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1985 NOV 25 PM 2:33

Notice of Agency Approval

Legislative Rule: Interim Standards for Lithotripsy Services

The above-titled legislative rule constitutes the official rule approved by the West Virginia Health Care Cost Review Authority on the 16th day of July, 1985 and filed pursuant to law in the office of the Secretary of State, State of West Virginia.

Sally K. Richardson

SALLY K. RICHARDSON, Chairperson

Nov. 25, 1985
ENTERED

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: 345-8000

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1985 NOV 25 PM 2:29

STATE OF WEST VIRGINIA
SECRETARY OF STATE
Charleston 25305

WILLIAM H. HARRINGTON
Chief of Staff

RICH O. HARTMAN
Director, Administrative Law

DONALD R. WILKES
Director Corporations

VIRGINIA SKEEN
Special Assistant

(Plus all the volunteer help we can get)

PROPOSED RULES

STATE REGISTER FILING

==========

AGENCY West Virginia Health Care Cost Review Authority

CONTACT PERSON John H. Kozak 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

++++++++++

CHECK APPLICABLE ITEMS BELOW TO SHOW KIND OF ACTION BEING TAKEN

- [x] NEW RULE
- [ ] AMENDMENTS TO EXISTING RULE
- [ ] REPEAL OF EXISTING RULE

NOTE: ALL FILINGS REQUIRE ONLY ONE COPY, EXCEPT FINAL FILING OF RULES WHICH REQUIRES AN ORIGINAL AND A COPY.

- [ ] NOTICE OF HEARING
- [x] NOTICE OF AGENCY APPROVAL (legislative rules only)
- [ ] NOTICE OF AGENCY ADOPTION (interpretive & procedural rules only)
- [ ] FINAL FILING
- [ ] FIRST EMERGENCY FILING
- [ ] SECOND EMERGENCY FILING

Arch A. Moore, Jr
Governor

HEALTH CARE COST REVIEW AUTHORITY

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

MEMORANDUM

DATE: November 25, 1985

TO: Legislative Rule-Making Committee

FROM: West Virginia Health Care Cost Review Authority

RE: Interim Standards For Lithotripsy Services: Circumstances Requiring the Rule; Brief Summary of the Content of the Rule

I. The Circumstances Requiring The Rule

Pursuant to West Virginia Code, §16-2D-3(e), (h), the Authority is required to review proposals to provide new services of hospitals and proposals to acquire major medical equipment with a fair market value of $400,000.00 or more. Extracorporeal shock-wave lithotripsy is a new technique for pulverizing kidney stones inside the body without surgery by focusing shock waves on the stone. A lithotripsy device is used to perform this service. These devices are valued in excess of $400,000.00. Thus, the provision of lithotripsy services and the acquisition of lithotripsy devices requires Certificate of Need approval. Pursuant to West Virginia Code, §16-2D-9(b), the Authority must make two determinations (plus others found elsewhere in the Code) before it can approve applications for these services and devices; first, is the service and device needed?; and second, is the service and acquisition of the device consistent with the State Health Plan?

Lithotripsy is a new technology. The State Health Plan does not yet have standards by which to judge either the need for or the best distribution of these services and devices. The Statewide Health Coordinating Council has begun the involved process of drafting amendments to the State Health Plan for the Governor's approval. In the meantime, the Authority has received several applications concerning lithotripsy services and expects additional applications in the near future. These rules will provide the necessary standards until the State Health Plan is amended so that the pending and future applications can be meaningfully reviewed.

II. Brief Summary of the Rule

The rule provides basic guidance for the development of lithotripsy services in West Virginia. The State is divided into two regions based upon projections in the professional literature on the size of a population necessary to efficiently use a lithotripsy device. Since only two devices are anticipated to be

initially needed in the State, the rules specify that a prevailing applicant must meet certain qualifications for competent delivery of the services and required back-up services and also to ensure that all residents of the State will have access to the service. The rules also require that an applicant document the financial costs associated with provision of the equipment and the delivery of the service so that the most efficient and economic cost to consumers can be obtained.

