



Arch A. Moore, Jr.
Governor

chairperson
Sally K. Richardson
members
Larry Fizer
William L. Gilligan

Health Care Cost Review Authority

NOTICE OF EMERGENCY RULE

RULE TITLE: Interim Standards for Magnetic Resonance Imaging Services.

The attached rule is filed as an emergency rule. Please note that this emergency rule amends and replaces the earlier version of this same rule filed with your office on March 19, 1985. Certain changes were made in this rule as a result of two (2) public hearings held by the Authority.

The rule is effective upon filing with your office in order to comport with time limitations established by West Virginia Code, §16-2-1 et seq. Reference should be made to our letter of March 19, 1985, which sets forth in detail the circumstances justifying the filing of this rule on an emergency basis.

FILED

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OFFICE OF THE
SECRETARY OF STATE

SALLY K. RICHARDSON

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W. FRED W. ...
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WEST VIRGINIA EMERGENCY LEGISLATIVE RULE
HEALTH CARE COST REVIEW AUTHORITY

Chapter 16-2D
Series II

TITLE: Interim Standards for Magnetic Resonance Imaging Services.

Section 1 General

1.1 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.

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

1.3 Filing Date - These rules are promulgated on the 17th day of June, 1985, and filed on the 24th day of June, 1985, in the Secretary of State's Office.

1.4 Effective Date - These rules become effective on the 24th day of June, 1985, on an emergency basis.

Section 2 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.

2.1 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:

2.1a Guidance in the orderly development of MRI services

2.1b The identification of data needs.

2.1c The review of Certificate of Need proposals for MRI services.

2.2 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.

Section 3 Definition - Magnetic Resonance Imaging is 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.

Section 4 Accessibility of Services

4.1 Organizations seeking to provide MRI services shall document:

4.1a Written clinical criteria clearly specifying who is eligible for diagnostic study.

4.1b 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.

4.1c A scheduling priority system based on patient need.

4.1d Charges for referral services shall be at rates no higher than those customarily charged to patients in the facility providing the services.

4.2 Organizations seeking to provide MRI services shall provide accessibility to the handicapped in accordance with the Rehabilitation Act of 1973.

4.3 Organizations who receive Certificate of Need approval to provide MRI services shall be prepared to provide emergency MRI services 24 hours a day, seven days a week.

Section 5 Availability of Services

5.1 The calculation of expected MRI inpatient scans shall be based on the number of the applicant's own inpatients 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.

5.2 An application for MRI services shall demonstrate a projection of at least 2,500 MRI procedures annually. The number of MRI procedures shall be determined by the calculation of expected MRI inpatient scans as specified in No. 1 of this section, plus an outpatient allowance which equals 40% of the applicant's own outpatient CT scan procedures.

5.3 Organizations who wish to develop a joint venture proposal for the development of either stationary or mobile MRI services are encouraged to do so. Joint applications must be in compliance with all standards and must document the joint venture 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 for which Certificate of Need approval is necessary unless that organization presents to the Authority for approval, documentation, inter alia, as to the cost savings, improvements in patient care, and lack of significant negative impact on the joint venture. Individual inpatient and outpatient projections for each institution in a joint venture must be presented in the application as outlined in No. 2 of this section.

5.4 A physician or physician group proposing to develop MRI services shall demonstrate a projection of at least 1,600 MRI procedures annually by documenting 4,000 CT scan procedures for the previous 12-month period.

5.5 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.

5.6 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.

5.7 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.

Section 6 Quality of Services

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

6.2 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.

6.3 Organizations seeking to provide MRI services shall prepare a written plan for training technologists in the use of MRI equipment to be acquired.

6.4 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.

Section 7 Cost of Services

7.1 Organizations proposing to provide MRI services shall document, as specified by the SHPDA, their ability to finance and operate such equipment.

7.2 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.

Section 8 Continuity of Services

8.1 Institutions or organizations proposing to provide MRI services shall have access to 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:

- 8.1a Oncology
- 8.1b Neurology
- 8.1c Internal medicine
- 8.1d Pathology
- 8.1e Radiology

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

8.3 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.

Section 9 Acceptability of Services

9.1 Organizations seeking to provide either stationary or mobile services shall demonstrate that the facility in which the services are to be offered is in accordance with the manufacturer's safety and operating standards and with applicable federal and state standards.

9.2 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.

Health Care Cost Review Authority
Legislative Rule 16-2D
Series II, Section 10

Section 10 Termination of Moratorium. The moratorium heretofore ordered upon the acceptance or processing of magnetic resonance imaging services is terminated.

Section 11 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 EMERGENCY LEGISLATIVE RULE
HEALTH CARE COST REVIEW AUTHORITY
Chapter 16-2D
Series II

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KEN HECHLER
Secretary of State

MARY P. RATLIFF
Deputy Secretary of State

BARBARA STARCHER
Deputy Secretary of State

RICHARD S. STEPHENSON
Deputy Secretary of State

Telephone: (304) 345-4000
Corporations: 342-8000



STATE OF WEST VIRGINIA
SECRETARY OF STATE

Charleston 25305

Dec. 23, 1985

WILLIAM H. HARRINGTON
Chief of Staff

RICH O. HARTMAN
Director, Administrative Law

DONALD R. WILKES
Director, Corporations

VIRGINIA SKEEN
Special Assistant

(Plus all the volunteers
help we can get)

NOTICE OF EXPIRATION OF EMERGENCY RULES

THE FOLLOWING EMERGENCY LEGISLATIVE RULE FILED BY
THE HEALTH CARE COST REVIEW AUTHORITY HAS EXPIRED.
THIS RULE WAS NOT FILED WITH THE LEGISLATIVE RULE-
MAKING REVIEW COMMITTEE WITHIN THE TIME REQUIRED
BY WV CODE 29A-3-15(a)(2).

Interim Standards for Magnetic Resonance
Imaging Services; Chapter 16-2D, Series 2
filed as an emergency rule on June 24, 1985.
This emergency rule expired on Dec. 24, 1985.

OFFICE OF THE SECRETARY OF STATE

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