

WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION

Form #8

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NOTICE OF AN EMERGENCY AMENDMENT TO AN EMERGENCY RULE

AGENCY: WV Health Care Cost Review Authority TITLE NUMBER: 65

DATE EMERGENCY RULE WAS ORIGINALLY FILED: July 7, 1987

IS THIS THE FIRST EMERGENCY AMENDMENT TO THE ORIGINALLY FILED EMERGENCY RULE:
yes

IS THIS THE SECOND EMERGENCY AMENDMENT TO THE ORIGINALLY FILED EMERGENCY RULE:
no

DATE OF FIRST EMERGENCY AMENDMENT: N/A

SERIES NUMBER OF RULE: XI TITLE OF RULE Exemptions From
Certificate Of Need Review

THE ATTACHED IS AN EMERGENCY AMENDMENT TO AN EXISTING EMERGENCY RULE. THIS
EMERGENCY AMENDMENT BECOMES EFFECTIVE UPON FILING.

Watt Hechler



Arch A. Moore, Jr.
Governor

STATE OF WEST VIRGINIA
HEALTH CARE COST REVIEW AUTHORITY

Walter J. Dale
Chairman

Board Members
Larry C. Fizer
Don M. Keesling

August 31, 1987

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

Dear Mr. Hechler:

Re: Emergency Amendment To Previously Filed
Emergency Legislative Rule -- "Exemptions
From Certificate of Need Review"

Please be advised that as a result of certain comments received at a August 10, 1987, public hearing, the Authority has made certain amendments to its previously filed emergency legislative rule.

Enclosed herewith is one copy of the amended rule showing the language deleted and the new language of the amended rule, one copy of the amended rule in its final form, a copy of your "Notice Of An Emergency Amendment To An Emergency Rule," and a copy of a cover letter to the Co-Chairman of the Legislative Rule-Making Review Committee which demonstrates that the proper filings have been made with that committee.

With much appreciation for your assistance in this matter, I remain

Sincerely,

A handwritten signature in cursive script that reads "Walter J. Dale".

WALTER J. DALE
Chairman

WJD/JHK/jmh

Enclosures

EMERGENCY
WEST VIRGINIA LEGISLATIVE RULE
HEALTH CARE COST REVIEW AUTHORITY
CHAPTER 16-2D
SERIES XI

Title: EXEMPTIONS FROM CERTIFICATE OF NEED REVIEW

Section 1. General

2. Introduction
3. Replacement Major Medical Equipment
4. Capital Expenditures Not For Health Services
5. Shared Services
6. Other Claims Of Exemption
7. Requests For Hearings And Reconsideration Hearings
8. Definitions
- ~~8.~~ 9. Severability

EMERGENCY
WEST VIRGINIA LEGISLATIVE RULE
HEALTH CARE COST REVIEW AUTHORITY
CHAPTER 16-2D

SERIES XI

Title: EXEMPTIONS FROM CERTIFICATE OF NEED REVIEW

Section 1. General

1.1. Scope - This emergency legislative rule establishes the standards for the exemptions from certificate of need review provided for by the 1987 amendments to the Certificate of Need Act, West Virginia Code, § 16-2D-1 et seq. Pursuant to West Virginia Code, § 16-29B-11, the Health Care Cost Review Authority is designated to be the state agency charged with administering the certificate of need program.

1.2. Authority - West Virginia Code, § 16-2D-8, § 16-2D-4(f)-(i), and § 16-29B-11.

1.3. Filing Date - ~~July 7,~~ August 31, 1987.

1.4. Effective Date - ~~July 7,~~ August 31, 1987.

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Series XI, Sec. 2

Section 2. Introduction

This emergency legislative rule implements certain of the provisions of Enrolled Committee Substitute For House Bill 2342 which was signed by the Governor. That bill amended West Virginia Code, § 16-2D-4, by adding to it four (4) new subsections. Those new subsections authorize the state agency to promulgate rules to exempt from certificate of need review certain activities of health care facilities. In the state agency's opinion, these new exemptions must be implemented immediately so as to prevent substantial harm to the public interest. The state agency concludes that the Legislature intended to alleviate the financial burden on health care facilities which wish to engage in the specified activities if the state agency deemed it advisable to implement the exemptions. Delays in implementing this rule would defeat this Legislative purpose by causing the health care facilities to continue to bear this financial burden until the rule receives final legislative approval. This unalleviated financial burden, which has been deemed unnecessary by the Legislature, would be passed along to health care consumers in the form of higher costs. Also, delay in effectuating the new provisions would defeat the Legislature's additional purpose of speeding-up the certificate of need process for certain items.