JHK/dlc

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

FILED

Rule Title: Interim Standards for Lithotripsy Services

1989 NOV 25 PM 2:36

Type of Rule: X Legislative _____ Interpretive _____ Procedural

Agency West Virginia Health Care Cost Review Authority Address Suite 200; 100 Dee Drive, Charleston, West Virginia 25311

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

2. Explanation of above estimates:
These 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:
These rules will be used as interim standards until the Governor approves changes in the State Health Plan for the review of 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 sontes 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 without necessary duplication of expensive equipment.

DATE: November 25, 1985

Signature of Agency Head or Authorized Representative

Lee C Richardson

FILED

1985 NOV 25 PM 2:30

SECRETARY of STATE

DATE: November 25, 1985

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: West Virginia Health Care Cost Review Authority

LEGISLATIVE RULE TITLE: Interim Standards for Lithotripsy Services

1. Authorizing statue(s) citation West Virginia Code, §16-2D-8

2. a. Date filed in State Register with Notice of Hearing:

June 5, 1985

b. What other notice, including advertising, did you give of the hearing?

Notices and copies of proposed rules sent to Health Care Cost Review Council; Lithotripsy Task Force; All Hospital Administrators; County/City Government Hospital Representatives; All Regional Health Advisory Committee Chairpersons; Certificate of Need Interested Persons List; State Register

c. Date of hearing (s): July 12, 1985

d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

Attached X No comments received

e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing: (be exact)

November 25, 1985

f. Name and phone number of agency person to contact for additional information:

JOHN H. KOZAK, GENERAL COUNSEL

(304) 343-3701

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

   a. Give the date upon which you filed in the State Register a notice of the time and place of a hearing for the taking of evidence and a general description of the issues to be decided.

      N/A

   b. Date of hearing: N/A

   c. On what date did you file in the State Register the findings and determinations required together with the reasons therefor?

      N/A

   d. Attach findings and determinations and reasons:

      Attached N/A

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.

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.

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.

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:

8.1.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.

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
HEALTH CARE COST REVIEW AUTHORITY
Chapter 16-2D
Series III

Title: Interim Standards for Lithotripsy Services

FILED

1985 NOV 25 PM 2:30

Secretary of State

Notice

Legislative Rule: Interim Standards for Lithotripsy Services

The above-titled legislative rule is hereby submitted to the Legislative Rule-Making Review Committee.

Sally K Richardson

SALLY K. RICHARDSON, Chairperson

Nov. 25, 1985

Entered

WEST VIRGINIA HEALTH CARE COST REVIEW AUTHORITY

Public Hearing Minutes
July 12, 1985

The Authority held a public hearing on the following proposed regulations:

Legislative Rules for Interim Standards
for Lithotripsy Services

Presiding: Robert Baer, Director of Certificate of Need

Staff Present:

Robert Baer
Robert Durbin
Steve Barthelmess
Mary Ann Johnson

Public Present:

See attached list.

PUBLIC COMMENTS

1. Joseph Miller, Spilman, Thomas, Battle and Klostermeyer, representing Charleston Area Medical Center.

   Mr. Miller recommended that the Interim Standards be adopted as proposed and incorporated in the State Health Plan. He further spoke to 3 sections of the Standards as follows:

   Section 4.1c - Since lithotripsy is an elective procedure, and very rarely performed on an emergency basis, CAMC believes the Standard to be unclear as to whether this section is meant to address flexible scheduling with respect to accommodating emergencies or whether it addresses a need for accommodating physicians and patients that may live and practice in outlying areas. CAMC would like clarification at to what it means.

   Section 4.3 - CAMC specifically supports this Standard and recommends its adoption. Lithotripters are expensive pieces of equipment, but potential to patients with kidney stones far outweighs that expense. Due to the cost of the machine, a lithotripter cannot be placed in every hospital in the State, therefore, the machines available must be situated in locations that are accessible to the greatest number of people.

1. Joseph Miller (continued)

Section 6.1 - CAMC views this Standard not as a mere repetition of Federal law, which requires that a device of this sort be approved by the Food and Drug Administration. It views it as a positive guideline for the health planning concept. CAMC recommends that the standard reflect that the SHPDA should give priority among competing lithotripter applications to lithotripters which have obtained the more advance PMA over those whose sponsors have merely obtained a permit to experiment upon humans.

2. Richard Clark, representing Cabell-Huntington Hospital.

Section 6.1 - Requested clarification as to the reasoning for inclusion of IDE language in this standard.

