

FIXED MAGNETIC RESONANCE IMAGING SERVICES

I. DEFINITIONS

A. Magnetic Resonance (MR): MR is a category of service that uses the magnetic spin property of certain atomic nuclei to visualize and analyze tissue. Diagnostic techniques include both MR imaging and spectroscopy.

B. Magnetic Resonance Imaging: MR imaging is a non-invasive diagnostic technique which produces cross-sectional anatomical pictures and has the potential for providing metabolic information. MR uses a combination of low energy radio waves and a strong magnetic field on the body's atomic nuclei. The response of the selected nuclei is converted into images for evaluation by the physician.

C. MR Procedure: A procedure conducted by an MR unit which is either a single diagnostic, magnetic resonance procedure or a research procedure conducted by a MR unit in conjunction with an approved diagnostic radiology residency program.

D. Magnetic Resonance Spectroscopy: The use of magnetic spin properties of certain atomic nuclei to perform chemical analyses of tissue.

E. Research Protocol: A document outlining a hypothesis to be tested and the procedures used to select patients who have given informed consent for imaging or spectroscopy. The protocol must have a purpose clearly stated and a method outlined to test the hypothesis presented. It also must detail the number needed for a meaningful result.

F. Replacement Equipment: Equipment which is functionally similar and is used for the same diagnostic or treatment purposes as the equipment currently in use, although it may possess expanded capabilities due to technological improvements; and, is not used to provide a new health service.

G. Open-Bore MRI Scanner: An MRI scanner with an open gantry rather than a closed gantry.

II. INVENTORY

The Authority shall provide to each applicant a current inventory of existing Magnetic Resonance Imaging (MRI) systems in the State. The inventory will identify each device as either fixed or mobile.

III. NEED METHODOLOGY

A. NEW SERVICE/ADDITIONAL EQUIPMENT

An applicant proposing the acquisition of a fixed MRI unit must document that it has performed more than 2000 procedures on a mobile unit within the last twelve (12) month period.

An applicant proposing the acquisition of an additional fixed MRI unit must document that each existing fixed unit has performed 3500 procedures. In addition, the applicant must demonstrate it has performed a minimum of 2600 procedures on a mobile unit.

An exception to the quantitative need methodology may be granted if an applicant can present clear and convincing evidence that approval of a new or additional fixed MRI unit is a superior alternative to the provision of mobile services.

B. REPLACEMENT EQUIPMENT

1. To replace an existing MRI unit, the applicant must demonstrate the following:
 - (a) The unit to be replaced can no longer function appropriately because:
 - (i) maintenance and repair costs plus lost revenue as a result of excessive downtime has become unreasonable; or
 - (ii) treatment is impaired by irreparable mechanical wear; or
 - (iii) parts or software cannot be obtained for a unit making a unit obsolete; or
 - (iv) the age of the equipment has exceeded the AHA guidelines for useful life.
 - (b) The unit being replaced must be removed from service upon the installation of the new replacement unit.

2. An application for the following is not considered a proposal for replacement equipment:
 - (a) A change from a closed gantry MRI scanner to an open-bore MRI scanner and vice versa, or
 - (b) A change from the provision of mobile MRI services to fixed MRI services and vice versa.

Proposals for these services must meet the need criteria specified under III A. New Service/Additional Equipment.

C. OTHER CRITERIA

The documented special needs of teaching and research institutions, children's hospitals, small rural hospitals, and providers that serve a disproportionately larger share of patients who are Medicaid recipients or who have no health insurance or insufficient health insurance may also be considered in the determination of need for a proposed MRI unit.

IV. QUALITY

A. An MRI unit to be acquired and used for direct patient care must have pre-market approval (PMA) by the FDA for clinical use prior to determining an application complete.

B. Applicants seeking to provide MRI services shall document that a full-time board-certified radiologist, who is a member in good standing of the American College of Radiology, shall be responsible for managing the operation of the MRI unit and for the written interpretation of MRI data.

C. The applicant must specify that personnel will be trained in the use of the specific equipment acquired and the safety procedures to follow in the event of an emergency.

D. An applicant seeking to provide MRI services shall ensure that at least one staff member trained in cardiac pulmonary resuscitation is on duty in the department during its use.

E. A safety manual governing the equipment and its location shall be provided. It should cover hazards and security measures, including, at least, fire precautions and evacuations to ensure the safety of the patients, staff and others.

F. An applicant must show that a range of imaging technologies are readily available through the individual applicant or a consortium participating in shared services. These technologies include, but are not limited to, computed tomography, ultrasound, angiography, conventional radiology, and nuclear medicine.

G. Prior to operation of the MRI unit, the applicant must develop a clinical oversight committee which shall be responsible for developing screening criteria for appropriate MR utilization, reviewing clinical procedures, developing educational programs, and supervising the data collection and evaluation activities generated by the MRI unit required by the department.

H. An applicant seeking to provide MRI services must document a scheduling priority system based on patient need, regardless of the source of referral or payment.

I. An applicant must provide accessibility to the disabled in compliance with applicable state and federal laws.

J. An applicant must provide emergency MRI services 24 hours a day, seven days per week.

K. An applicant must provide evidence that the proposed MRI equipment is safe and effective for its proposed use.

L. An applicant must demonstrate that the proposed services will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.

V. CONTINUUM OF CARE

A. An applicant proposing to provide MRI services shall have on staff, or through referral, qualified physicians in at least the following medical specialties: oncology, neurology, internal medicine, pathology, radiology, neurosurgery and other appropriate surgical specialties.

B. An applicant must address service alternatives and specify why the proposed project is the best alternative and how the new service will integrate with the primary care and prevention oriented comprehensive delivery system.

C. Appropriate linkages, such as referral protocols and joint venture agreements, must be established with similar or complementary services:

1. The applicant must develop a referral network to eliminate the possibility for duplication of MRI procedures for patients.
2. The applicant must provide orientation and continuing education to support appropriate referrals and use of services to the venture.

D. An application for a replacement MRI unit or an additional MRI unit shall not be approved unless the applicant is an acute care facility or a joint venture of two or more acute care facilities. This provision shall not apply to an entity, which is not an acute care facility, that currently provides MRI services.

VI. COSTS

A. An applicant proposing to acquire new, additional or replacement MRI equipment shall document, as specified by the Authority, its ability to finance and operate the equipment by providing an analysis of the cost effectiveness of the proposed project including:

1. A three (3) year projection of revenues and expenses for the project;
2. Evidence that sufficient capital is available to initiate and operate the proposed project;
3. Evidence that financing arrangements are reasonable and secure; and
4. Evidence regarding the reimbursement, if any, of research expenses.

B. An applicant is required to demonstrate in its financial projections that all indigent persons needing the service can be served without jeopardizing the viability of the project.

C. An applicant must demonstrate that it has in place effective utilization review, quality assurance, and peer review. The applicant must demonstrate a willingness to participate in reasonable utilization management programs sponsored by peer review or managed care organizations.

D. An applicant must demonstrate financial feasibility. The applicant must also demonstrate that the capital costs of the project are consistent with current Authority rate setting methodology. The applicant must further demonstrate that the charges and costs used in projecting financial feasibility are equitable in comparison to prevailing rates for similar services in similar hospitals.

VII. OTHER

An applicant or provider of MRI services must provide additional information, as may be requested by the Authority, regarding demographics data, financial data, and clinical data for patients receiving MRI procedures.