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FIXED MAGNETIC RESONANCE IMAGING SERVICES

Exemptions from Certificate of Need (CON) which require submission of information to the Health Care Authority (Authority).

West Virginia Code § 16-2D-11(b)(5) states:

Shared Health services between two or more hospitals licensed in West Virginia providing health services made available through existing technology that can reasonably be mobile. This exemption does not include providing mobile cardiac catheterization.

West Virginia Code § 16-2D-11(b)(9) states:

The replacement of major medical equipment with like equipment, only if the replacement major medical equipment cost is more than the expenditure minimum.

The expenditure minimum is updated annually by the Authority and can be found on the Authority's website at www.hca.wv.gov.

Like Equipment means medical equipment in which functional and technological capabilities are similar to the equipment being replaced; and the replacement equipment is to be used for the same or similar diagnostic, therapeutic, or treatment purposes as currently in use; and it does not constitute a substantial change in health services or a proposed health service.

Major Medical Equipment means a single unit of medical equipment or a single system of components with related functions which is used for the provision of medical and other health services and costs in excess of the expenditure minimum. This term does not include medical equipment acquired by or on behalf of a clinical laboratory to provide clinical laboratory services if the clinical laboratory is independent of a physician's office and a hospital and it has been determined under the Title XVIII of the Social Security Act to meet the requirements of paragraphs ten and eleven, Section 1861(s) of such act, Title 42 U.S.C. §1395x. In determining whether medical equipment is major medical equipment, the cost of studies, surveys, designs, plans, working drawings, specifications and other activities essential to the acquisition of such equipment shall be included. If the equipment is acquired for less than fair market value, the term "cost" includes the fair market value.

West Virginia Code § 16-2D-11(b)(27) states:

The acquisition and utilization of one computed tomography scanner and/or one magnetic resonance imaging scanner with a purchase price of up to \$750,000 by a hospital.

The exemption application is available on the Authority's website at: <https://hca.wv.gov/certificateofneed/Pages/Exemptions.aspx>.

The provision of MRI Services that does not qualify for one of the above exemptions must submit an expedited application that addresses the standards below.

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

A current inventory of approved Magnetic Resonance Imaging (MRI) service providers in the State may be obtained from the Authority. The inventory will identify each device as either fixed or mobile.

III. NEED METHODOLOGY

A. NEW SERVICE

An application for MRI services shall not be approved unless the applicant is an acute care hospital or a joint venture of two or more acute care hospitals. An acute care hospital may enter into a joint agreement to provide MRI services with an ambulatory care facility or private physician practice. This agreement must reflect that the acute care hospital owns, operates, and does the patient billing for the MRI services. An acute care hospital that enters into a joint agreement to provide MRI services with an entity that is not located on the hospital's campus will require the hospital to obtain a CON for the development of an ambulatory care center.

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 exception to the above stated quantitative need methodology may be granted if an applicant can present clear and convincing evidence that approval of a fixed MRI unit is a superior alternative to the provision of mobile services and the applicant is able to demonstrate a need for MRI services exists in the proposed service area. In order to demonstrate the need for the fixed MRI services, the applicant must delineate the proposed service area for the service by documenting the expected areas around where the proposed unit will be located and from which the unit is expected to draw patients. The applicant may submit testimony or documentation regarding the expected service area, based upon national data or statistics, or upon projections generally relied upon by professionals engaged in health planning or the development of health services. Any assumptions must be reasonable and supported by the evidence in the record. The applicant must then document expected utilization for the service to be provided for the population in the service area. As used in this section, "expected utilization", in addition to the expected demand for the service, may be expressed as the number of providers typically required to service any given population, or as the number of persons in a population that are typically serviced by a single provider. Where a population is known to have specific characteristics, such as age, or disease rates, that affect utilization, then those characteristics may be taken into consideration. The services provided by existing

providers of MRI services in the service area must be factored into the demonstration of need.

B. 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. 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. The following staff must be available to the Fixed MRI unit:

1. A full-time board-certified radiologist, who is a member in good standing of the American College of Radiology, which shall be responsible for managing the operation of the MRI unit and for the written interpretation of MRI data; and,

2. At least one staff member trained in cardiac pulmonary resuscitation is on duty in the department during its use.

C. 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.

D. 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.

E. 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.

F. 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.

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

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

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

J. 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.

VI. COSTS

A. An applicant proposing to provide fixed 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.

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.