

Proposed Revision of Need Methodology for Non-Hospital-Based Magnetic Resonance Imaging (MRI) Facilities

**Certificate of Need
Criteria and Standards
for
Diagnostic Imaging Services**

Should the Mississippi State Department of Health receive a Certificate of Need application regarding the acquisition and/or otherwise control of major medical equipment or the provision of a service for which specific CON criteria and standards have not been adopted, the application shall be deferred until the Department of Health has developed and adopted CON criteria and standards. If the Department has not developed CON criteria and standards within 180 days of receiving a CON application, the application will be reviewed using the general CON review criteria and standards presented in the *Mississippi Certificate of Need Review Manual* and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

Policy Statement Regarding Certificate of Need Applications for the Acquisition or Otherwise Control of Magnetic Resonance Imaging (MRI) Equipment and/or the Offering of MRI Services

1. CON Review Requirements: The Certificate of Need process regarding the acquisition or otherwise control of MRI equipment and/or the offering of MRI services involves separate requirements for CON review: (a) an entity proposing to acquire or otherwise control MRI equipment must obtain a CON to do so if the capital expenditure for the MRI unit and related equipment exceeds \$1,500,000; and (b) an entity proposing to offer MRI services must obtain a CON before providing such services.
2. CON Approval Preference: The Mississippi State Department of Health shall give preference to those applicants proposing to enter into joint ventures utilizing mobile and/or shared equipment. However, the applicant must meet the applicable CON criteria and standards provided herein and the general criteria and standards contained in the currently approved *Mississippi Certificate of Need Review Manual*.
3. Procedures Estimation Methodology: The applicant shall use the procedures estimation methodology appearing in this section of the *Plan* to project the annual patient service volume for MRI services/equipment. The DRG disease classification system to be used for MRI is available from the Mississippi State Department of Health Division of Health Planning and Resource Development.
4. Addition of a Health Care Facility: An equipment vendor who proposes to add a health care facility to an existing or proposed route must obtain an amendment to the original Certificate of Need before providing such service. Additionally, an equipment vendor must inform the Department of any proposed changes, i.e. additional health care facilities or route deviations, from those presented in the Certificate of Need application prior to such change.

Certificate of Need Criteria and Standards for the Acquisition or Otherwise Control of Magnetic Resonance Imaging (MRI) Equipment and/or the Offering of MRI Services

The Mississippi State Department of Health will review applications for a Certificate of Need for the acquisition or otherwise control of MRI equipment and/or the offering of MRI services under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. The MSDH will also review applications for Certificate of Need according to the general criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of the Mississippi State Department of Health; and the specific criteria and standards listed below.

The acquisition or otherwise control of MRI equipment is reviewable if the equipment cost is in excess of \$1,500,000; if the equipment and/or service is relocated; and if the proposed provider of MRI services has not provided such services on a regular basis within the period of twelve (12) months prior to the time such services would be offered.

Certificate of Need Criteria and Standards for the Acquisition or Otherwise Control of MRI Equipment

- 1. Need Criterion: The entity desiring to acquire or otherwise control the MRI equipment must document that the specified equipment shall perform a minimum of 1,700 procedures per year by the end of the second year of operation. The applicant shall use the procedures estimation methodology appearing in this section of the *Plan* to project the annual patient service volume of the proposed equipment. This criterion includes both fixed and mobile MRI equipment.**

Applicants for non-hospital based MRI facilities may submit affidavits from referring physicians in lieu of the estimation methodology required for hospital based facilities. MRI procedures projected in affidavits shall be based on actual MRI procedures referred during the past year.

It is recognized that an applicant desiring to acquire or otherwise control an MRI unit may make or propose to make the MRI unit available to more than one provider of MRI services; some of which may be located outside of Mississippi. In such cases all existing or proposed users of the MRI unit must jointly meet the required service volume of 1,700 procedures annually. If the MRI unit in question is presently utilized by other providers of MRI services, the actual number of procedures performed by them during the most recent 12-month period may be used instead of the formula projections.

- 2. In order to receive CON approval to acquire or otherwise control MRI equipment, the applicant shall provide a copy of the proposed contract and document the following:**
 - a. that the equipment is FDA approved;**
 - b. that only qualified personnel will be allowed to operate the equipment; and**

- c. that if the equipment is to be rented, leased, or otherwise used by other qualified providers on a contractual basis, no fixed/minimum volume contracts will be permitted.
3. Applicants shall provide written assurance that they will record and maintain, at a minimum, the following information and make it available to the Mississippi State Department of Health:
- a. all facilities which have access to the equipment;
 - b. utilization by each facility served by the equipment, e.g., days of operation, number of procedures, and number of repeat procedures;
 - c. financial data, e.g., copy of contracts, fee schedule, and cost per scan; and
 - d. demographic and patient origin data for each facility.

In addition, if required by the Department, the above referenced information and other data pertaining to the use of MRI equipment will be made available to the MSDH within 15 business days of request. The required information may also be requested for entities outside of Mississippi that use the MRI equipment in question.

- 4. The entity desiring to acquire or otherwise control the MRI equipment must be a registered entity authorized to do business in Mississippi.
- 5. Before the specified equipment can be utilized, the applicant desiring to provide the MRI equipment shall have CON approval or written evidence that the equipment is exempt from CON approval, as determined by the Mississippi State Department of Health. Each specified piece of equipment must be exempt from or have CON approval.