Section 5.3 - On what rationale were the service areas based. Other methodologies should be looked at -- possibly looking at the merits of each application, rather than service areas. Allowing one lithotripter per service area limits the consideration of individual applications.

Clarification requested regarding the one-year review period. Mr. Baer stated that he felt the 12-month period would be used to maintain the set of Standards until such time as a permanent change to the State Health Plan is authorized.

3. Stephen Tancin, representing West Virginia University.

Section 6.1 - Mr. Tancin requested that West Virginia University Hospitals support of this Standard be included in the record. WVU Hospitals is, at this time, investigating the possibility of joining with Biomedics as an IDE site and would, therefore, like to become part of this advance in medical technology.

There being no further comments, the hearing adjourned.

maj

HEALTH CARE COST REVIEW AUTHORITY

MEETING REGISTRATION

DATE OF MEETING Lithotripsy 7/2/85
TYPE OF MEETING Public

NAME	Organization	Desire to speak Yes	No
1. [illegible]	CHMC		
2. Karen Stauss	CAMC		X
3. [illegible]			/
4. Mark [illegible]	[illegible]		/
5. [illegible]	CAMC	✓	
6. Jose Acevedo / mc	CAMC		X
7. [illegible]	[illegible]		X
8. Robyn Davis	Goodwin & Goodwin		X
9. Christy Holland	[illegible]		✓
10. [illegible]	[illegible]		X
11 Neil Clark	" "	X	
12. [illegible]	[illegible]		X
13. Stephen [illegible]	WVU Hospitals		
14.			
15.			
16.			
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27.			

Copy: Board
JEK

DIPLOMAT, AMERICAN BOARD OF UROLOGY
(PEDIATRIC, ADULT AND ONCOLOGIC UROLOGY)

Tara C. Sharma, M.D., F.A.C.S., F.I.C.S.

OFFICE (304) 523-6421
HOME (304) 522-4583

Hoffman Urological Clinic
SUITE 800
FIRST HUNTINGTON BUILDING, HUNTINGTON, WEST VIRGINIA 25701-2227

May 28, 1985

Mr. Bob Peck
Health Care Cost Review Authority
100 Dee Drive
Charleston, West Virginia 25311

Dear Bob:

It was nice to talk with you on the telephone the other day in reference to the standards for the development of lithotripsy service. As explained earlier, and you are quite aware of the fact, the lithotripters are going to be available at a much cheaper price than the ones that are available at this time. The technology is here and different machines are being developed which are simpler, more effective, and less costly. My statement as per our telephone conversation still is that we, in our State, should not restrict ourselves to only one or two CON's just because one machine which is FDA approved at this time happens to cost three to four times the cost of the machines that will be available within less than two years.

I would hate to see our State suffer on the basis of restrictive actions provided in the standards. Further, as discussed on Page 3, under Availabilities, Paragraph 1, I feel we should delete the word "urology" in residency program in urology. Also, on Page 5, #2, a full-time Board Certified Urologist, I feel the word "full-time" should be omitted and a urologist with at least 80 hours to read as having experience of observing at least 30 cases rather than hours which is recommended by AUA. As far as approval by FDA, I think we should take a very, very serious look and keep our minds open. I don't feel that we should be restrictive in providing the services to the citizens of West Virginia and the surrounding communities since most of our cities like Morgantown, Bluefield, Beckley, and Huntington are on the periphery of the State. We must keep that in mind prior to deciding anything.

If I can be of any assistance, please do not fail to contact me at any time. These are my suggestions, not criticisms.

Very truly yours,

Tara C. Sharma, M.D.
President, W. Va. Urological Society

TCS/bb

cc: Mr. Bill J. Crouch

Cog. Board
BQC
9.HK

Arch A. Moore, Jr.
Governor

David K. Heydinger, M.D.
Director

State of West Virginia

DEPARTMENT OF HEALTH
CHARLESTON 25305

M E M O R A N D U M

DATE: May 30, 1985

TO: Bill Crouch, Executive Director
WV Health Care Cost Review Authority

FROM: Robert Peck, Director
Division of Planning

RE: Comments regarding Lithotripsy Standards

Enclosed you will find the comments I received relative to the draft Lithotripsy Standards being developed by the Authority. Two sets of comments were taken verbally by telephone. One set was submitted in writing by Cabell-Huntington Hospital (see attachment).

