

**WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION**

Form #7

Do Not Mark In This Box
Filing Date

FILED
1991 JUN 24 PM 3:54
OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

Effective Date

July 1, 1991 *je*

NOTICE OF AN EMERGENCY RULE

AGENCY: Health Care Cost Review Authority TITLE NUMBER: 65

CITE AUTHORITY: W.Va. Code §16-2D-4(f), 8

EMERGENCY AMENDMENT TO AN EXISTING RULE: YES NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 16

TITLE OF RULE BEING AMENDED Exemption For Shared Services

IF NO, SERIES NUMBER OF RULE BEING FILED AS AN EMERGENCY: _____

TITLE OF RULE BEING FILED AS AN EMERGENCY: _____

THE ABOVE RULE IS BEING FILED AS AN EMERGENCY RULE TO BECOME EFFECTIVE AFTER APPROVAL BY SECRETARY OF STATE OR 35TH DAY AFTER FILING, WHICHEVER OCCURS FIRST.

THE FACTS AND CIRCUMSTANCES CONSTITUTING THE EMERGENCY ARE AS FOLLOWS:

H. B. 2194, effective March 20, 1991, significantly reduced the thresholds for certificate of need review and eliminated many prior exemptions from certificate of need review. This proposed amendment adds mobile, shared CT services to the list of exempt services since it is less costly than MRI which is already exempt by statute.

Use Additional Sheets If Necessary.


Signature
Larry C. Fizer, Chairman



FILED

STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

1991 JUN 24 PM 3:54

Building 3, Capitol Complex
Charleston, WV 25305

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

Gaston Caperton
Governor

June 18, 1991

The Honorable Ken Hechler
Secretary of State
State Capitol Complex
Building 1, Suite 157-K
Charleston, West Virginia 25305

Re: Amendments to Certificate of Need Rules

Dear Secretary Hechler:

Enclosed please find copies of the Health Care Cost Review Authority's proposed amendments to two legislative rules currently in effect: "Health Services Offered By Health Professionals" and "Exemption For Shared Services." The proposed amendments are necessary to bring the rules into conformity with the provisions of H.B. 2194 and the procedural requirements of the "Certificate of Need" Rule, §65 C.S.R. 7. I hereby approve these amended rules for filing.

Very truly yours,

Taunja Willis Miller, Secretary
Department of Health and Human Resources

TWM/jah

Enclosures

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES **FILED**

1991 JUN 24 PM 3:54

Rule Title: Exemption For Shared Services

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

Type of Rule: Legislative Interpretive Procedural

Agency Health Care Cost Review Authority Address 100 Dee Drive, Suite 201

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	0	0	0	0	0
Current Expense	0	0	0	0	0
Repairs and Alterations	0	0	0	0	0
Equipment	0	0	0	0	0
Other	0	0	0	0	0

2. Explanation of above estimates.

The agency estimates no cost associated with the implementation of this rule.

3. Objectives of these rules:

To implement exemptions from certificate of need review for shared mobile services as required by W.Va. Code §16-2D-4(f).

4. Explanation of Overall Economic Impact of Proposed Rule.

A. Economic Impact on State Government.

None

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

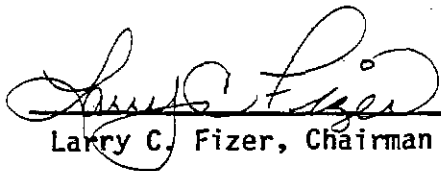
Acute care facilities affected by this rule should realize a savings by sharing the costs of major medical equipment.

C. Economic Impact on Citizens/Public at Large.

The public should benefit from the cost savings to the acute care facilities when the savings are reflected in a reduction in hospital rates and charges.

Date June 24, 1991

Signature of Agency Head or Authorized Representative


Larry C. Fizer, Chairman

FILED

1991 JUN 24 PM 3 54

TITLE 65
WEST VIRGINIA LEGISLATIVE RULE
HEALTH CARE COST REVIEW AUTHORITY
EMERGENCY
SERIES 16

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

Title: EXEMPTION FOR SHARED SERVICES

§ 65-16-1 General

1.1. Scope - This legislative rule establishes an exemption from certificate of need review for certain shared services between two or more acute care facilities when the shared services can reasonably be mobile as provided by W. Va. Code, § 16-2D-4(hf). This rule further repeals section 5 of "Exemptions From Certificate of Need Review," § 65 C.S.R. 11 (1988).

