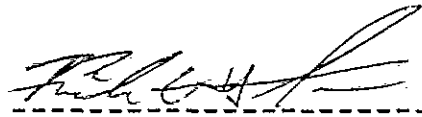


NOTICE OF ADOPTION OF A LEGISLATIVE RULE AUTHORIZED BY
THE LEGISLATURE

The Health Care Cost Review Authority's legislative rule
Interim Standards For Lithotripsy Services is being adopted
by this agency and final filed with the Secretary of State.
This rule is authorized by the Legislature in Senate Bill 434
passed March 8, 1986.

FILED IN THE OFFICE OF
THE SECRETARY OF STATE
THIS DATE April 28, 1986
ADMINISTRATIVE LAW D.



Rich O. Hartman for
David S. Frazer, Chairman
West Virginia Health Care Cost
Review Authority

ANALYSIS OF PROPOSED LEGISLATIVE RULE

Agency: West Virginia Health Care Cost Review Authority

Subject: Proposed rules and regulations relating to interim standards for lithotripsy services

PERTINENT DATES

Filed for public comment: June 5, 1985

Public comment period ended: July 12, 1985

Filed following public comment period: November 25, 1985

Filed LRMRC: November 25, 1985

Filed as emergency:

FN: \$0

ABSTRACT

This rule is new.

Section 1 is a general section providing the rule's scope, authority, filing date and effective date. The rule establishes interim standards for use by the State Health Planning and Development Agency in ruling upon applications proposing lithotripsy services. The State Health Plan is silent on this issue, thus requiring interim standards until the State Health plan can be amended.

Section 2 outlines the need for interim standards and states that the standards should be used in addressing the following issues: (a) guidance in the orderly development of lithotripsy services (b) the identification of data needs and (c) the review of Certificate of Need proposals for lithotripsy services. The standards do not affect other state licensure regulations, federal certification standards or accreditation standards.

Section 3 defines extracorporeal shock-wave lithotripsy.

Section 4 relates to accessibility of services. Organizations seeking to provide lithotripsy services must document: the criteria which will be used to determine who is eligible for the service; nondiscriminating patient selection policies; a scheduling priority system; and reasonable rates. Services must be accessible to the handicapped and priority consideration will be given to applicants which will make the services accessible to the greatest number of people.

Section 5 states consideration shall be given to

the access of lithotripsy services to medical school research and teaching hospitals with approved residency programs in urology.

For initial CON decisions, this section divides the State into two regions and provides that only one application will be approved in each service area unless a more cost effective, technologically and clinically superior alternative is available for clinical use.

Section 6 requires that lithotripsy units must either have pre-market approval by the FDA for clinical use or an Investigational Device Exemption from the FDA. A full time board-certified urologist with at least eighty hours of training in lithotripsy services must be responsible for managing the operation of the lithotripsy unit.

Section 7 requires that organizations proposing to provide lithotripsy services document their ability to finance and operate the equipment and document that lithotripsy is the most cost-effective form of stone management.

Section 8 mandates that staff in specified medical specialities be available to an organization proposing to provide lithotripsy services.

Section 9 relates to acceptability of services and requires that the facilities in which services are to be offered are in accordance with the manufacturers safety standards and applicable federal and state standards.

Section 10 specifies that this rule will automatically terminate upon the approval of the Governor of an amendment to the State Health Plan concerning lithotripsy services.

AUTHORITY

Statutory authority: W. Va. Code, §16-2D-8(a)(1) which provides as follows:

(a) The state agency is hereby empowered to promulgate additional rules and regulations:

(1) To carry out the provisions of this article; and

ANALYSIS

I. HAS THE AGENCY EXCEEDED THE SCOPE OF ITS STATUTORY AUTHORITY IN APPROVING THE PROPOSED LEGISLATIVE RULE?

No, assuming that the West Virginia Health Care Cost

Review Authority is the agency "selected by the Governor and designated as the state health planning and development agency in an agreement entered into pursuant to section 1521 of the Public Health Services Act, as amended, Title 42 United States Code Section 300m" to serve as the state agency for the purposes of certificate of need law. (W. Va. Code, §16-2D-hh).