Comment 1: Offered by Mr. Bruce Goldshorn May 17, 1985 by telephone

1. Page 4 Quality Standard

Comment: Mr. Goldstown objected to the first standard related to pre-market approval (PMA) in that he indicated that such a requirement was too restrictive for a research medical school institution. He suggested that the Authority also allow for IDE approval as as well as PMA approval.

Comment 2: Offered by Dr. Tara C. Shama May 28, 1985 by telephone

2. Page 5 #2 under Quality

Comment: Dr. Shama suggested that the "80 hours" in the standard be changed to "30 patients and he also suggested that the words "fulltime" in line two be deleted.

Page 3

Comment: #1 under Availibility. Dr. Shama suggested that the word "urology" in the last line be deleted.

Page 4

Comment: Dr. Shama suggested that the standard also reflect IDE approval by the FDA.

These are all of the comments I received during the comment period. Please let me know if you want to meet prior to the public hearing to discuss the issues raised in the comments or any additional issues that have surfaced since the Task Force meeting.

BP:bem

Copy: Board Members
Bob Baer
Bill Crouch
John Kozole

LAW OFFICES

SPILMAN, THOMAS, BATTLE & KLOSTERMEYER

Suite 1200 KB&T Center
P. O. Box 273
Charleston, West Virginia 25321-0273

Telephone (304) 344-4081
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July 12, 1985

Mr. Robert Baer
State Health Planning and Development
Agency of the Health Care Cost
Review Authority
100 Dee Drive
Charleston, WV 25311

Dear Mr. Baer:

I am enclosing a copy of my remarks made on behalf of Charleston Area Medical Center, Inc. (CAMC) at the public comment hearing on the proposed lithotripter standards held in Charleston City Council Chambers on July 12, 1985 at 1:30 p.m. In the interest of the timely and efficient processing of currently submitted lithotripter certificate of need applications, and if the Standard 6.1 is adopted as written, CAMC suggests the establishment of a cutoff date in advance of the public hearing by which time the applicant with an Investigational Device Exemption must document that its site has received approval as an IDE site, thus eliminating the need for substantial preparation for a hearing in cases where the applicant cannot possibly meet the standard.

I am today supplying copies of my remarks to representatives of Cabell Huntington Hospital and West Virginia University Hospitals, Inc.

Very truly yours,

Joseph J. Miller

cc: Robert Savage
Karen Starks
Daphne Schreiber
Nancy Hiscoe
Steven Tanzen

Mr. Baer, my name is Joseph Miller. I am an attorney practicing with the law firm of Spilman, Thomas, Battle and Klostermeyer. We are representing Charleston Area Medical Center, Inc. at this hearing. Subject to the comments I will make, CAMC urges this Authority to adopt the Interim Standards for Lithotripsy Services as proposed. CAMC also recommends their inclusion as a permanent amendment to the State Health Plan.

I will comment briefly upon three of the standards.

Standard 4.1.c.

First, Standard 4.1.c states that "organizations seeking to provide lithotripsy services shall document a scheduling priority system based on patient need." I think that a standard of this nature is common with respect to medical services and devices, but lithotripsy is largely an elective procedure. It is a procedure which only very rarely would be performed on an emergency basis. For that reason, CAMC believes it to be unclear whether this standard is meant to address flexible scheduling with respect to accommodating emergencies or whether it perhaps addresses the need for accommodating physicians and patients who must travel some distance in order to make use of the facility. Perhaps "patient need" is defined in some other way. Charleston Area Medical Center wishes to meet this standard in its own lithotripter application but would like clarification as to its meaning.

Standard 4.3.

The second standard I wish to comment upon is standard 4.3 which states that "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." CAMC specifically supports this standard and recommends its adoption. Lithotripters are expensive peices of equipment. Their potential benefit to patients with kidney stones far outweighs the expense, but the cost of the machine makes it evident that they cannot be placed in every hospital or clinic in the state. Therefore, the machines which are available must be situated in locations which are accessible to the greatest number. Given the need for accessibility, our public policy requires that priority be given to the machines which will be accessible to the greatest number of West Virginians.