Section 3. Replacement Major Medical Equipment

3.1. Any legal entity which wishes to acquire, either by purchase, lease, or other comparable arrangement, major medical equipment which merely replaces medical equipment already owned by the entity and which has become outdated, worn-out, or obsolete may do so without undergoing certificate of need review but must first notify the state agency of its intention to do so and obtain an exemption from review. This exemption is not available to any entity which previously utilized mobile equipment and who now wishes to replace the mobile equipment with non-mobile equipment. In order to qualify for this exemption, the old equipment must have been defined as major medical equipment when it was initially obtained by the applicant and the applicant must have obtained either certificate of need approval or an exemption for its acquisition. In addition, in order for the exemption to be obtained, the applicant must divest itself of the old equipment and not utilize it in the future.

3.2. The verified notice shall identify the legal entity involved, the location or locations of the present medical equipment, the location or locations where the new major medical equipment will be placed, the cost including installation of the equipment, the fair market value of the new equipment, the cost of any renovations needed for the installation of the new equipment, a description of the functions and uses of the old and of the new equipment, and utilization rates for the old equipment for the immediate past three (3) calendar

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~~years. The notice shall be verified under oath by the chief executive officer of the legal entity.~~

3.3. Upon receipt of the notice, the state agency shall within ~~thirty (30)~~ fifteen (15) days determine whether the new equipment acquisition is eligible for the exemption. In the event the state agency needs more information to make its determination, it shall request that information in writing. Such request shall terminate the applicable ~~thirty (30)~~ fifteen (15) day review period and a new ~~thirty (30)~~ fifteen (15) day review period shall begin upon receipt by the state agency of the requested information. Submission of incomplete or inadequate additional information shall not cause the new ~~thirty (30)~~ fifteen (15) day review period to begin.

3.4. Upon determining that the major medical equipment that is proposed to be acquired will merely replace equipment which is already owned by the entity and which has become outdated, worn-out, or obsolete, the state agency shall grant the entity an exemption from certificate of need review.

~~3.4.~~ 3.5. The state agency's ruling upon the applicability of the exemption shall be in writing and shall be a final decision for purposes of West Virginia Code, § 16-2D-7(r) and § 16-2D-10. The legal entity wishing to acquire the new major medical equipment may not do so until the entry of a final decision.

Section 4. Capital Expenditures Not For Health Services.

~~4.1. Any legal entity otherwise subject to the certificate of need review program may obtain an exemption for capital expenditures in excess of the expenditure minimum for items not directly related to the provision of health services. The exemption may be applied for by the filing of a verified notice by the legal entity.~~

~~4.2. The verified notice shall identify the legal entity involved, the amount of the capital expenditure involved, a statement explaining the purpose of the capital expenditure, and the location or site to be affected by the proposal. The notice shall be verified under oath by the chief executive officer of the legal entity.~~

~~4.3. Only those capital expenditures equal to or less than Two Million Dollars and, if the entity is an acute care facility, which will not result in an increase in rates charged to the entity's patients shall be eligible for this exemption. The term "items not directly related to the provision of health services" refers, among others, to computer hardware and software, telephone systems, parking lots and buildings, and medical office buildings. Any item obtained by an acute care facility pursuant to this exemption and the expenditure and expenses related thereto shall not be considered a part of the~~

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~~acute care facility's expense base for purposes of West Virginia Code, § 16-29B-1
et seq.~~

~~4.4. Upon receipt of the notice, the state agency shall within thirty (30) days determine whether the proposal is eligible for the exemption. In the event the state agency needs more information to make its determination, it shall request that information in writing. Such request shall terminate the applicable thirty (30) day review period and a new thirty (30) day review period shall begin upon receipt by the state agency of the requested information. Submission of incomplete or inadequate additional information shall not cause the new thirty (30) day review period to begin.~~

~~4.5. The state agency's ruling upon the applicability of the exemption shall be in writing and shall be a final decision for purposes of West Virginia Code, § 16-2D-7(r) and § 16-2D-10. The legal entity wishing to make the capital expenditure may not do so until the entry of a final decision.~~

4.1. Any legal entity otherwise subject to the certificate of need program may obtain an exemption for capital expenditures in excess of the expenditure minimum for the purpose of making emergency repairs to the entity's physical facility or equipment.

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4.2. An "emergency repair" refers to a sudden and unforeseen breakdown or failure in the physical plant or equipment of a health care provider. The breakdown or failure must result in an imminent threat to the safety and well-being of the entity's patients or result in the inability of the entity to render health care services to its patients. Examples of such failures or breakdowns include the collapse of a wall of a building or the failure of a facility's boiler if that boiler is the primary source of heat or electricity for the facility.

4.3. The exemption may be obtained by the filing of a verified notice. The verified notice shall identify the legal entity involved, the amount of the capital expenditure involved, a description of the breakdown or failure involved, and a description of why that breakdown or failure constitutes an emergency as required by subsection 4.2.

4.4. Upon receipt of the verified notice, the state agency shall determine whether the proposal is eligible for the exemption. This determination shall be made as soon as possible and is not to exceed three (3) working days. In the event that additional or more complete information is needed, the state agency may first request and receive that information before a decision is made.

