

Arch A. Moore, Jr.
Governor



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

Health Care Cost Review Authority

NOTICE OF PUBLIC HEARING

Pursuant to Section five, Article three, Chapter twenty-nine-A of the Code of West Virginia, 1931, as amended, the West Virginia Health Care Cost Review Authority shall convene a public hearing at 10:00 a.m. on August 12, 1985 at the Health Care Cost Review Authority headquarters, 100 Dee Drive, Charleston, West Virginia for the purpose of taking evidence pertaining to the filing of proposed Legislative Rule, Interim Standards for Magnetic Resonance Imaging Services.

Any citizen or other interested party may appear in person to present evidence. Any citizen or other interested party may submit written evidence at the public hearing or mailed to the Health Care Cost Review Authority, 100 Dee Drive, Charleston, West Virginia 25311. All comments, written or oral, will be made a part of the public hearing record. The department requests that parties wishing to comment make an effort to submit written copies of their comments in order to facilitate review of the comments.

The issues to be heard shall be limited to the proposed rule. Copies of the proposed rule may be obtained by telephoning 304-343-3701 or writing to 100 Dee Drive, Charleston, West Virginia 25311.

SALLY K. RICHARDSON
Chairperson

July 1, 1985
Entered

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SECRETARY OF STATE

Arch A. Moore, Jr.
Governor



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OFFICE OF THE SECRETARY OF STATE

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

Health Care Cost Review Authority

NOTICE OF PUBLIC HEARING

Pursuant to Section 29A-3-5 of the West Virginia Code, the Health Care Cost Review Authority shall convene a public hearing at 1:00 p.m. on Wednesday, May 15, 1985, at its offices located at 100 Dee Drive, Charleston, West Virginia, for the purpose of taking testimony pertaining to the filing of emergency Legislative Rules - Interim Standards for Magnetic Resonance Imaging Services.

Anyone may appear and present testimony or mail written testimony to the Health Care Cost Review Authority to be received not later than the close of the hearing.

The issues to be heard shall be limited to the need for and the contents of the emergency rules. Copies of the rules may be obtained from the Health Care Cost Review Authority at the address above or by telephoning 343-3701.

April 10, 1985
Date


SALLY K. RICHARDSON, Chairperson
Health Care Cost Review Authority

Arch A. Moore, Jr.
Governor



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

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Health Care Cost Review Authority

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OFFICE OF THE SECRETARY OF STATE

May 20, 1985

TO: Advisory Council Members
MRI Task Force Members
Hospital Administrators
County or City Government Representatives
Regional Health Advisory Committee Chairpersons
Interested Persons

Enclosed is a copy of a proposed set of Legislative Rules dealing with Magnetic Resonance Imaging Services in the State of West Virginia. These rules were filed as emergency rules with the Secretary of State on March 19, 1985, effective the same date, and will serve as Interim Standards for the Authority's guidance in the development of MRI services until the State Health Plan is amended.

A notice of public hearing was filed with the Secretary of State on April 10, 1985, and a hearing was held on these rules on May 15, 1985. However, it was determined that the hearing would be continued on June 7, 1985, at 1:30 p.m., at the Authority's office at 100 Dee Drive, Charleston, West Virginia, to hear additional comments on these rules. To assure that everyone concerned has the opportunity to review these regulations, we are mailing copies to Hospital Administrators and other interested parties for their review prior to the public hearing.

Anyone may appear and present testimony or mail written testimony to the Health Care Cost Review Authority to be received not later than the close of the hearing.

Sincerely,

SALLY K. RICHARDSON
Chairperson

LARRY C. FIZER
Board Member

WILLIAM L. GILLIGAN
Board Member

RFG/maj

100 Dee Drive

Charleston, West Virginia 25311

304-343-3701

Arch A. Moore, Jr.
Governor



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

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SECRETARY OF STATE

Health Care Cost Review Authority

NOTICE OF CONTINUATION OF PUBLIC HEARING

A continuation of the public hearing for the purpose of taking testimony pertaining to the filing of emergency Legislative Rules - Interim Standards for Magnetic Resonance Imaging Services shall convene at 1:30 p.m. on Friday, June 7, 1985, at the office of the Health Care Cost Review Authority, 100 Dee Drive, Charleston, West Virginia.

Anyone may appear and present testimony or mail written testimony to the Health Care Cost Review Authority to be received not later than the close of the hearing.

The issues to be heard shall be limited to the need for and the contents of the emergency rules. Copies of the rules may be obtained from the Health Care Cost Review Authority at the address above or by telephoning 343-3701.

5/16/85

Date

Sally K. Richardson, Chairperson
Health Care Cost Review Authority

maj

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Emergency Filing-Interim Standards for Magnetic Resonance Imaging Services.

Type of Rule: xx Legislative Interpretive Procedural

Agency West Virginia Health Care Address 100 Dee Drive
Cost Review Authority Charleston, WV 25311

1. Effect of Proposed Rule	ANNUAL		FISCAL YEAR		
	Increase	Decrease	Current	Next	Thereafter
Estimated Total Cost	\$ -0-	\$ -0-	\$ -0-	\$ -0-	\$ -0-
Personal Services					
Current Expense					
Repairs and Alterations					
Equipment					
Other					

2. Explanation of above estimates.

These emergency rules will be used as standards in reviewing Certificate of Need applications and will, therefore, have no financial impact on the State Certificate of Need Program.

3. Objectives of these rules:

Again, these emergency rules will be used as interim standards in reviewing Certificate of Need applications for magnetic resonance imaging equipment in West Virginia.

4. Explanation of Overall Economic Impact of Proposed Rule.

A. Economic Impact on State Government.

No impact.

B. Economic Impact on Political Subdivisions; Specific Industries;
Specific groups of citizens.

No impact.

C. Economic Impact on Citizens/Public at Large.

Those patients in West Virginia needing this diagnostic procedure will no longer have to travel to other states in order to have access to these services. Although the cost of individual procedures on this equipment may be somewhat higher than for CAT Scanning services, the overall impact in the medical treatment of cancer, as well as other illnesses, should outweigh those costs.

Date _____

Signature of Agency Head or Authorized Representative

WEST VIRGINIA LEGISLATIVE RULE
HEALTH CARE COST REVIEW AUTHORITY
Chapter 16-2D
Series II

Title: Interim Standards for Magnetic Resonance Imaging Services

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WEST VIRGINIA 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 _____ day of _____, and filed on the _____ day of _____, in the Secretary of State's Office.

1.4 Effective Date - These rules become effective on the _____ day of _____.

1.5 Termination - These rules shall automatically terminate and be of no further legal effect upon the adoption by the State Health Coordinating Council of an amendment to the State Health Plan concerning this same subject matter.

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.

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.