The West Virginia certificate of need law and the State Health Plan are designed for "the general welfare and protection of the lives, health and property of the people of this State," the people of West Virginia. The need for lithotripter accessibility to the greatest number of people and the stated public policy to provide for the welfare of West Virginians are both served by this standard, and therefore the standard should be adopted.

Standard 6.1.

The final standard I wish to comment on is Standard 6.1. This standard states that:

"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."

CAMC urges adoption of this standard as a means of guiding the Authority in developing lithotripsy services in this state. CAMC views this standard not as mere repetition of federal law (for federal law requires the same approvals before any lithotripter can be put in operation on humans); it views this standard as a positive guideline for the health planning process. The certificate of need review process in West Virginia is a very thorough one and that thoroughness leads to some expense -- not only expense to the applicant, but to persons affected by the applicant's proposed project. State administrative resources which include this Authority's time and the time of its staff are considerable in any certificate of need review. It would be a waste of these resources to put this review process in motion and then to engage the resources needed to bring it to completion without assurance that, once obtained, the certificate of need can actually be used to lawfully operate the lithotripter on human beings. This standard protects against such a waste. It protects the public purse and it facilitates the orderly development of health services in West Virginia. It should be adopted. [COMPROMISE: The standard could include a cutoff time period such

that a CON application could not be processed beyond a certain point until the lithotripter device applied for has been FDA approved.]

While it urges adoption of standard 6.1, CAMC recommends that the standard reflect that the SHPDA should give priority among competing lithotripter applications to lithotripters which have obtained the more advanced PMA over those whose sponsors who have merely obtained a permit to experiment upon humans.

These are the comments of Charleston Area Medical Center. Once again, CAMC believes the standards to be well considered and, subject to these comments, urges their adoption and inclusion into the State Health Plan. Thank you for your attention.

ACEA | ARTHUR CLARK ELMORE associates inc.

816-471-0076
1102 GRAND AVE., SUITE 601 • KANSAS CITY, MO. 64106

July 15, 1985

Mr. Robert Baer
Director Certificate of Need
100 Dee Drive
Charleston, WV 25311

Dear Mr. Baer:

The comments discussed in the paragraphs which follow are in regard to the Interim Standards for Lithotripsy Services filed on June 5, 1985 under the authority of West Virginia Code, Chapter 16, Article 2 D, Section 8. We are offering these comments on behalf of Cabell Huntington Hospital and are requesting that these comments be provided as information to the Health Care Cost Review Authority of West Virginia for their review and adoption of the Lithotripsy Services Standards.

The standards and our comments regarding the noted standards are as follows:

Section 5.3 "The initial Certificate of Need approval issued by the SPHDA 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 1-4. Service Area II shall consist of RHAC Areas 5-11. 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 decision, and shall be reviewed by the SHPDA thereafter on a yearly basis and modified if appropriate.

Response:

It is our understanding that the determination of Service Areas I and II described above was made on the basis of dividing the State of West Virginia into two areas approximately the same size of population in each. While we would support the underlying principle of using a "population-based" model for determining need, the reasons for selecting two service areas within West Virginia are not clear. Perhaps, 3, 4, or 5 areas can be justified within West Virginia at this time. Additionally, several of the locations that may be candidates for providing lithotripsy services to meet the needs of persons residing within their own service areas can and would serve a portion of persons residing outside of the State of West Virginia. Those

persons living in the out-of-state areas must be taken into consideration when developing a population-based service area such as proposed by SHPDA. We feel it would be appropriate for each CON application to be evaluated on the basis of individual service areas and a determination of need and expected use of lithotripsy services to be made on the basis of service area need as substantiated by the applicant. We would also take exception to the limit of only one application in each service area until a more cost effective, technologically and clinically superior alternative is available for clinical use. Again, there may well be a need for three, four or five lithotripter units in the State of West Virginia and each Certificate of Need application should be judged individually with regard to that determination of need. Therefore, it would seem inappropriate to limit the number of lithotripter units.

Further, it would appear that additional applications in each service area will only be approved if there is a more cost-effective, technologically and clinically superior alternative available for clinical use. We would agree that criteria such as cost-effectiveness, technological superiority and scope of clinical applications should be considered among other criteria such as accessibility, availability, capital costs, etc. We disagree that only one application in each service area should be approved until other applications can show that they are superior to the initial applications. We feel it is more appropriate to state that each application should meet the standards and criteria used for determination of need with regard to lithotripsy services whether they are the initial or subsequent applications. Finally, it is not clear as to whether the SHPDA will modify and update the interim lithotripsy standards prior to the expiration of a calendar year from the adoption of those standards. It is our understanding that the standards should be reviewed as the lithotripsy methodologies become more refined and as alternative equipment is developed.