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4.5. The state agency's ruling upon the applicability of the exemption shall be in writing and shall be a final decision for purposes of West Virginia Code, § 16-2D-7(r) and § 16-2D-10. The legal entity wishing to make the capital expenditure may not do so until after the entry of a final decision.

Section 5. Shared Services.

5.1. Any acute care facility otherwise subject to the certificate of need review program may obtain an exemption from certificate of need review for shared services between two or more acute care facilities. The shared services must be those ~~available through~~ provided by major medical equipment and which through new or existing technology ~~which~~ can reasonably be made mobile. Examples of such "shared services" are mobile computerized tomography (CT) scanners, magnetic resonance imaging (MRI) devices, and extra-corporeal lithotripters. Other technologies which are similar in mobility may be included in this exemption. In order to qualify as a "shared service," the equipment must be on site at each acute care facility at least four (4) days out of each month unless good cause is established by the acute care facilities for waiving or modifying this requirement.

5.2. In order to obtain the exemption, the acute care facilities must file a verified notice with the state agency. The verified notice shall identify the hospitals and all other entities involved in the proposal, identify the

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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, ~~and each hospital's annual operating expenses for the each of the first three (3) years of operation of the shared services, and the proposed schedule for the equipment's use at each hospital.~~ The notice shall be verified under oath by the chief executive officer of each hospital involved in the project.

5.3. ~~This exemption is not available if any participant in the shared services or if the ownership of the equipment to be obtained is not by an acute care facility.~~

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. However, 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.

5.4. Upon receipt of the verified notice, the state agency shall within ~~thirty (30)~~ fifteen (15) days determine whether the proposal is eligible for the exemption. In the event the state agency needs more information to make its determination, it shall request that information in writing. Such request shall terminate the applicable ~~thirty (30)~~ fifteen (15) day review period and a new ~~thirty (30)~~ fifteen (15) day review period shall begin upon receipt by the state agency of the requested information. Submission of incomplete or inadequate

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additional information shall not cause the new ~~thirty (30)~~ fifteen (15) day review period to begin.

5.5. Upon determining that the equipment to be acquired to provide the shared services meets the conditions stated above in subsection 5.1. and in 5.3., the state agency shall grant the entities involved an exemption from certificate of need review.

~~5.5. 5.6.~~ The state agency's ruling upon the applicability of the exemption shall be in writing and shall be a final decision for purposes of West Virginia Code, § 16-2D-7(r) and § 16-2D-10. ~~The hospitals wishing to enter into the shared services relationship may not do so until~~ The major medical equipment affected by this exemption shall not be acquired or contracted for until after the entry of a final decision.

Section 6. Other Claims Of Exemption.

~~6.1. Any health care facility which is otherwise subject to the certificate of need program that wishes to make a capital expenditure, to institute a new health service, or to change an existing health service which is exempt from certificate of need review for reasons other than those set forth in sections 3, 4, and 5 of this rule shall file a verified notice of such action with the state agency.~~

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6.1. Any health care facility which is otherwise subject to the certificate of need program that intends to enter into a capital expenditure in an amount less than the expenditure minimum but not by more than \$100,000.00 shall file a verified notice in the form prescribed by subsection 6.3 of this rule with the state agency. For example, if the expenditure minimum is \$1,000,000.00 and the facility intends to make a capital expenditure of \$900,000.00, then a notice is required. But, if the intended capital expenditure is \$899,999.00, then a notice is not required. Of course, as the expenditure minimum changes, this requirement will change with it.

6.2. If any health care facility proposes to add health services to those offered by the health care facility and if such services were not offered on a regular basis by or on behalf of that facility within the twelve-month period prior to the time such services would now be offered, then that proposal may be exempt from certificate of need review if it meets both of the requirements stated below in this subsection. Otherwise, the proposal is subject to certificate of need review.

6.2.1. If the proposed addition to health services meets the requirements of subsection 4.3. of the Legislative Rule for the Certificate of Need Program, Series 7, Title 65 (1983); and

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6.2.2. If a health care facility proposes to develop or to acquire a new physical location separate and apart from its existing physical site upon which the additional health service will be offered or provided, the proposal may be exempt from certificate of need review unless the state agency determines that subsection 6.5. of this legislative rule bars such an exemption. If no new physical site is involved in the proposal, then this subsection 6.2.2. is not applicable to the proposal and only subsection 6.2.1. shall be considered. In the event that it is determined that the proposal actually constitutes the development of an ambulatory health care facility as defined at section 2(b) of the Act, then the proposal shall be subject to certificate of need review under section 3(a) of the Act as being for the construction, development, acquisition, or other establishment of a new health care facility.

