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Charleston 25305

PROPOSED RULES

STATE REGISTER FILING

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AGENCY Health Care Cost Review Authority

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TYPE OF RULE Legislative

TITLE OF RULE Interim Standards for Magnetic Resonance Imaging Services

CHAPTER 16 ARTICLE 2D SERIES II

AUTHORITY §16-2D-8

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Health Care Cost Review Authority

1985 MAR 19 PM 4:32

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

March 19, 1985

The Honorable Ken Hechler
Secretary of State
State Capitol Complex
Charleston, WV 25305

Dear Mr. Hechler:

Re: Emergency Filing; Legislative
Rules - Interim Standards for
Magnetic Resonance Imaging
Services

Pursuant to the provisions of West Virginia Code, Section 29A-3-15, enclosed herewith please find the original and two (2) copies of the above-noted emergency legislative rules. Please stamp the extra copy indicating filing with your office and return it to us for our records.

The fact constituting the emergency for the promulgation of these rules is the need to comply with a time limitation established by West Virginia Code, §16-2D-1 et seq. The Authority, sitting as the State Health Planning and Development Agency, has received a number of letters of intent and applications for the offering of magnetic resonance imaging services. Under the provisions of the West Virginia Certificate of Need Program, it is necessary for the Authority to process these applications within a strict time frame. Heretofore, the Authority has declared a moratorium on the processing of these applications until interim standards could be developed for the Authority's use in ruling upon the applications. Promulgation of these interim standards will allow the resumption of processing of the applications which will benefit both the applicant hospitals and the public interest. The absence of the interim standards will place the Authority in the untenable position of not having standards in the State Health Plan by which to judge the merits of the pending applications. Finally, the State Health Plan itself cannot be amended as provided by law within the time frames required by the State Certificate of Need Program.

With much appreciation for your assistance in this matter, I remain

Very truly yours,

JOHN H. KOZAK
General Counsel

JHK/jmh

cc: Legislative Rule-Making Review Committee

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OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

WEST VIRGINIA LEGISLATIVE RULES
HEALTH CARE COST REVIEW AUTHORITY

Emergency Filing

Legislative Rules for Interim Standards
For Magnetic Resonance Imaging Services

Chapter 16-2D
Series II
(1985)

WEST VIRGINIA LEGISLATIVE RULES
HEALTH CARE COST REVIEW AUTHORITY

Emergency Filing
Legislative Rules for Interim Standards
For Magnetic Resonance Imaging Services

Chapter 16-2D
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HEALTH CARE COST REVIEW AUTHORITY
EMERGENCY FILING - LEGISLATIVE RULES

Chapter 16-2D
Series II

(1985)

Subject: Interim Standards For Magnetic Resonance Imaging Services.

Section 1. General.

1.01. Scope - These rules establish interim standards for use by the State Health Planning and Development Agency in ruling upon applications proposing magnetic resonance imaging services. Since the State Health Plan is silent regarding such services, it is necessary for the SHPDA to promulgate interim standards for its use until the State Health Plan is amended.

1.02. Authority - These rules are issued under the authority of West Virginia Code, Chapter 16, Article 2D, Section 8.

1.03. Filing Date - These rules are promulgated on the 19th day of March, 1985, and filed on the 19th day of March, 1985, in the Secretary of State's Office.

1.04. Effective Date - These rules become effective on the 19th day of March, 1985, on an emergency basis.

Section 2. Interim Standards.

Interim standards for the development of magnetic resonance imaging services.

2.01. Introduction. These interim standards seek to provide guidance in the development of Magnetic Resonance Imaging (MRI) Services in West Virginia. The field of MRI is an emerging one; considerable development and refinement in its technology can be expected in the relatively near future. Thus, these interim standards are directed to initial services development, with the expectation that the Plan Development Committee of the Statewide Health Coordinating Council will further consider costs, benefits and areas of utilization of MRI services in their development of standards for inclusion into the West Virginia State Health Plan.

These interim standards will be utilized by the State Health Planning and Development Agency (SHPDA), and should be used by other interested or impacted parties in addressing the following issues:

- 1) Guidance in the orderly development of MRI services
- 2) The identification of data needs
- 3) The review of Certificate of Need proposals for MRI services.

These standards are intended for use in the review procedures of the WV SHPDA; they do not supplant or supercede state licensure regulations, federal

certification standards, or accreditation standards. The standards and criteria stated here apply to organizations and institutions proposing to provide MRI services.

2.02. Definitions.

Magnetic Resonance Imaging - a non-invasive diagnostic technique which produces cross-sectional anatomical pictures and has the potential for providing metabolic information. MRI 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.

2.03. Services.

A. Accessibility.

1. Organizations seeking to provide MRI services shall document:
 - a. Written clinical criteria clearly specifying who is eligible for diagnostic study.
 - b. Patient selection policies which provide that no person shall be denied services on account of age, sex, race, color, creed, national origin, physical or behavioral disability, type of payor or ability to pay.