It is recommended that the West Virginia Health Care Cost Review authority consider the modification of Standard 5.3 to allow consideration and approval of Certificate of Need applications for lithotripsy services to be provided within the State of West Virginia based on individual determination of need using a population-based approach. Further, service areas should not be restricted geographically, but should in fact include those areas that represent appropriate referral patterns including consideration of in-migration from residents located in States adjacent to West Virginia. Finally, approval of Certificate of Need applications for lithotripsy services should be based on conformance of the application with the Standards and Criteria used for determining need for lithotripsy services and should not be limited to an arbitrary number of sites within the State of West Virginia at this time or in the future.

Standard 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.

Response:

In previous meetings of the task force regarding discussion of the standards for lithotripsy services, to our knowledge, the fact that the unit to be acquired should have received an Investigational Device Exemption from the FDA was to our knowledge not discussed. Further, the West Virginia Certificate of Need Law states that a health care facility is not required to obtain a Certificate of Need for the acquisition of major medical equipment to be used solely for research, the addition of health services to be offered soley for research, or the obligation of a capital expenditure to be made soley for research if the acquisition does not affect the charges of the facility for services other than those included in the research, or result in a substantial change to bed capacity, or result in substantial change to the health services of the facility. It would appear that the requirement for an applicant proposing lithotripsy services to have received an investigation device exemption from the FDA in order to obtain a CON could be superceded by the exemption section of the West Virginia Certificate of Need Law regarding research applications. We are requesting clarification of this issue.

It is our understanding that Charleston Area Medical Center (CAMC) asked that consideration be given to setting priorities for approval of lithotripsy equipment based on the approval stage within the FDA. For example, equipment that has received full FDA approval should be given top priority while equipment receiving pre-market approval (PMA) should be given second priority and equipment being used for Investigational Device purposes should be given third priority. We would object to this setting of priorities on the basis of levels of FDA approval since there would appear to be no precedent for this action to be taken. Secondly, we feel that progress in developing cost-effective, technologically advanced, and clinically superior alternatives should not be limited by restricting approvals in terms of giving IDE the lowest priority. In fact, it would appear that the CON law for West Virginia encourages development of research alternatives by granting exemptions from requiring a CON approval. It could also be noted that the setting of such priorities if extended to other diagnostic services, such as CAT Scanners would possibly have restricted the development and acquisition of third and fourth generation of CAT Scanners by giving priority to "older" equipment simply because it had been in existence for

a longer period of time. We fail to see the reasons for setting priorities on the basis of length of time the equipment has been in existence and object to that criteria as a basis for determination of need and awarding of CON approvals.

We appreciate the opportunity to offer these comments for consideration in developing the interim standards for the review of lithotripsy services. We would be pleased to provide additional information to the West Virginia Health Care Cost Review Authority concerning our comments.

Sincerely,

Richard L. Clark

Richard L. Clark
Principal

RLC/jlv

cc: Nancy Hiscoe
Dave Campbell
Keith Biddle

WVU Medical Corporation/WVU Hospitals, Inc.
CON Case File 85-6-2252-E

WVUMC/WVUH RESPONSE
to
HCCRA GUIDELINES
for
LITHOTRIPSY SERVICES

The following responses are provided as requested by HCCRA as a supplement to verbal testimony by the WVU Medical Corporation and WVU Hospitals, Inc. on their CON proposal for establishment of extracorporeal shockwaves Lithotripsy service in Morgantown, West Virginia.

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.

Patients selected for ESWL treatment will have symptomatic urinary tract radiograph calculi and would otherwise be candidates for invasive percutaneous lithotripsy. A specific clinical criteria may be developed by the attending urologist in concurrence with 1) specifications of use provided by the Dornier Company if Dornier equipment is selected or, 2) clinical protocols required for IDE testing by the FDA if the International Biomedics device is obtained.

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.

