI Units in operation fewer than 150 days of service per year. Applications for hybrid MRI Units (e.g., MRI Units combined with PET Units or MRT Units) may be assessed under the primary use of the hybrid unit.
2. **Other Access Issues:** The provision of health care doesn't recognize state boundaries. Accordingly, applicants may include non-Tennessee counties in proposed service areas if that data are available.
3. **Economic Efficiencies:** To support the goal of reducing health care costs, applicants should document that other options have been investigated and found less advantageous.
4. **Specialty MRI Units Standards:** Dedicated Breast MRI Units have a proposed total capacity estimate of 2,000 procedures per year. Dedicated Extremity and Dedicated Multi-position MRI Units do not have a defined estimate; an applicant must demonstrate total capacity as well as its estimated annual utilization that, by the third year, will be at least 80% of total capacity.
5. **Inventories:** Given that there are proposed different standards for Specialty and non-Specialty MRI Units, separate inventories should be maintained. Additionally, a CON granted for the institution of a Specialty MRI Unit should not be permitted to be used for non-Specialty MRI purposes; it is recommended that any CON granted for Specialty MRI purposes so state on its face.
6. **Quality of Care:** Specific staffing, training, and education standards are included to help ensure patient safety and quality of care provided.