- c. A scheduling priority system based on patient need.
 - d. Charges for referral services shall be at rates no higher than those customarily charged to patients in the facility providing the service.
- 2. Organizations seeking to provide MRI services shall provide accessibility to the handicapped in accordance with the Rehabilitation Act of 1973.
 - 3. Organizations shall be prepared to provide emergency MRI services 24 hours a day, seven days a week.

B. Availability.

- 1. The study area for MRI proposals involving the provision of MRI services will be the county of proposal and any in-state or out-of-state county significantly impacted.

A significantly impacted county is:

- a. A county wherein at least 10% of the residents rely on or will rely on the services in the county of proposal; or
- b. A county which generates or will generate at least 10% of the patient load in the county of proposal.

2. The calculation of expected MRI scans shall be based on the numbers of patients with ICD-9-CM codes most likely to utilize MRI technology as outlined in the American Hospital Association Expert Panel High Correlation Average (HCAVG) methodology No. 2. The SHPDA-approved methodology will be reviewed by SHPDA at least annually which may result in the adoption of a new or revised methodology.

3. An application for MRI services shall not be approved unless there is a projection of at least 2,500 MRI procedures annually as determined by the calculation of expected MRI scans as specified in No. 2 of this section.
 - a. Individual organizations seeking to initiate MRI services whose own case mix of patients cannot project at least 2,500 annual MRI scans as calculated by utilizing the approved methodology may, with the written consent of other study area hospitals, count the case mix of patients from those consenting hospitals in the calculation of expected MRI scans. Individual projections for each institution must be presented.

 - b. Organizations within a study area who wish to develop a joint venture proposal for the development of MRI services are encouraged to do so. Joint applications must be in compliance with all standards and must document the existence of a written agreement among those organizations

proposing a joint venture that in part specifies that none of the organizations in the joint proposal may enter into like agreements with other organizations seeking to initiate MRI services, unless the applicant or referral hospital presents to the Authority for approval, documentation as to the cost savings, improvements in patient care, etc .

4. Organizations seeking to provide MRI services shall document the capacity of the proposed unit to perform 60 MRI procedures per week, 52 weeks per year for a minimum annual capacity of 3,120 procedures.
5. Consideration shall be given to the access of MRI services for medical school research and for teaching hospitals with approved residency programs in radiology and other specialty areas.
6. Organizations seeking to provide MRI services shall document policies which assure availability of the MRI unit to graduate education programs in diagnostic radiology and other medical specialties approved by the appropriate national accrediting bodies, and to programs training physicists, technologists or other high technology staff.

C. Quality.

1. A MRI unit to be acquired and used for direct patient care must be approved by the FDA for clinical use.

2. Organizations seeking to provide MRI services shall document that a fulltime board-certified radiologist with at least 50 hours of training in MRI imaging shall be responsible for managing operation of the MRI unit, and for written interpretation of MRI data.
3. Organizations seeking to provide MRI services shall prepare a written plan for training technologists in the use of MRI equipment to be acquired.
4. Organizations seeking to provide MRI services shall ensure that at least one staff member trained in Cardiac Pulmonary Resuscitation is on duty in the unit during its use.

D. Cost.

1. Organizations proposing to provide MRI services shall document, as specified by the SHPDA, their ability to finance and operate such equipment.
2. Charges for the provision of clinical MRI services as determined by the Preliminary Financial Feasibility Study shall be reasonably consistent with the allowable costs of providing these services as specified by the WV Health Care Cost Review Authority.

E. Continuity.

1. Institutions or organizations proposing to provide MRI services shall have available on staff physicians which are board-certified, or have completed a residency program and are currently eligible for board certification in at least the following medical specialties:
 - a. Oncology
 - b. Neurology
 - c. Internal medicine
 - d. Pathology
 - e. Radiology

2. Organizations proposing to provide MRI services shall assure that such services are part of an integrated program of imaging techniques with on-site access to the equipment and personnel for high resolution computerized tomography, ultrascund, angiography, conventional radiology and nuclear medicine.

3. Organizations seeking to provide MRI services shall document the design of a complete data base, which includes technical factors which may be related to patient safety; indications for examination; and results in correlation with clinical, surgical, and/or pathological findings. The data base shall be designed so that it can become a part of a national data-base, such as the MRI Registry of the American College of Radiology.

F. Acceptability.

1. Organizations seeking to provide services shall demonstrate that the facility in which the services are to be offered is in accordance with the manufacturer's safety standards and with applicable federal and state standards.
2. Organizations seeking to provide MRI services shall specify a mechanism for limiting the hazardous effects of the magnetic field of the MRI device, including emergency procedures for patients, including removing the patient from the magnetic field and/or shutting the magnet down, as necessary.

Section 3. Termination of Moratorium. The moratorium heretofore ordered upon the acceptance or processing of magnetic resonance imaging services is terminated.

Section 4. Severability. If any provision or provisions of these rules or the application thereof to any person or circumstance shall be held invalid, such invalidity shall not affect the provisions or applications of these rules which can be given effect without the invalid provision or provisions or application, and to this end the provisions of these rules are declared to be severable.

WEST VIRGINIA LEGISLATIVE RULES
HEALTH CARE COST REVIEW AUTHORITY

Emergency Filing

Legislative Rules for Interim Standards
For Magnetic Resonance Imaging Services

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