II. IS THE PROPOSED LEGISLATIVE RULE IN CONFORMITY WITH THE INTENT OF THE STATUTE WHICH THE RULE IS INTENDED TO IMPLEMENT, EXTEND, APPLY, INTERPRET OR MAKE SPECIFIC?

Yes. It is clearly the intent of the Legislature that a certificate of need must be obtained from the Authority for a proposed "new institutional health service." Under W. Va. Code, §16-2D-3(h) "new institutional health service is defined to include "The acquisition of major medical equipment which will be owned by or located in a health care facility." A lithotripsy machine is a piece of major medical equipment, therefore, rules and regulations are necessary to set up standards for the issuance of certificates of need to health care facilities proposing to operate such equipment.

III. DOES THE PROPOSED LEGISLATIVE RULE CONFLICT WITH OTHER CODE PROVISIONS OR WITH ANY OTHER RULE ADOPTED BY THE SAME OR A DIFFERENT AGENCY?

No.

IV. IS THE PROPOSED LEGISLATIVE RULE NECESSARY TO FULLY ACCOMPLISH THE OBJECTIVES OF THE STATUTE UNDER WHICH THE PROPOSED RULE WAS PROMULGATED?

Yes.

V. IS THE PROPOSED LEGISLATIVE RULE REASONABLE, ESPECIALLY AS IT AFFECTS THE CONVENIENCE OF THE GENERAL PUBLIC OR OF PERSONS AFFECTED BY IT?

Yes, for the most part. Whether or not Section 5.3 of the rule is reasonable as it affects the general public or health care facilities proposing to provide lithotripsy services is a very subjective decision. The Authority has made a policy decision in this section to divide the State into two service areas and to only initially allow the approval of one CON application in each service region. Several comments were received by the Authority on this provision, relating to the way the service areas are designated, in that they do not take into account provision of service to out-of-state areas, and relating to the limitation on the number of CON's which will be issued initially, in that less expensive models of the lithotripsy machine will soon be on the market.

VI. CAN THE PROPOSED LEGISLATIVE RULE BE MADE LESS COMPLEX OR MORE READILY UNDERSTANDABLE BY THE GENERAL PUBLIC?

Basically, no. There are just a few minor language clarifications which may be necessary.

VII. WAS THE PROPOSED LEGISLATIVE RULE PROMULGATED IN COMPLIANCE WITH THE REQUIREMENTS OF CHAPTER 29A, ARTICLE 3 AND WITH ANY REQUIREMENTS IMPOSED BY ANY OTHER PROVISION OF THE CODE?

The proposed legislative rule was promulgated in compliance with Chapter 29A, Article 3 of the W. Va. Code. However, from the information available, it is not possible to determine if the agency complied with the requirements of W. Va. Code, §16-2D-8(b), which requires notice be given to certain parties and in specified manner, and which reads as follows:

(b) All rules and regulations shall be promulgated pursuant to chapter twenty-nine-A of this Code and as described herein. In addition, before adopting proposed rules and regulations the state agency shall give interested persons an opportunity to offer written comments on the rules and regulations, or any revisions thereof, which it proposes to adopt, as follows:

(1) The state agency shall distribute copies of its proposed review rules and regulations, and proposed revisions thereof, to statewide health agencies and organizations, the statewide health coordinating council, and each health systems agency for a health service area located in whole or in part within the State and any agency which establishes rates for health care facilities in the State;

(2) The state agency shall publish, in at least one newspaper in each planning and development region in this State, a notice stating that rules and regulations for review of certificate of need applications or any revisions thereof, have been proposed for adoption and are available at specified address for inspection and copying by interested persons. In addition, notice may be given through other public information channels; and

(3) The state agency shall distribute copies of its adopted review rules and regulations, and any revisions thereof, to the agencies and organizations specified in this section and to the secretary

of health and human services, and shall provide such copies to other persons upon request.