~~6.2.~~ 6.3. In the case of either subsection 6.1. or 6.2., ~~the~~ verified notice shall identify the health care facility involved, shall describe the proposal, shall state the amount of capital expenditure involved including all acquisition or lease costs, renovation costs, and installation costs, and shall state the annual operating expenses for each of the first three (3) years of operation, ~~and shall be verified under oath by the chief executive officer of the health care facility.~~

~~6.3.~~ 6.4. In those instances where the health care facility wishes to institute a new health service, the verified notice shall also identify all of the existing health care facilities in the geographic area which are similar to the

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applicant or to the proposed facility and shall explain why those health care facilities which provide the same or similar services to those proposed by the claimant would not be in competition with those proposed by the claimant. The applicant must also provide the state agency with projections for its first three (3) years of operations of each county in or out of the state from which it expects the proposal to generate at least 10% of its patients or 10% of its gross revenues.

~~6.4.~~ 6.5. If the state agency determines based upon economic and geographic factors within the geographic area of the proposed health service that such proposed additional health service will be offered in competition with other health care facilities providing the same or similar services, then the exemption shall be denied and the health care facility shall file the appropriate application for certificate of need approval. This determination shall be made within ten (10) days of the receipt by the state agency of the verified notice. In making this determination, the state agency may obtain additional information from the claimant, other health care facilities, and its own files. The decision on the applicability of the exemption shall identify all of the information obtained by the state agency and the claimant shall be informed of the information obtained and the sources thereof.

6.6. In determining whether or not economic and geographic factors within the geographic area of the proposed health service would result in the

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proposed health service being offered in competition with other health care facilities providing the same or similar services, the following criteria shall be used.

6.6.1. In determining what the "geographic area" is of the proposed health service, reference shall first be made to the service area described for that health service by the state health plan. If the state health plan designates a "service area" for that service, then that service area shall form the basis of the geographic area of the proposed health service. To that service area shall be added each county -- in or out of the state -- from which the applicant projects obtaining at least 10% of its clients or 10% of its gross revenue.

6.6.2. Any health care facility that provides the same or similar services to that proposed to be offered by the applicant that is located in the geographic area determined under subsection 6.6.1. shall be determined to be in competition with the proposal. In addition, if a health care facility that is not located in the geographic area determined pursuant to subsection 6.6.1. for the proposal but that does itself derive 10% of its patients or 10% of its gross revenue from within that same geographic area shall be determined to be in competition with the proposal.

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~~6.5.~~ 6.7. For those instances other than those proposals which are denied pursuant to subsection ~~6.4~~ 6.5., the state agency shall within ten (10) days of its receipt of the verified notice make one of the following responses:

~~6.5.1.~~ 6.7.1. Accept the claim of exemption;

~~6.5.2.~~ 6.7.2. Require the health care facility to furnish the state agency with additional information in which event a new ten (10) day review period shall begin upon receipt of the additional information;

~~6.5.3.~~ 6.7.3. Reject the claim of exemption; or

~~6.5.4.~~ 6.7.4. Determine that a certificate of need application is necessary for ~~a review of the proposed expenditure, new health service, or change in a health service~~ the proposal in order to determine if the claim of exemption may be upheld. ~~One instance where this last determination may be necessary is where the state agency receives a request for a hearing from an affected person.~~ The application required by this section shall be an expedited application and the review period for it shall be the same as for any other expedited application.

6.8. For an application arising under subsection 6.1., the state agency shall determine the proposed capital expenditure to be exempt from review if

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the entire expenditure is found to be less than the then applicable expenditure minimum.

6.9. The state agency's ruling upon the applicability of the exemption shall be in writing and shall be a final decision for purposes of West Virginia Code, § 16-2D-7(r) and § 16-2D-10. The health care facility wishing to make the capital expenditure or to add the health service shall not do so until the proposal is determined to be exempt.

Section 7. Requests For Hearings And Reconsideration Hearings.

7.1. In the event that an affected person requests a hearing or a reconsideration hearing on any exemption provided for by this rule, the exemption review period shall be terminated. A hearing shall then be held ~~at the earliest opportunity of the parties and the state agency.~~ 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.

7.2. The state agency may conduct a prehearing conference in accordance with Rule 16 of the West Virginia Rules of Civil Procedure. The parties may engage in discovery as provided by the West Virginia Rules of Civil Procedure if an order is first obtained from the state agency or a hearing examiner appointed by it.

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7.3. 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 ~~thirty (30)~~ twenty (20) 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.

7.4. Upon receipt of any verified claim for an exemption other than one under section 4 of this rule, the state agency shall cause a notice to the public to be issued of that claim. The notice shall identify the applicant and shall describe the proposal. The notice shall be published as part of the state agency's legal advertisement in the Saturday Charleston newspapers and shall be included in the state agency's weekly newsletter and in the publication in the State Register.

7.5. Notice of a section 4 verified claim shall be in such form and manner as the state agency can reasonably provide and may include a post-decision notice as described in subsection 7.4. of this rule.