1.2. Authority - W. Va. Code § 16-2D-4(hf) and § 16-2D-8.

1.3. Filing Date - June 24, 1991.

1.4. Effective Date - _____.

1.5. This legislative rule repeals and replaces section 5 of the "Exemptions From Certificate of Need Review," § 65 C.S.R. 11 (1988).

~~§ 65-16-2~~ Introduction

~~This legislative rule implements Enrolled House Bill 4230 which was passed by the Legislature on March 10, 1990 and became effective ninety (90) days from passage. This bill amended W. Va. Code, § 16-2D-4(h) by placing more stringent requirements upon the eligibility for an exemption for shared services and also by limiting the exemption to lithotripsy and magnetic resonance imaging (MRI). This bill authorizes the state agency to promulgate rules to implement the exemption.~~

§ 65-16-32 Definitions

As used in this legislative rule, all terms that are defined in the Act at section 2 thereof have those same meanings which are in some cases further clarified herein. All terms not defined in the Act have the following meanings unless the context expressly requires otherwise.

32.1. "Act" means the certificate of need act, West Virginia Code, § 16-2D-1 et seq.

32.2. "State agency" means the West Virginia Health Care Cost Review Authority which is designated to administer the certificate of need program by West Virginia Code, § 16-29B-11.

32.3 "Verified notice" means a notice containing the facts required by this rule and which has attached to it a statement made under oath before a notary public or other official entitled to administer oaths by the chief executive officer of the entity applying for the exemption that the facts and circumstances set forth in the notice are true or are believed to be true by the chief executive officer.

§ 65-16-~~43~~ Exemption Criteria

43.1 Any acute care facility otherwise subject to the certificate of need program may obtain an exemption from certificate of need review for shared services between two (2) or more acute care facilities. The shared services must be those provided by major medical equipment and through existing technology can reasonably be made mobile. The major medical equipment which is eligible for this exemption is magnetic resonance imaging (MRI) devices, ~~and lithotripters~~ and computerized tomography (CT) scanners. On an annual basis the state agency shall review existing technologies to determine if other major medical equipment should be included in this exemption. Qualification for an exemption under this rule shall not constitute a waiver or exemption from certificate of need review for the offering of magnetic resonance imaging, ~~or lithotripsy~~ or CT services by the acute care facility if these services are provided by major medical equipment which is not mobile and is not shared with another acute care facility.

43.2. To qualify as a "shared service," the equipment must be on site at each acute care facility at least four (4) days per month. This requirement may be waived by the state agency if three (3) or more acute care facilities share the equipment.

43.3. This exemption is limited to one piece of major medical equipment per shared service. An acute care facility may obtain only one exemption for each shared service permitted under this rule.

43.4. This exemption is not available if the shared services mobile unit is less cost effective than a fixed unit. The state agency shall determine cost effectiveness based upon patient charges.

43.5. This exemption is not available if any non-acute care facility or entity will utilize the major medical equipment for the provision of health services to that facility's or entity's patients. The equipment may be owned by a non-acute care facility or entity, which in turn contracts, leases, or rents it exclusively for use by acute care facilities.

§ 65-16-4 Exemption Procedure

4.1. Each acute care facility seeking an exemption pursuant to this rule, must file with the state agency a letter of intent at least fifteen (15) days

before the submission of the verified notice. The letter of intent shall contain sufficient information to advise the state agency of the nature of the exemption sought and outline the grounds for such exemption.

4.2. Upon receipt of the letter of intent, the board shall publish a notice of such receipt in the Saturday Charleston newspapers and the State Register. The notice shall identify the legal entity seeking an exemption and the grounds alleged for such exemption. The notice shall also state the rights of affected parties to a hearing.

4.63. In order to obtain the exemption, each acute care facility must file a verified notice with the state agency no sooner than the fifteenth day or later than the thirtieth day following the filing of the letter of intent. The verified notice shall identify the hospitals and all other entities involved in the proposal, identify the equipment to be acquired and the services to be provided, the fair market value of the equipment to be provided, the capital expenditures to be made by each hospital, each hospital's annual operating expenses for each of the first three (3) years of operation of the shared services, the proposed schedule for the equipment's use at each hospital, a complete list of all persons and/or entities with an ownership interest in the equipment and a complete list of all persons with an ownership interest in the entity which owns the equipment, a complete list of all physicians with admitting privileges at the facility, and the proposed charges to the patient for the service.