Certificate of Need Criteria and Standards for the Offering of MRI Services

An entity proposing to offer MRI services shall obtain Certificate of Need (CON) approval before offering such services.

- 1. **Need Criterion: The entity desiring to offer MRI services must document that the equipment shall perform a minimum of 1,700 procedures per year. The applicant shall use the procedures estimation methodology appearing in this section of the *Plan* to project the annual patient service volume for the applicant hospital. This criterion includes both fixed and mobile MRI equipment.**

Applicants for non-hospital based MRI facilities may submit affidavits from referring physicians in lieu of the estimation methodology required for hospital based facilities. MRI procedures projected in affidavits shall be based on actual MRI procedures referred during the past year.

It is recognized that a particular MRI unit may be utilized by more than one provider of MRI services; some of which may be located outside of Mississippi. In such cases all existing or proposed providers of MRI services must jointly meet the required service volume of 1,700 procedures annually. If the MRI unit in question is presently utilized by other providers of MRI services, the actual number of procedures

performed by them during the most recent 12-month period may be used instead of the formula projections.

2. An applicant desiring to offer MRI services must document that a full range of diagnostic imaging modalities for verification and complementary studies will be available at the time MRI services begin. These modalities shall include, but not be limited to, computed tomography (full body), ultrasound, angiography, nuclear medicine, and conventional radiology.
3. All applicants proposing to offer MRI services shall give written assurance that, within the scope of its available services, neither the facility where the service is provided nor its participating medical personnel shall have policies or procedures which would exclude patients because of race, color, age, sex, ethnicity, or ability to pay.
4. The applicant must document that the following staff will be available:
 - a. Director - A full-time, board eligible radiologist or nuclear medicine imaging physician, or other board eligible licensed physician whose primary responsibility during the prior three years has been in the acquisition and interpretation of clinical images. The Director shall have a knowledge of MRI through training, experience, or documented post-graduate education. The Director shall document a minimum of one week of full-time training with a functional MRI facility.
 - b. One full-time MRI technologist-radiographer or a person who has had equivalent education, training, and experience, who shall be on-site at all times during operating hours. This individual must be experienced in computed tomography or other cross-sectional imaging methods, or must have equivalent training in MRI spectroscopy.
5. The applicant shall document that when an MRI unit is to be used for experimental procedures with formal/approved protocols, a full-time medical physicist or MRI scientist (see definition in Glossary) with at least one year of experience in diagnostic imaging shall be available in the facility.
6. The applicant shall provide assurances that the following data regarding its use of the MRI equipment will be kept and made available to the Mississippi State Department of Health upon request:
 - a. Total number of procedures performed
 - b. Number of inpatient procedures
 - c. Number of outpatient procedures
 - d. Average MRI scanning time per procedure
 - e. Average cost per procedure
 - f. Average charge per procedure
 - g. Demographic/patient origin data
 - h. Days of operation

In addition to the above data recording requirements, the facility should maintain the source of payment for procedures and the total amounts charged during the fiscal year when it is within the scope of the recording system.

7. Before the service can be provided, the CON applicant desiring to offer MRI services shall provide written evidence that the specified MRI equipment provider has

received CON approval or is exempt from CON approval as determined by the Mississippi State Department of Health. Each specified piece of equipment must be exempt from or have CON approval.

Procedures Estimation Methodology for MRI Equipment

MRI patient service volume shall be based on a DRG disease classification system of all inpatients of the hospital, other participating hospitals, and the number of outpatients in receipt of CT scans from the respective hospitals. Under this system, the DRGs are classified and ranked in relation to the expected applicability of MRI imaging. Diagnoses for which MRI imaging is not likely to be useful in current application fall into Category 1. Category 2 includes those diagnoses for which MRI imaging may be a useful secondary imaging modality in some cases. Category 3 encompasses diagnoses for which MRI is likely to be a useful secondary imaging modality. Category 4 includes those diagnoses for which MRI is expected to be the primary imaging modality. The listing of DRG categories to be used in establishing the need for MRI services may be obtained from the Mississippi State Department of Health Division of Health Planning and Resource Development.

First, the methodology classifies the total number of inpatient admissions into the four categories. The admission total for each category is zero, five, 15, and 50 percent, respectively. This derives the estimated number of inpatients most likely to benefit from MRI services. Secondly, the methodology identifies the total number of outpatients referred for CT scanning during the previous fiscal year. A 25 percent utilization factor is applied to that total in order to derive the number of outpatients most likely to benefit from MRI imaging. Inpatient and outpatient estimates are summed to derive the total MRI volume for the first year of operation. The mathematical formula for calculating volume estimates is as follows:

$$EC = .50 (TN_4) + .15 (TN_3) + .05 (TN_2) + .25 (TN_{ct})$$

Where:

EC = Estimated MRI patient service volume for the first or next year of operation.

TN₄ = Total number of inpatient hospital admissions in DRG Category 4 for the preceding fiscal year.

TN₃ = Total number of inpatient hospital admissions in DRG Category 3 for the preceding fiscal year.

TN₂ = Total number of inpatient hospital admissions in DRG Category 2 for the preceding fiscal year.

TN_{ct} = Total number of outpatients who received CT scans for the preceding fiscal year.

If the hospital projects a greater number of procedures for the end of the second year than the formula estimates, this projection must be based on the actual increases in the number of diagnoses within each category over the past three years.