

Arch A. Moore, Jr.
Governor



Chairman
David S. Frazer
Board Members
Walter J. Dale
Larry C. Fizer

HEALTH CARE COST REVIEW AUTHORITY

100 Dee Drive, Charleston, West Virginia 25311
(304) 343-3701

NOTICE OF RULE MODIFICATION

FILED IN THE OFFICE OF
THE SECRETARY OF STATE
THIS DATE Jan. 8, 1986
ADMINISTRATIVE LAW DIVISION

LEGISLATIVE RULE: Interim Standards for
Lithotripsy Services-Proposed

The above titled rule has been modified as a result of comments by the Legislative Rule-Making Review Committee and the attached modifications have been incorporated into the above titled rule and filed with the Secretary of State's office on January 8, 1986.

A handwritten signature in cursive script, appearing to read "John H. Kozak".

John H. Kozak
General Counsel

Arch A. Moore, Jr.
Governor



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HEALTH CARE COST REVIEW AUTHORITY

100 Dee Drive, Charleston, West Virginia 25311
(304) 343-3701

January 6, 1986

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

Attn: Administrative Division

Dear Mr. Hechler:

Re: Proposed Rules: Interim Standards For
Lithotripsy Services

Please be advised that at its Sunday, January 5, 1986, meeting, the Legislative Rule-Making Review Committee gave its recommendation for approval to these rules. However, certain minor modifications to the rules had been suggested by the Committee's counsel, Debra A. Graham. Those modifications were agreed to by the board of the Authority and were subsequently approved by the Committee.

Enclosed herewith for filing with your office, please find the following:

- (1) Three (3) copies of the proposed rules showing the language deleted (struck-through) and the language added (underlined); the changes appear in sections 1.2, 4.2, 4.3, 5.3, 6.1, and 7.1;
- (2) Three (3) copies of the proposed rules in final form.

Please return to us with your stamp showing filing with your office one (1) copy of each version of these proposed rules.

With much appreciation for your assistance, I remain

Very truly yours,

A handwritten signature in cursive script that reads "John H. Kozak".

JOHN H. KOZAK
General Counsel

JHK/jmh

Enclosures

cc: Debra A. Graham, Esquire

1986 JAN -8 AM 9:41
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**WEST VIRGINIA
HEALTH CARE COST REVIEW AUTHORITY
Chapter 16-2D
Series III**

Title: Interim Standards for Lithotripsy Services

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SECRETARY'S OFFICE

**WEST VIRGINIA LEGISLATIVE RULES
HEALTH CARE COST REVIEW AUTHORITY**

Chapter 16-2D
Series III

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. The West Virginia Health Care Cost Review Authority was made responsible for administration of the Certificate of Need Program pursuant to West Virginia Code, §16-29B-11.

1.3 Filing Date - _____.

1.4 Effective Date - _____.

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.

Health Care Cost Review Authority
Leg. Rule 16-2D
Series III, Sec. 2

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:

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

4.1.b 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.

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

4.1.d 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: .29 U.S.C. §701 et seq.

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.~~ which make lithotripsy services available at the greatest economic benefit for 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.

Health Care Cost Review Authority
Leg. Rule 16-2D
Series III, Sec. 5

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~~ Regional Health Advisory Council areas one through four. Service Area II shall consist of ~~RHAC~~ Regional Health Advisory Council 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~~ Certificate of Need 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~~ Federal Drug Administration (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~~, Health Care Cost Review Authority, their ability to finance and operate such equipment.

Health Care Cost Review Authority
Leg. Rule 16-2D
Series III, Sec. 7

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:

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

Health Care Cost Review Authority
Leg. Rule 16-2D
Series III, Sec.10

Section 10 Termination of Interim Standards. These interim standards shall automatically and without further action by either the Legislature or the West Virginia health Care Cost Review Authority terminate upon the approval by the Governor of an amendment to the State Health Plan concerning this same subject matter. Such termination shall not affect the validity or finality of decisions made pursuant to these interim standards prior to such termination nor be a basis for reconsideration of any such prior decision.

WEST VIRGINIA LEGISLATURE
Legislative Rule-Making Review Committee



FILED
1986 JAN -7 AM 9:41

NOTICE OF ACTIONS TAKEN BY LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

January 6, 1986

TO: / Ken Hechler, Secretary of State; State Register

TO: David Frazer, Chairman
Health Care Cost Review Authority
Suite 200; 100 Dee Drive
Charleston, WV 25311

FROM: Legislative Rule-Making Review Committee

PROPOSED RULE: Interim Standards for Lithotripsy Services

The Legislative Rule-Making Review Committee recommends that the West Virginia Legislature:

1. Authorize the agency to promulgate the Legislative Rule as originally filed or as modified by the agency X
2. Authorize the agency to promulgate part of the Legislative rule; a statement of reasons for such recommendation is attached.
3. Authorize the agency to promulgate the Legislative rule with certain amendments; amendments and a statement of reasons for such recommendation is attached.
4. Recommends that the rule be withdrawn; a statement of reasons for such recommendation is attached.

Pursuant to Code 29A-3-11(c), this notice has been filed in the state register and with the agency proposing the rule.

cc: John H. Kozak
General Counsel