HCCRA
Leg. Rule
Series 16, Sec. 4

~~4.7. Following receipt of the verified notice, the state agency shall publish a notice of the filing in the Saturday Charleston newspapers, the State Register, and in the state agency's newsletter. The notice shall identify the applicants and describe the proposal. It shall also describe the review period including the rights of affected parties to a hearing.~~

4.84. Following receipt of the verified notice, the state agency shall determine within fifteen (15) days whether or not the verified notice is complete. If the verified notice is not complete, the state agency shall request additional information. Upon receipt of that additional information, the state agency shall have fifteen (15) days within which to determine if the verified notice is complete. Upon determining that the verified notice is complete and after the date has passed in which an affected person may request a hearing, the state agency shall publish a notice of that fact in the Saturday Charleston newspapers, and the State Register, ~~and in the state agency's newsletter~~. The notice shall identify the applicants, shall describe the proposal, and shall, if a hearing on the exemption has been requested, state the time, place, and date of the hearing.

4.95. If a hearing has not been requested, then following the publication of the notice in the Saturday Charleston newspapers and the State Register, ~~determination of completeness~~ the state agency shall within ten (10) days issue a written decision on the verified notice which decision shall be a final

decision. ~~for purposes of West Virginia Code, § 16-2D-7(r) and § 16-2D-10.~~ The state agency shall publish notice of the decision in the Saturday Charleston newspapers, and the State Register, ~~and the state agency's newsletter.~~ The major medical equipment affected by this rule shall not be acquired or contracted for until after entry of a final decision.

4.10.6 If a hearing has been requested by an affected party, the state agency shall follow the provisions of subsections 5.1, 5.2 and 5.3 of this legislative rule.

4.11.7. In order to be effective, the request for a hearing must be from an affected party and must be filed in writing with the state agency within fifteen (15) days of the publication of the notice in the Saturday Charleston newspapers as required by subsection 4.72.

§ 65-16-5 Requests For Hearings

5.1. . In the event that an affected person requests a hearing, the exemption review period shall be terminated. A hearing shall then be held within thirty (30) days of the request for a hearing unless the state agency sets a later date upon a showing of good cause therefor.

HCCRA
Leg. Rule
Series 16, Sec. 5

5.2. The state agency may conduct a prehearing conference in accordance with Rule 16 of the West Virginia Rules of Civil Procedure. If an order is first obtained from the state agency or a hearing examiner appointed by it, the parties may engage in discovery as provided by the West Virginia Rules of Civil Procedure; except that the scope of discovery shall be limited to relevant and admissible evidence.

5.3. At the conclusion of the hearing, the parties may submit proposed findings of fact, conclusions of law, and legal briefs. The state agency shall then have ~~twenty (20)~~ ten (10) days from the receipt of those items or the closure of the record if those items are not tendered to make its determination in writing.

5.4. A written decision made pursuant to subsection 5.3 shall be a final decision. ~~for purposes of West Virginia Code, § 16-2D-7(r) and § 16-2D-10.~~ The state agency shall publish notice of the decision in the Saturday Charleston newspapers, and the State Register. The major medical equipment affected by this rule shall not be acquired or contracted for until after entry of a final decision.

KEN HECHLER
Secretary of State

MARY P. RATLIFF
Deputy Secretary of State

ROBERT E. WILKINSON
Deputy Secretary of State

CATHERINE FREROTTE
Executive Assistant

Telephone: (304) 345-4000
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STATE OF WEST VIRGINIA

SECRETARY OF STATE

Charleston 25305

WILLIAM H. HARRINGTON
Chief of Staff

JUDY COOPER
Director, Administrative Law

DONALD R. WILKES
Director, Corporations

SHEREE COHEN
Special Assistant

(Plus all the volunteer
help we can get)

FILED IN THE OFFICE OF
THE SECRETARY OF STATE
THIS DATE July 1, 1991
ADMINISTRATIVE LAW DIVISION

July 1, 1991

NOTICE OF EMERGENCY RULE DECISION BY THE SECRETARY OF STATE

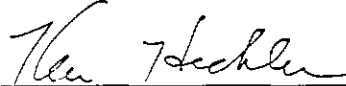
AGENCY: Health Care Cost Review Authority

RULE: Amendments, Series 16 Exemption for Shared Services

DATE RULE FILED AS AN EMERGENCY RULE: June 24, 1991

DECISION NO. 37-91

Following review under WV Code 29A-3-15a, it is the decision of the Secretary of State that the above emergency rule be approved. A copy of the complete decision with required findings is available from this office.