Section 8. 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

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clarified herein. All terms not defined in the Act have the following meanings unless the context expressly requires otherwise.

8.1. "Act" means the Certificate of Need Act, West Virginia Code, § 16-2D-1 et seq.

8.2. "Capital expenditure" has the meaning ascribed to it by section 2(f) of the Act. In particular, the state agency calls attention to fact that the term "capital expenditure" includes expenditures for studies, surveys, designs, plans, working drawings, specifications, and other activities, including staff effort and consulting and other services, essential to the proposal. Also, as section 2(f) of the Act notes, a series of expenditures, each less than the expenditure minimum, may be taken together if the state agency determines the expenditures should be combined as provided for by the Act.

8.3 "Merely replaces" as used in section 3 of this rule means that the new major medical equipment does not differ in essential purpose or function from the equipment that is being replaced. Examples of a "mere replacement" is a second generation CT scanner by a fourth generation CT scanner. However, replacement of a CT scanner with a CT scanner that also provides radiation therapy is not a "mere replacement." Also, replacement of a CT scanner with a magnetic resonance imaging device is not a mere replacement since the essential purpose and function of the two types of imaging devices are dissimilar.

8.4. The term "not offered on a regular basis" means that the applicant has not held itself out to the public as offering the health service in issue or has not actually provided the service to any patient during the requisite twelve (12) months. It does not mean merely maintaining the capability of providing the health service.

8.5. "Obsolete" means no longer used or useful because of outmoded design or construction. This term is subjective and varies from user to user. What is obsolete to one facility may be quite useful to another facility because of varying needs between facilities. Hence, in determining whether or not an item of major medical equipment is "obsolete," the needs of the possessor of the equipment must be taken into account.

8.6. "Outdated" means that the major medical equipment has become obsolete and has been replaced in common usage by other equipment.

8.7. "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.

8.8 "Verified notice" means a notice containing the facts required by the various subsections of these rules and which has attached to it a statement made under oath before a notary public or other official entitled to administer

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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.

8.9. "Worn-out" means that the maintenance and repair costs together with lost revenue resulting from excessive downtime exceeds the annual depreciation expense of the major medical equipment.

Section 8. 9. Severability

If any provision of these rules or the application thereof to any person or circumstance shall be held invalid, such invalidity shall not affect the provisions or the applications of these rules which can be given effect without the involved provisions or application and to this end the provisions of these rules are declared to be severable.



Arch A. Moore, Jr.
Governor

STATE OF WEST VIRGINIA
HEALTH CARE COST REVIEW AUTHORITY

Walter J. Dale
Chairman

Board Members
Larry C. Fizer
Don M. Keesling

August 31, 1987

Honorable Larry A. Tucker
Honorable Thomas A. Knight
Co-Chairman, Legislative
Rule-Making Review Committee
Room M-438, State Capitol
Charleston, WV 25305

FILED IN THE OFFICE OF
THE SECRETARY OF STATE
THIS DATE Aug 31, 1987
ADMINISTRATIVE LAW DIVISION

Gentlemen:

Re: Emergency Amendment To Previously Filed
Emergency Legislative Rule - "Exemptions
From Certificate of Need Review"

Pursuant to your requirements, enclosed herewith please find fifteen (15) copies of the following documents.

- (1) The text of the amended version of this rule.
- (2) The text of the amended version of this rule with strike-throughs of deleted language and underlining of new language.
- (3) A memorandum briefly summarizing the content of this rule.
- (4) A memorandum statement of the circumstances which require the rule.
- (5) A fiscal note for the rule.
- (6) A completed questionnaire from your committee on the rule.

With much appreciation for your assistance in this matter, I remain

Very truly yours,

WALTER J. DALE
Chairman

WJD/JHK/jmh

Enclosures

cc: Secretary of State

EMERGENCY
WEST VIRGINIA LEGISLATIVE RULE
HEALTH CARE COST REVIEW AUTHORITY
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SERIES XI

FILED IN THE OFFICE OF
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THIS DATE Aug 31, 1987
ADMINISTRATIVE LAW DIVISION

Title: EXEMPTIONS FROM CERTIFICATE OF NEED REVIEW

Section 1. General

1.1. Scope - This emergency legislative rule establishes the standards for the exemptions from certificate of need review provided for by the 1987 amendments to the Certificate of Need Act, West Virginia Code, § 16-2D-1 et seq. Pursuant to West Virginia Code, § 16-29B-11, the Health Care Cost Review Authority is designated to be the state agency charged with administering the certificate of need program.

