

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

Form #8

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1988 JAN 27

**NOTICE OF AN EMERGENCY AMENDMENT TO AN EMERGENCY RULE**

AGENCY: West Virginia Health Care Cost Review Authority TITLE NUMBER: 16-2D

DATE EMERGENCY RULE WAS ORIGINALLY FILED: July 7, 1987

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

No

IS THIS THE SECOND EMERGENCY AMENDMENT TO THE ORIGINALLY FILED EMERGENCY RULE:

Yes

DATE OF FIRST EMERGENCY AMENDMENT: August 31, 1987

SERIES NUMBER OF RULE: 65 CSR 11 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.

The reason for this filing is to amend the emergency rule to keep it  
consistent with the proposed permanent legislative rule and the modifications  
made to that latter rule by the Legislative Rule  
Making Review Committee.



WALTER J. DALE  
Chairman

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

SERIES XI

Title: EXEMPTIONS FROM CERTIFICATE OF NEED REVIEW

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Section 1. General

1.1. Scope - This emergency 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., and repeals subsection 4.3 of "Certificate of Need" Legislative Rule, § 65 CSR 7 (1983). 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(e)-(h), § 16-2D-6(c), and § 16-29B-11.

1.3. Filing Date - January 22, 1988.

1.4. Effective Date - January 22, 1988.

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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. Upon proof by the state agency that the equipment to be replaced was acquired in an unlawful manner under the Act, this exemption is not available. In addition, in order for the exemption to be obtained, the applicant must agree not to utilize the old equipment on a regular basis in the future; except that, the old equipment may be retained and used on a back-up basis when the new equipment is not available.

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 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. Notwithstanding the provisions contained either in those portions of the state health plan which identify specialized acute care services or in section 6 of this rule, this section, "Replacement of Major Medical Equipment," shall govern any action which merely replaces any equipment which has become outdated, worn out, or obsolete.

3.5. 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.

3.6. 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 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 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.

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.

4.6. 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 items not directly related to the provision of health services. The provisions of this subsection 4.6 et seq., do not replace or limit the emergency repair provisions stated above in subsections 4.1 through 4.5.

4.7. The legal entity wishing to make a capital expenditure in excess of the expenditure minimum for items not directly related to the provision of health services shall complete the requisite expedited exempt review application form. Following the filing of the application, 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 legal entity, shall describe the proposed expenditure and its purpose, and shall describe the review period including the rights of affected parties to a hearing.

4.8. Following receipt of the application, the state agency shall determine within fifteen (15) days whether or not the application is complete. If the application 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 application is complete. Upon determining that the application is complete, the state agency shall publish a notice of that fact in the Saturday Charleston newspapers, the State Register, and in the state agency's newsletter. The notice shall identify the legal entity, shall describe the proposed expenditure and its purpose, and shall, if a hearing on the exemption has been requested, state the time, place, and date of the hearing.

4.9. If a hearing has not been requested, then following the determination of completeness the state agency shall within ten (10) days issue a written decision on the application which decision shall be a final decision for



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purposes of West Virginia Code, § 16-2D-7(r) and § 16-2D-10. The legal entity wishing to make the expenditure may not do so until the entry of a final decision. The state agency shall publish notice of the decision in the Saturday Charleston newspapers, the State Register, and the state agency's newsletter.

4.10. If a hearing has been requested by an affected party, the state agency shall follow the provisions of subsections 7.1 and 7.2 of this legislative rule. At the conclusion of the hearing, the parties may submit proposed findings of fact, conclusions of law, and legal briefs within five (5) days of the close of the hearing. This period may be extended only with the consent of the applicant. The state agency shall then have 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.

4.11. 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 4.7.

4.12. A written decision made pursuant to subsection 4.10 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 expenditure may not do so until the entry of a final decision. The state agency shall publish notice of the decision in the

Saturday Charleston newspapers, the State Register, and the state agency's newsletter.

4.13. The only criteria for review that shall be applicable to the review of a proposed expenditure under subsections 4.6 et seq., shall be the financial feasibility of the proposal. Findings that the proposal is financially feasible shall satisfy the requirements of West Virginia Code, § 16-2D-6(e) and - 9(b). No other conclusions shall be required for approval of the proposal.

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 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 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.

5.7. Notwithstanding the provisions contained either in those portions of the state health plan which identify specialized acute care services or in section 6 of this rule, this section, "Shared Services," shall govern any action for the sharing of services between two or more acute care facilities.

Section 6. New Services.

6.1. Any legal entity which is otherwise subject to the certificate of need program which wishes to offer one or more of the health services set forth in subsection 6.3 and which health service was not or services were not offered on a regular basis by or on behalf of such legal entity within the twelve-month period prior to the time such service or services would now be offered shall

follow either the procedures set forth here or those described in the legislative rule "Certificate of Need," § 65 CSR 7 (1983). It is expressly provided that subsection 4.3 of the legislative rule "Certificate of Need," § 65 CSR 7 (1983), is hereby repealed and no longer in effect from the date of the final promulgation of this legislative rule.