For example, there is no indication that the agency complied with the newspaper publication requirement or that a copy of the rule was distributed to the Secretary of Health and Human Services.

1 Bill 15

2 H. B. 1760

3 (By Delegate Casey)

4 (Introduced February 5, 1986; referred to the
5 Committee on Government Organization with the direc-
6 tion that it later be referred to the Committee
7 on the Judiciary.]

8
9
10 A BILL to amend and reenact section sixteen(two-d)(eight)
11 article two, chapter sixty-four of the code of West Virginia,
12 one thousand nine hundred thirty-one, as amended, relating to
13 authorizing the West Virginia health care cost review
14 authority to promulgate rules relating to interim standards
15 for lithotripsy services.

16 Be it enacted by the Legislature of West Virginia:

17 That section sixteen(two-d)(eight), article two, chapter
18 sixty-four of the code of West Virginia, one thousand nine
19 hundred thirty-one, as amended, be amended and reenacted, to read
20 as follows:

21 ARTICLE 2. EXECUTIVE AGENCY AUTHORIZATION TO PROMULGATE
22 LEGISLATIVE RULES.

23 §64-2-16(2d)(8). State board of health; West Virginia health
24 care cost review authority.

1760

1 (a) The rules authorized by the legislature in subsection
2 (a), section sixteen (2d)(5) of this article were also proposed
3 by the state board of health pursuant to section eight, article
4 two-d, chapter sixteen of this code.

5 (b) The legislative rules filed in the state register on the
6 twenty-fifth day of November, one thousand nine hundred eighty-
7 five, modified by the West Virginia health care cost review
8 authority to meet the objections of the legislative rule-making
9 review committee and refiled in the state register on the twenty-
10 eighth day of January, one thousand nine hundred eighty-six,
11 relating to the West Virginia health care cost review authority
12 (interim standards for lithotripsy services) are authorized.

14
15 NOTE: The purpose of this bill is to authorize the West
16 Virginia health care cost review authority to promulgate
17 legislative rules relating to interim standards for lithotripsy
18 services.

19
20 This section is new; therefore, strike-throughs and
21 underscoring have been omitted.
22

1 Bill 15

SENATE BILL NO. 443

2 (By Senator R. Williams

3
4 [Introduced February 3, 1986

5 referred to the Committee on Health and Human Resources;
6 then to the Committee on the Judiciary

7
8
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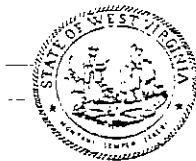
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(Plus all the volunteer
help we can get)

STATE OF WEST VIRGINIA

SECRETARY OF STATE

Charleston 25305

March 11, 1986

IMPORTANT NOTICE *****

TO: John Kozak

FROM: RICH O. HARTMAN, DIRECTOR

RE: LEGISLATIVE RULE Interim Standards for Lithotripsy Services

THE 1986 LEGISLATURE HAS AUTHORIZED YOUR AGENCY TO FINAL FILE AND ADOPT THE ABOVE LEGISLATIVE RULE. THIS AUTHORIZATION IS IN S.B.434 SECTION 64-2-16(2d)(8)(b) PASSED ON March 8, 1986, EFFECTIVE FROM PASSAGE. YOU HAVE 60 DAYS FROM THAT DATE TO FINAL FILE THE ABOVE RULE WITH THIS OFFICE. NO RULE WILL BE ACCEPTED AFTER THAT DATE. YOU MAY ESTABLISH ANY EFFECTIVE DATE FOR YOUR RULE RANGING FROM THE SAME DATE YOU FINAL FILE TO 90 DAYS FROM THE DATE YOU FINAL FILE. REMEMBER TO RE-TYPE YOUR RULE IN ITS ENTIRETY FOLLOWING THE PROPER FORMAT. PLEASE CALL IF YOU HAVE ANY QUESTIONS.