The WVU Medical Corporation and WVU Hospitals, Inc. will make ESWL service available to any patient diagnosed as requiring such service, referred to this facility, and meeting clinical protocols. This service will be provided to citizens of West Virginia and surrounding states on a non-discriminatory basis without restriction. WVUH's admission policies have been previously provided in Replacement Hospital CON Application Case File 84-6-2086-H.

4.1.c A scheduling priority system based on patient need.

Scheduling of patients requiring ESWL services will be based upon the acuteness and severity of the patient's disorder. An evaluation of patient priority requirements will be completed by the attending urologist.

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

Services for ESWL at WVU will be the same for all patients regardless of attending physician, payor, or referral source.

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

The proposed ESWL facility at WVU will be designed to meet and exceed standards for design and construction of the Joint Commission on Accreditation of Hospitals and the standards of the American National Standards Institute for accessibility for handling handicapped outpatients, visitors and qualified handicapped employees. As with all other services, WVU will design the ESWL facility so as to 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 sevices accessible to the greatest number of people and for the greatest economic benefit of West Virginia residents.

WVUMC and WVUH are proposing the development of a regional facility serving twenty-eight counties in RHAC regions VI-XI in West Virginia. The WVU Medical Center already serves residents of these counties as a major regional referral center. The location and accessibility of the proposed WVU service will make use of already existing referral patterns and will eliminate the need for residents of northern West Virginia to travel to out of state facilities for ESWL treatment. WVU is able to begin providing ESWL service immediately given the existing clinical expertise of its urology faculty. The facility will also be available for use by other qualified board certified community urologists in northern West Virginia assuring further accessibility in high enough volume for an optimally economic operation. The economic benefits of ESWL services versus conventional surgical needs have been documented within the WVU CON application.

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.

Lithotripsy services will be a integral and essential component in training of Urology residents at the WVU Medical Center. WVU presently maintains the only approved residency program in Urology within the state. Graduates of the WVU residency program will continue to be prepared through this proposal to meet the Urology physician manpower needs of the state of West Virginia with state of the art skills and knowledge.

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.

The proposed WVU regional ESWL facility would be located at the WVU Medical Center and available to the state's major academic teaching hospital. The facility will be available to all health professional training programs at WVU and its affiliated institutions.

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 or 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.

WVU Medical Center is located in Monongalia County, West Virginia and RHAC Planning Area XI. As such, WVU's proposed facility will be located in Lithotripsy Service Area II as designated by HCCRA. At this time, WVU is the sole applicant to provide lithotripsy services in Service Area II.

The existing WVU service area for all inpatient referral services in the Medical Center already encompass those counties included in in HCCRA ESWL Service Area II. The proposed regional lithotripsy service can be established within northern West Virginia as a logical extension of already existing referral relationships. WVU Medical Center will also draw patients from bordering counties in surrounding states, allowing a high volume, low cost service serving a population of approximately 1.5 million.

Note: West Virginia counties not included in the initial WVU service area proposal, prepared prior to issuance of the HCCRA guidelines, include Wood, Jackson, Roane, Calhoun, Wirt, Brooke, and Hancock. Webster County, which had been included in the initial WVU Proposal, would be considered by HCCRA to be a part of Service Area I. The above counties add a net population (using 1990 projections) of approximately 175,000 to the initial WVU projections.

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

Policies for medical staff implementation at WVUH have been previously provided in CON Case File 84-6-2086-H. Supplementary policies will be developed allowing qualified board-certified community urologists access to the proposed ESWL facility. The timing of this final policy development will be dependent on the technology acquired. The Dornier unit, having received PMA FDA approval, will allow such policies to be developed and implemented immediately. Alternatively, the International Biomedics technology will require a period of testing by investigators acceptable to the FDA before the facility can be made available for more routine use. In any event, WVU intends that the ESWL service will be made available in the future to physicians in northern West Virginia who are qualfied to use it. Initial letters of interest have been obtained by WVU from community urologists and have been included within WVU CON application.

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.

WVUMC and WVUH have provided documentation during the CON hearings of the availability to the applicants of the lithriptor from Dornier company. This device has received FDA PMA approval.

The applicant will also continue to pursue potential designation by the FDA as an IDE test site for the International Biomedics device. Should such designation not be obtained on a timely basis, the applicants will purchase the FDA approved Dornier equipment. If IDE designation is received for International Biomedics equipment and this option is elected, documentation of action by the FDA would be provided to HCCRA prior to implementation. At a minimum, WVU will meet the approved criterion for the Dornier alternative.