6.2. If a health service is one of the health services set forth in subsection 6.3, the proposed initial offering of that service by an established legal entity is subject to review. If the legal entity is established and if it proposes to add a health service not on the following list, then such addition is not reviewable under the Act unless it is associated with a capital expenditure in excess of the expenditure minimum. In this latter event, the proposed expenditure will be subject to review as provided for by the legislative rule "Certificate of Need," § 65 CSR 7 (1983).

6.3. The list of health services subject to review pursuant to section 3(e) of the Act is as follows. This list is all inclusive and may not be added to except by formal amendment to this legislative rule. A health service on the list shall hereafter be referred to as a "listed health service."

6.3.1. Alcohol and other drug treatment and rehabilitation if offered in a discrete unit.

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- 6.3.2. Ambulatory surgical facilities or ambulatory surgical centers.
- 6.3.3. Cardiac catheterization.
- 6.3.4. Comprehensive medical rehabilitation on an inpatient basis.
- 6.3.5. End-stage renal dialysis stations and home training.
- 6.3.6. Hyperbaric oxygen therapy.
- 6.3.7. Intermediate care for the mentally retarded.
- 6.3.8. Discrete units for intermediate or skilled nursing care.
- 6.3.9. Lithotripsy.
- 6.3.10. Magnetic resonance imaging.
- 6.3.11. Medical or surgical beds.
- 6.3.12. Discrete obstetrical units.

6.3.13. Organ transplants such as heart, lungs, kidney, liver, and other organs.

6.3.14. Open heart surgery.

6.3.15. Discrete pediatric units.

6.3.16. Discrete inpatient psychiatric units.

6.3.17. Special care units for burns, intensive care, cardiac care, neonatal intensive care, neonatal intermediate care, and pediatric intensive care.

6.3.18. Surgical services.

6.3.19. Radiation therapy.

6.4. If a listed health service is proposed to be added and if the proposed capital expenditure associated with that addition is either zero or less than the expenditure minimum and if the annual operating costs for each of the first three (3) twelve-month periods following the initiation of the offering of the listed health service are projected to be less than the expenditure minimum for annual operating costs, then the proposed addition is eligible for the review

procedures set forth below. If either the capital expenditure exceeds the expenditure minimum or if the annual operating costs are projected to exceed the expenditure minimum for annual operating costs for any of the first three (3) twelve-month periods following the initiation of the offering of the listed health service, then the legal entity shall be subject to review under the expedited review provisions of the legislative rule "Certificate of Need," § 65 CSR 7 (1983).

6.5. An eligible listed health service as provided by subsection 6.4 of this legislative rule shall be reviewed as follows.

6.5.1. The legal entity shall file an expedited exempt application with the state agency. Upon receipt of the application, the state agency shall publish a notice of the filing in the Saturday Charleston newspaper, the State Register, and the state agency's newsletter. The notice shall identify the legal entity, shall describe the proposal, and shall state the rights of affected parties to a hearing.

6.5.2. Upon the receipt of the application, the state agency shall have fifteen (15) days in which to determine whether or not the application is complete. If the application is not complete, then the state agency may request additional information. Upon receipt of that additional information, the state



agency shall have fifteen (15) days within which to determine if the application is complete.

6.5.3. Upon determining that the application is complete, the state agency shall publish a notice in the Saturday Charleston newspapers, the State Register, and the state agency's newsletter. The notice shall identify the legal entity, shall describe the proposal, and, if a hearing has been requested, shall state the time, date, and place of the hearing.

6.5.4. If a hearing has been requested by an affected party, the state agency shall follow the provisions of subsections 7.1 and 7.2 of this legislative rule. At the conclusion of the hearing, the parties may submit proposed findings of fact, conclusions of law, and legal briefs within five (5) days of the close of the hearing. This period may be extended only with the consent of the applicant. The state agency shall then have 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.

6.5.5. If a hearing has not been requested, then the state agency shall make a written decision within ten (10) days of the determination of completeness.

6.5.6. 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 6.5.1.

6.5.7. A written decision made pursuant to subsections 6.5.4 or 6.5.5 shall be a final decision for purposes of West Virginia Code, § 16-2D-7(r) and § 16-2D-10. Notice of such decision shall be made by publication in the Saturday Charleston Newspapers, the State Register, and the state agency's newsletter.

6.5.8. The only criteria for review that shall be applicable to the review of a listed health service under this section shall be that the proposal has no obvious inconsistency with the state health plan and that the proposal is financially feasible. Findings that the proposal is not obviously inconsistent with the state health plan and that the proposal is financially feasible shall satisfy the requirements of West Virginia Code, § 16-2D-6(e) and -9(b). No other conclusions shall be required for approval of the proposal.

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

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. 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.

7.3. Except as otherwise provided in this rule, 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. Except as otherwise provided in this rule, upon receipt of a verified claim for an exemption, 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 4.1 verified claim shall be in such form and manner as the state agency can reasonably provide and may include a post-decision notice containing the information 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.

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 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.

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Title:       EXEMPTIONS FROM CERTIFICATE OF NEED REVIEW

Section 1. General

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