

WEST VIRGINIA EMERGENCY LEGISLATIVE RULES
HEALTH CARE COST REVIEW AUTHORITY

Chapter 16-2D
Series III

FILED
1985 JUL 22 PM 12:45
SECRETARY OF STATE

Subject: Interim Standards For Lithotripsy 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 lithotripsy 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 - July 23, 1985

1.4 Effective Date - July 23, 1985

Section 2 Introduction - These interim standards seek to provide guidance in the development of lithotripsy services in West Virginia. The field of lithotripsy 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 lithotripsy 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:

2.1.1 Guidance in the orderly development of lithotripsy services.

2.1.2 The identification of data needs.

2.1.3 The review of Certificate of Need proposals for lithotripsy 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. These standards and criteria stated here apply to organizations and institutions proposing to provide lithotripsy services.

Section 3 Definition - Extracorporeal shock-wave lithotripsy (ESWL) is a technique primarily used for pulverizing kidney stones in vivo by focusing shock waves on the stone.

Section 4 Accessibility of Services

4.1 Organizations seeking to provide lithotripsy services shall document:

4.1a written clinical criteria clearly specifying who is eligible for the service.

4.1b Patient selection policies which provide that no otherwise eligible person shall be denied services on account of age, behavioral disability, type of payor or ability to pay.

4.1c A scheduling priority system, without regard to patient origin, should be based on patient need.

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

4.2 Organizations seeking to provide lithotripsy services shall provide accessibility to the handicapped through implementation of the Rehabilitation Act of 1973.

4.3 The SHPDA shall initially give priority consideration to those applications for a Certificate of Need for lithotripsy services which make lithotripsy services accessible to the greatest number of people and for the greatest economic benefit of West Virginia residents.

Section 5 Availability of Services

5.1 Consideration shall be given to the access of lithotripsy services to medical school research and teaching hospitals with approved residency programs in urology.

5.2 Organizations seeking to provide lithotripsy services shall document policies which assure availability of the lithotripsy unit to graduate education programs in urology and other medical specialties approved by the appropriate national accrediting bodies.

5.3 The initial Certificate of Need approvals issued by the SHPDA relative to the development of lithotripsy services in West Virginia shall be

limited to one site in each service area. Service Area I shall consist of RHAC areas one through four. Service Area II shall consist of RHAC areas five through eleven. SHPDA will approve only one application in each service area unless a more cost-effective, technologically and clinically superior alternative is available for clinical use. These service areas shall be used only for the initial CON decisions, and shall be reviewed by the SHPDA thereafter on a yearly basis and modified if appropriate.

5.4 The ESWL program should ensure that Board certified/qualified urologists have the opportunity to obtain privileges to use the lithotripter unit.

Section 6 Quality of Services

6.1 The lithotripsy unit to be acquired and used for patient care must have pre-market approval (PMA) by the FDA for clinical use, or the applicant must document that the unit to be acquired has received an Investigational Device Exemption (IDE) from the FDA, and the applicant must document that its site has received approval from the FDA as an IDE site.

6.2 Organizations seeking to provide lithotripsy services shall document prior to implementation, that a full-time board-certified urologist with at least 80 hours of training in lithotripsy services shall be responsible for managing operation of the lithotripsy unit.

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

6.4 Organizations seeking to provide lithotripsy services shall ensure that at least one staff member trained in CPR is on duty in the unit during its use.

Section 7 Cost of Services

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

7.2 Charges for the provision of clinical lithotripsy services shall be reasonably consistent with the allowable costs of providing these services as specified by the West Virginia Health Care Cost Review Authority.

7.3 Organizations proposing lithotripsy services shall document that lithotripsy is the most cost-effective form of stone management.

Section 8 Continuity of Services

8.1 Organizations proposing to provide lithotripsy services shall have available on staff, or through referral, physicians who have completed a residency

program or are currently eligible for board certification in at least the following medical specialties:

- 8.1a Urology
- 8.1b Nephrology
- 8.1c Internal medicine
- 8.1d Pathology
- 8.1e Radiology
- 8.1f Anesthesiology

8.2 Organizations proposing to provide lithotripsy services shall assure that such services are part of an integrated program of urology services including endo-urological expertise with on-site access to the necessary equipment and personnel.

8.3 Organizations seeking to provide lithotripsy services shall, prior to the implementation of the service, 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 patho-logical findings. The data base shall be designed so that it can become a part of a national data base.

Section 9 Acceptability of Services

9.1 Organizations seeking to provide lithotripsy 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.

9.2 Organizations seeking to provide lithotripsy services shall specify the mechanism for limiting the hazardous effects of the lithotripsy machine.