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.

WVU has available on its medical staff five board-certified urologists. One of more of these individuals will receive at least 80 hours of training in ESWL within the next six months at an existing ESWL facility (most likely at the University of Virginia Hospital in Charlottesville, Virginia). Dr. Donald Lamm has already been approved by the FDA as a qualified IDE investigator should the International Biomedics device be elected.

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.

Manufacturers of lithotripsy technology being considered by WVUMC/ WVUH (Dornier and International Biomedics) will provide all required training for safe and efficacious operation of their equipment. Upon CON approval and final selection of equipment, a formal plan of training will be prepared and provided to the Authority.

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.

At a minimum, at least one staff member trained in CPR will be available and on duty at the proposed WVU ESWL facility during the house it is in operation. WVU policy requires the presence of staff with such training in all diagnostic treatment services.

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.

WVU Medical Corporation has provided evidence of its ability to obtain all or part of required capital financing for an ESWL facility through a bank letter of credit.

Revenue and expense projections submitted to HCCRA by both Dornier and International Biomedics alternatives indicate the ability of the applicants to operate the proposed facility at least at a break even level with reasonable charges and based upon conservative volume forecasts.

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.

To date, the West Virginia Health Care Cost Review Authority has not developed allowable costs for reasonable charges for the provision of lithotripsy services. As outlined in the WVU revenue and expense projections, the applicants forecast charges of $2600 and $4000 per procedure for the International Biomedics and Dornier equipment alternatives respectively. These charges are assumed to increase in the future by a factor of 6% annually. While there exists no current rate structure in West Virginia for comparison purposes, the forecasted rates are comparable to those charged by institutions in other states utilizing ESWL technology.

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

See Section Q of the WVUMC/WVUH ESWL CON application. Substantial cost savings over existing surgical alternatives have been demonstrated.

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

WVU maintains board-certified medical faculty in all of the above specialties.

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.

WVU has the most extensive urological and endo-urological services available of any hopsital within the state of West Virginia. Lithotripsy services will be an integral part of the overall urology programs of WVU for patient care, education and research. WVU faculty will be available to provide training in endo-urology to other approved ESWL facilities within the state.

8.3 Organizations seeking to provide lithotripsy services shall, prior to the implementation fo 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.

WVU will have an active research program in ESWL and will provide leadership in developing appropriate clinical protocols and data bases within West Virginia. WVU will be pleased to participate in any HCCRA data initiative and requirements for ESWL. WVU will also participate actively in national data base development and evaluation.

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.

If the Dornier equipment is selected by WVU, all FDA requirements for operation of this device will be followed within the proposed facility. If the International Biomedics equipment is elected, FDA IDE specifications will be established and followed at WVU.

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

Appropriate sound and shielding protection will be included in the WVU ESWL facility per manufacturer and FDA specifications.

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

Emergency response protocols will be established by the proposed ESWL facility in conjunction with WVUH and the WVU Emergency Service.

Equipment Procedure Capacity

An ESWL procedure will take approximately 30-60 minutes for stone disintegration. It is expected that approximately two (2) hours should be allotted for the entire procedure including patient, room and machine preparation.

The ESWL facility will be operating eight hours a day, five days a week. Based on the above time estimate, a lithotripter has the capacity to accommodate 1040 procedures per year.

HEALTH CARE COST REVIEW AUTHORITY

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

DATE: November 25, 1985

TO: Secretary of State

FROM: West Virginia Health Care Cost Review Authority

RE: Interim Standards for Lithotripsy Services - Amendments as a Result of public Comments

There were two changes made to these rules as a result of comments received at the public hearings.

First, language was inserted into Section 4.1c as follows:

"A scheduling priorty system, without regard to patient origin, should be based on patient need." [Insertion is underlined.]

This amendment was made to clarify the Authority's intentions that scheduling the use of the lithotripsy device was to be dependant upon patient need and not whether the patient was a patient of the facility owning the device.

The second change was the addition of a new section 10 to clearly express the Authority's intention that these rules terminate upon the approval of an amendment to the State Health Plan by the Governor on this same subject matter.