1.2. Authority - West Virginia Code, § 16-2D-8, § 16-2D-4(f)-(i), and § 16-29B-11.

1.3. Filing Date - August 31, 1987.

1.4. Effective Date - August 31, 1987.

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HCCRA
Leg. Rule, 16-2D
Series XI, Sec. 2

Section 2. Introduction

This emergency legislative rule implements certain of the provisions of Enrolled Committee Substitute For House Bill 2342 which was signed by the Governor. That bill amended West Virginia Code, § 16-2D-4, by adding to it four (4) new subsections. Those new subsections authorize the state agency to promulgate rules to exempt from certificate of need review certain activities of health care facilities. In the state agency's opinion, these new exemptions must be implemented immediately so as to prevent substantial harm to the public interest. The state agency concludes that the Legislature intended to alleviate the financial burden on health care facilities which wish to engage in the specified activities if the state agency deemed it advisable to implement the exemptions. Delays in implementing this rule would defeat this Legislative purpose by causing the health care facilities to continue to bear this financial burden until the rule receives final legislative approval. This unalleviated financial burden, which has been deemed unnecessary by the Legislature, would be passed along to health care consumers in the form of higher costs. Also, delay in effectuating the new provisions would defeat the Legislature's additional purpose of speeding-up the certificate of need process for certain items.

Section 3. Replacement Major Medical Equipment

3.1. Any legal entity which wishes to acquire, either by purchase, lease, or other comparable arrangement, major medical equipment which merely replaces medical equipment already owned by the entity and which has become outdated, worn-out, or obsolete may do so without undergoing certificate of need review but must first notify the state agency of its intention to do so and obtain an exemption from review. This exemption is not available to any entity which previously utilized mobile equipment and who now wishes to replace the mobile equipment with non-mobile equipment. In order to qualify for this exemption, the old equipment must have been defined as major medical equipment when it was initially obtained by the applicant and the applicant must have obtained either certificate of need approval or an exemption for its acquisition. In addition, in order for the exemption to be obtained, the applicant must divest itself of the old equipment and not utilize it in the future.

3.2. The verified notice shall identify the legal entity involved, the location or locations of the present medical equipment, the location or locations where the new major medical equipment will be placed, the cost including installation of the equipment, the fair market value of the new equipment, the cost of any renovations needed for the installation of the new equipment, a description of the functions and uses of the old and of the new equipment, and

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utilization rates for the old equipment for the immediate past three (3) calendar years.

3.3. Upon receipt of the notice, the state agency shall within fifteen (15) days determine whether the new equipment acquisition is eligible for the exemption. In the event the state agency needs more information to make its determination, it shall request that information in writing. Such request shall terminate the applicable fifteen (15) day review period and a new fifteen (15) day review period shall begin upon receipt by the state agency of the requested information. Submission of incomplete or inadequate additional information shall not cause the new fifteen (15) day review period to begin.

3.4. Upon determining that the major medical equipment that is proposed to be acquired will merely replace equipment which is already owned by the entity and which has become outdated, worn-out, or obsolete, the state agency shall grant the entity an exemption from certificate of need review.

3.5. The state agency's ruling upon the applicability of the exemption shall be in writing and shall be a final decision for purposes of West Virginia Code, § 16-2D-7(r) and § 16-2D-10. The legal entity wishing to acquire the new major medical equipment may not do so until the entry of a final decision.

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Section 4. Capital Expenditures Not For Health Services.

4.1. Any legal entity otherwise subject to the certificate of need program may obtain an exemption for capital expenditures in excess of the expenditure minimum for the purpose of making emergency repairs to the entity's physical facility or equipment.

4.2. An "emergency repair" refers to a sudden and unforeseen breakdown or failure in the physical plant or equipment of a health care provider. The breakdown or failure must result in an imminent threat to the safety and well-being of the entity's patients or result in the inability of the entity to render health care services to its patients. Examples of such failures or breakdowns include the collapse of a wall of a building or the failure of a facility's boiler if that boiler is the primary source of heat or electricity for the facility.

4.3. The exemption may be obtained by the filing of a verified notice. The verified notice shall identify the legal entity involved, the amount of the capital expenditure involved, a description of the breakdown or failure involved, and a description of why that breakdown or failure constitutes an emergency as required by subsection 4.2.

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4.4. Upon receipt of the verified notice, the state agency shall determine whether the proposal is eligible for the exemption. This determination shall be made as soon as possible and is not to exceed three (3) working days. In the event that additional or more complete information is needed, the state agency may first request and receive that information before a decision is made.

4.5. The state agency's ruling upon the applicability of the exemption shall be in writing and shall be a final decision for purposes of West Virginia Code, § 16-2D-7(r) and § 16-2D-10. The legal entity wishing to make the capital expenditure may not do so until after the entry of a final decision.

Section 5. Shared Services.

5.1. Any acute care facility otherwise subject to the certificate of need review program may obtain an exemption from certificate of need review for shared services between two or more acute care facilities. The shared services must be those provided by major medical equipment and which through new or existing technology can reasonably be made mobile. Examples of such "shared services" are mobile computerized tomography (CT) scanners, magnetic resonance imaging (MRI) devices, and extra-corporeal lithotripters. Other technologies which are similar in mobility may be included in this exemption. In order to qualify as a "shared service," the equipment must be on site at each

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acute care facility at least four (4) days out of each month unless good cause is established by the acute care facilities for waiving or modifying this requirement.