KEN HECHLER
Secretary of State

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Secretary of State

MARY P. RATLIFF
Deputy Secretary of State

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(Plus all the volunteer
help we can get)

DECISION — EMERGENCY RULE DECISION
(ERD 37-91)

AGENCY: Health Care Cost Review Authority
RULE: Amendments, Series 16, Exemption for Shared Services
FILED AS AN EMERGENCY RULE: June 24, 1991

- par. 1 The Health Care Cost Review Authority (HCCRA) has filed amendments to the above emergency rule.
- par. 2 West Virginia Code 29A-3-a requires the Secretary of State to review all emergency rules filed after March 8, 1986. This review requires the Secretary of State to determine if the agency filing such emergency rule: 1) has complied with the procedures for adopting an emergency rule; 2) exceeded the scope of its statutory authority in promulgating the emergency rule; or 3) can show that an emergency exists justifying the promulgation of an emergency rule.
- par. 3 Following review, the Secretary of State shall issue a decision as to whether or not such an emergency rule should be disapproved [(29A-3-a(a))].
- par. 4 (A) Procedural Compliance: WV Code 29A-3-15 permits an agency to adopt, amend or repeal, without hearing, any legislative rule by filing such rule, along with a statement of the circumstances constituting the emergency, with the Secretary of State and forthwith with the Legislative Rule-Making Review Committee (LRMRC).
- par. 5 If an agency has accomplished the above two required filings with the appropriate supporting documents by the time the emergency rule decision is issued or the expiration of the forty-two day review period, whichever is sooner, the Secretary of State shall rule in favor of procedural compliance.

par. 6 The HCCRA filed this emergency rule with supporting documents with the Secretary of State June 24, 1991 and with the LRMRC June 24, 1991.

par. 7 It is the determination of the Secretary of State that the HCCRA has complied with the procedural requirements of WV Code §29A-3-15 for adoption of an emergency rule.

par. 8 (B) Statutory Authority -- WV Code §16-2D-4(f) reads:

(f) The state agency shall adopt rules within 90 days of the effective date of the amendment of this section in the year 1990 pursuant to section eight of this article to specify the circumstances under which and the procedures by which a certificate of need may not be required for shared services between two or more acute care facilities providing services made available through existing technology that can reasonably be mobile. The state agency shall specify the types of items in the regulations and under what circumstances mobile MRI and mobile lithotripsy may be so exempted from review. In no case, however, will mobile cardiac catheterization be exempted from certificate of need review. In addition, if the shared services mobile unit proves less cost effective than a fixed unit, the acute care facility will not be exempted from certificate of need review.

On a yearly basis, the state shall review existing technologies to determine if other shared services should be included under this exemption.

par. 9 It is the determination of the Secretary of State that the HCCRA has not exceeded its statutory authority in promulgating this emergency rule.

par. 10 (C) Emergency WV Code 29A-3-15(g) defines "emergency" as follows:

(g) For the purposes of this section, an emergency exists when the promulgation of a rule is necessary for the immediate preservation of the public peace, health, safety or welfare or is necessary to comply with a time limitation established by this code or by a federal statute or regulation or to prevent substantial harm to the public interest.

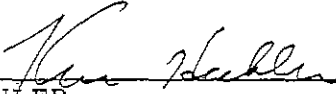
par. 11 There are essentially three classes of emergency broadly presented with the above provision: 1) immediate preservation; 2) time limitation; and 3) substantial harm. An agency need only document to the satisfaction of the Secretary of State that there exists a nexus between the proposal and the circumstances creating at least one of the above three emergency categories.

par. 12 The facts and circumstances as presented by the HCCRA are as follows:

HB 2194, effective March 20, 1991, significantly reduced the thresholds for certificate of need review and eliminated many prior exemptions from certificate of need review. This proposed amendment adds mobile, shared CT services to the list of exempt services since it is less costly than MRI which is already exempt by statute.

par. 13 It is the determination of the Secretary of State that this proposal qualifies under the definition of an emergency as defined in §29A-3-15(g). . . "time limitation." (HB 2194)

par. 14 This decision shall be cited as Emergency Rule Decision 37-91 or ERD 37-91 and may be cited as precedent. This decision is available from the Secretary of State and has been filed with the Health Care Cost Review Authority, the Attorney General and the Legislative Rule Making Review Commission.



KEN HECHLER
Secretary of State

Entered _____ FILED IN THE OFFICE OF
THE SECRETARY OF STATE
THIS DATE July 1, 1991
ADMINISTRATIVE LAW DIVISION