9.3 Organizations seeking to provide lithotripsy services shall specify appropriate emergency procedures for patients.

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Title: Interim Standards for Lithotripsy Services

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APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

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1985 JUL 22 PM 12:56

Rule Title: Emergency Filing-Interim Standards for Lithotripsy Services

SECRETARY OF STATE

Type of Rule: Legislative Interpretive Procedural

Agency West Virginia Health Care Cost Review Authority Address 100 Dee Drive
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 lithotripsy 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.

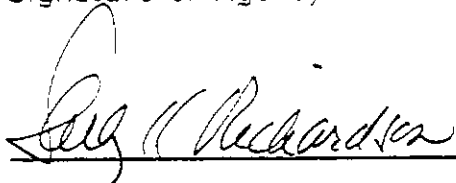
C. Economic Impact on Citizens/Public at Large.

The citizens of West Virginia who are in need of hospitalization for kidney stones will have the opportunity to have their kidney stones eliminated by lithotripsy equipment rather than go through surgery and a lengthy hospital stay. This will save West Virginians increased expenditures in health care dollars.

Date

6/5/85

Signature of Agency Head or Authorized Representative



NOTICE OF PUBLIC HEARING OR COMMENT PERIOD ON A PROPOSED RULE

1985 JUL 22 PM 12:56

PUBLIC HEARING

DEPARTMENT OF HEALTH
SECRETARY OF STATE

AGENCY: West Virginia Health Care Cost Review Authority
RULE TYPE: Legislative
RULE TITLE: Interim Standards for Lithotripsy Services

A PUBLIC HEARING ON THE ABOVE PROPOSED RULE WILL BE HELD AT 1:30 p.m.
(Time)
ON July 12, 1985 AT City Council Chambers, City Building,
(Date) (Location)
Virginia and Court Streets, Charleston, West Virginia.

COMMENTS ARE LIMITED TO: ORAL _____ WRITTEN _____ BOTH X

COMMENTS MAY ALSO BE MAILED TO: West Virginia Health Care Cost Review
(Address)
Authority, 100 Dee Drive, Charleston, West Virginia 25311

THE DEPARTMENT REQUESTS THAT PERSONS WISHING TO MAKE COMMENTS AT THE
HEARING MAKE AN EFFORT TO SUBMIT WRITTEN COMMENTS IN ORDER TO FACILITATE
A REVIEW OF THESE COMMENTS.

THE ISSUES TO BE HEARD SHALL BE LIMITED TO THE PROPOSED RULE.

Edw. C. Richardson
Chairperson

Arch A. Moore, Jr.
Governor



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

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Health Care Cost Review Authority

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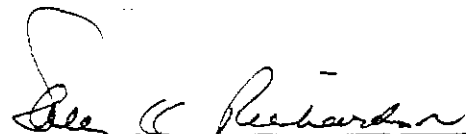
SECRETARY OF STATE

NOTICE OF EMERGENCY RULE

RULE TITLE: Interim Standards for Lithotripsy Services

The attached rule is filed as an Emergency Rule. The facts and circumstances constituting the emergency are as follows:

The purpose of this emergency rule is to adopt a legislative rule containing standards for use in reviewing applications requesting Certificate of Need approvals for proposed lithotripsy services. The facts constituting the emergency are that the Authority has received three (3) applications for such services. The State Health Plan is silent on standards for such services. Hence, the Authority is without standards by which to judge the merits of the applications. West Virginia Code, §16-2D-7, sets forth strict time limitations within which applications must be reviewed. Without these interim standards, the time requirements for reviews cannot be met.


Chairperson



KEN HECHLER
Secretary of State

MARY P RATLIFF
Deputy Secretary of State

BARBARA STARCHER
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Special Assistant

(Plus all the volunteer
help we can get)

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STATE OF WEST VIRGINIA
SECRETARY OF STATE

Charleston 25305

PROPOSED RULES

STATE REGISTER FILING

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AGENCY West Virginia Health Care Cost Review Authority

CONTACT PERSON Bill J. Crouch PHONE 343-3701

TYPE OF RULE Legislative

TITLE OF RULE Interim Standards for Lithotripsy Services

CHAPTER 16 ARTICLE 2D SERIES III

AUTHORITY §16-2D-8

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CHECK APPLICABLE ITEMS BELOW TO SHOW KIND OF ACTION BEING TAKEN

NEW RULE

NOTICE OF HEARING

AMENDMENTS TO EXISTING RULE

NOTICE OF AGENCY APPROVAL
(legislative rules only)

REPEAL OF EXISTING RULE

NOTICE OF AGENCY ADOPTION
(interpretive & procedural
rules only)

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REQUIRES AN ORIGINAL AND
A COPY.

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FIRST EMERGENCY FILING

SECOND EMERGENCY FILING

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 Lithotripsy 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 June 5, 1985. Certain changes were made in this rule as a result of a public hearing 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.


SALLY K. RICHARDSON

7/23/85

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