5.2. In order to obtain the exemption, the acute care facilities must file a verified notice with the state agency. 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 the each of the first three (3) years of operation of the shared services, and the proposed schedule for the equipment's use at each hospital.

5.3. 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. However, 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.

5.4. Upon receipt of the verified notice, the state agency shall within fifteen (15) days determine whether the proposal is eligible for the exemption. In the event the state agency needs more information to make its determination, it shall request that information in writing. Such request shall terminate the

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applicable fifteen (15) day review period and a new fifteen (15) day review period shall begin upon receipt by the state agency of the requested information. Submission of incomplete or inadequate additional information shall not cause the new fifteen (15) day review period to begin.

5.5. Upon determining that the equipment to be acquired to provide the shared services meets the conditions stated above in subsection 5.1. and in 5.3., the state agency shall grant the entities involved an exemption from certificate of need review.

5.6. The state agency's ruling upon the applicability of the exemption shall be in writing and shall be a final decision for purposes of West Virginia Code, § 16-2D-7(r) and § 16-2D-10. The major medical equipment affected by this exemption shall not be acquired or contracted for until after the entry of a final decision.

Section 6. Other Claims Of Exemption.

6.1. Any health care facility which is otherwise subject to the certificate of need program that intends to enter into a capital expenditure in an amount less than the expenditure minimum but not by more than \$100,000.00 shall file a verified notice in the form prescribed by subsection 6.3 of this rule with the state agency. For example, if the expenditure minimum is

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\$1,000,000.00 and the facility intends to make a capital expenditure of \$900,000.00, then a notice is required. But, if the intended capital expenditure is \$899,999.00, then a notice is not required. Of course, as the expenditure minimum changes, this requirement will change with it.

6.2. If any health care facility proposes to add health services to those offered by the health care facility and if such services were not offered on a regular basis by or on behalf of that facility within the twelve-month period prior to the time such services would now be offered, then that proposal may be exempt from certificate of need review if it meets both of the requirements stated below in this subsection. Otherwise, the proposal is subject to certificate of need review.

6.2.1. If the proposed addition to health services meets the requirements of subsection 4.3. of the Legislative Rule for the Certificate of Need Program, Series 7, Title 65 (1983); and

6.2.2. If a health care facility proposes to develop or to acquire a new physical location separate and apart from its existing physical site upon which the additional health service will be offered or provided, the proposal may be exempt from certificate of need review unless the state agency determines that subsection 6.5. of this legislative rule bars such an exemption. If no new physical site is involved in the proposal, then this subsection 6.2.2. is not applicable to the

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proposal and only subsection 6.2.1. shall be considered. In the event that it is determined that the proposal actually constitutes the development of an ambulatory health care facility as defined at section 2(b) of the Act, then the proposal shall be subject to certificate of need review under section 3(a) of the Act as being for the construction, development, acquisition, or other establishment of a new health care facility.

6.3. In the case of either subsection 6.1. or 6.2., the verified notice shall identify the health care facility involved, shall describe the proposal, shall state the amount of capital expenditure involved including all acquisition or lease costs, renovation costs, and installation costs, and shall state the annual operating expenses for each of the first three (3) years of operation.

6.4. In those instances where the health care facility wishes to institute a new health service, the verified notice shall also identify all of the existing health care facilities in the geographic area which are similar to the applicant or to the proposed facility and shall explain why those health care facilities which provide the same or similar services to those proposed by the claimant would not be in competition with those proposed by the claimant. The applicant must also provide the state agency with projections for its first three (3) years of operations of each county in or out of the state from which it expects the proposal to generate at least 10% of its patients or 10% of its gross revenues.

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6.5. If the state agency determines based upon economic and geographic factors within the geographic area of the proposed health service that such proposed additional health service will be offered in competition with other health care facilities providing the same or similar services, then the exemption shall be denied and the health care facility shall file the appropriate application for certificate of need approval. This determination shall be made within ten (10) days of the receipt by the state agency of the verified notice. In making this determination, the state agency may obtain additional information from the claimant, other health care facilities, and its own files. The decision on the applicability of the exemption shall identify all of the information obtained by the state agency and the claimant shall be informed of the information obtained and the sources thereof.

6.6. In determining whether or not economic and geographic factors within the geographic area of the proposed health service would result in the proposed health service being offered in competition with other health care facilities providing the same or similar services, the following criteria shall be used.

6.6.1. In determining what the "geographic area" is of the proposed health service, reference shall first be made to the service area described for that health service by the state health plan. If the state health plan designates a "service area" for that service, then that service area shall form the basis of the

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geographic area of the proposed health service. To that service area shall be added each county -- in or out of the state -- from which the applicant projects obtaining at least 10% of its clients or 10% of its gross revenue.

6.6.2. Any health care facility that provides the same or similar services to that proposed to be offered by the applicant that is located in the geographic area determined under subsection 6.6.1. shall be determined to be in competition with the proposal. In addition, if a health care facility that is not located in the geographic area determined pursuant to subsection 6.6.1. for the proposal but that does itself derive 10% of its patients or 10% of its gross revenue from within that same geographic area shall be determined to be in competition with the proposal.

6.7. For those instances other than those proposals which are denied pursuant to subsection 6.5., the state agency shall within ten (10) days of its receipt of the verified notice make one of the following responses:

6.7.1. Accept the claim of exemption;

6.7.2. Require the health care facility to furnish the state agency with additional information in which event a new ten (10) day review period shall begin upon receipt of the additional information;

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6.7.3. Reject the claim of exemption; or

6.7.4. Determine that a certificate of need application is necessary for the proposal in order to determine if the claim of exemption may be upheld. The application required by this section shall be an expedited application and the review period for it shall be the same as for any other expedited application.

6.8. For an application arising under subsection 6.1., the state agency shall determine the proposed capital expenditure to be exempt from review if the entire expenditure is found to be less than the then applicable expenditure minimum.

6.9. The state agency's ruling upon the applicability of the exemption shall be in writing and shall be a final decision for purposes of West Virginia Code, § 16-2D-7(r) and § 16-2D-10. The health care facility wishing to make the capital expenditure or to add the health service shall not do so until the proposal is determined to be exempt.

Section 7. Requests For Hearings And Reconsideration Hearings.

7.1. In the event that an affected person requests a hearing or a reconsideration hearing on any exemption provided for by this rule, the exemption review period shall be terminated. A hearing shall then be held within

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thirty (30) days of the request for a hearing unless the state agency sets a later date upon a showing of good cause therefor.

7.2. The state agency may conduct a prehearing conference in accordance with Rule 16 of the West Virginia Rules of Civil Procedure. The parties may engage in discovery as provided by the West Virginia Rules of Civil Procedure if an order is first obtained from the state agency or a hearing examiner appointed by it.

7.3. 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) 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.

7.4. Upon receipt of any verified claim for an exemption other than one under section 4 of this rule, the state agency shall cause a notice to the public to be issued of that claim. The notice shall identify the applicant and shall describe the proposal. The notice shall be published as part of the state agency's legal advertisement in the Saturday Charleston newspapers and shall be included in the state agency's weekly newsletter and in the publication in the State Register.

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7.5. Notice of a section 4 verified claim shall be in such form and manner as the state agency can reasonably provide and may include a post-decision notice as described in subsection 7.4. of this rule.

Section 8. 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.

8.1. "Act" means the Certificate of Need Act, West Virginia Code, § 16-2D-1 et seq.

8.2. "Capital expenditure" has the meaning ascribed to it by section 2(f) of the Act. In particular, the state agency calls attention to fact that the term "capital expenditure" includes expenditures for studies, surveys, designs, plans, working drawings, specifications, and other activities, including staff effort and consulting and other services, essential to the proposal. Also, as section 2(f) of the Act notes, a series of expenditures, each less than the expenditure minimum, may be taken together if the state agency determines the expenditures should be combined as provided for by the Act.

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8.3 "Merely replaces" as used in section 3 of this rule means that the new major medical equipment does not differ in essential purpose or function from the equipment that is being replaced. Examples of a "mere replacement" is a second generation CT scanner by a fourth generation CT scanner. However, replacement of a CT scanner with a CT scanner that also provides radiation therapy is not a "mere replacement." Also, replacement of a CT scanner with a magnetic resonance imaging device is not a mere replacement since the essential purpose and function of the two types of imaging devices are dissimilar.

8.4. The term "not offered on a regular basis" means that the applicant has not held itself out to the public as offering the health service in issue or has not actually provided the service to any patient during the requisite twelve (12) months. It does not mean merely maintaining the capability of providing the health service.

8.5. "Obsolete" means no longer used or useful because of outmoded design or construction. This term is subjective and varies from user to user. What is obsolete to one facility may be quite useful to another facility because of varying needs between facilities. Hence, in determining whether or not an item of major medical equipment is "obsolete," the needs of the possessor of the equipment must be taken into account.

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8.6. "Outdated" means that the major medical equipment has become obsolete and has been replaced in common usage by other equipment.

8.7. "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.

8.8 "Verified notice" means a notice containing the facts required by the various subsections of these rules 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.

8.9. "Worn-out" means that the maintenance and repair costs together with lost revenue resulting from excessive downtime exceeds the annual depreciation expense of the major medical equipment.

Section 9. Severability

If any provision of these rules or the application thereof to any person or circumstance shall be held invalid, such invalidity shall not affect the provisions or the applications of these rules which can be given effect without the involved

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provisions or application and to this end the provisions of these rules are
declared to be severable.