



**WEST VIRGINIA
SECRETARY OF STATE**

NATALIE E. TENNANT

ADMINISTRATIVE LAW DIVISION

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OFFICE OF
WEST VIRGINIA SECRETARY OF STATE

FORM 8 -- NOTICE OF AN EMERGENCY AMENDMENT TO AN EMERGENCY RULE (Page 1)

AGENCY **Health Care Authority**
RULE TYPE **Legislative** AMENDMENT TO EXISTING RULE No TITLE-SERIES **65-33**
RULE NAME **Exemption for Kidney Disease Treatment Centers**

CITE AUTHORITY **§16-2D-4(a)and(6)m 16-2D-11-(22) and 16-29B-8(a)(1)**

DATE EMERGENCY RULE WAS ORIGINALLY FILED

Wednesday, June 08, 2016

FIRST EMERGENCY AMENDMENT TO AN EXISTING RULE

SECOND EMERGENCY AMENDMENT TO AN EXISTING RULE

DATE OF FIRST EMERGENCY AMENDMENT

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENTS ARE TRUE AND CORRECT.

Yes

Marianne Kapinos -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.



Title-Series: 65-33



Rule Id: 10168



Document: 28815



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FORM 8 -- NOTICE OF AN EMERGENCY AMENDMENT TO AN EMERGENCY RULE (Page 2)

AGENCY **Health Care Authority**
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RULE NAME **Exemption for Kidney Disease Treatment Centers**

CITE AUTHORITY **§16-2D-4(a)and(6)m 16-2D-11-(22) and 16-29B-8(a)(1)**

THE ATTACHED IS AN EMERGENCY AMENDMENT TO AN EXISTING EMERGENCY RULE. THIS EMERGENCY AMENDMENT BECOMES EFFECTIVE AFTER APPROVAL BY SECRETARY OF STATE OR 42ND DAY AFTER FILING, WHICHEVER OCCURS FIRST. THE FACTS AND CIRCUMSTANCES CONSTITUTING THE EMERGENCY AMENDMENT ARE AS FOLLOWS:

An important change has been made to the rule following the receipt of public comments. This change has been made and submitted to the SOS and the Legislative Rule Making Review Committee in the proposed legislative rule. This amendment is necessary for the two rules to be the same.

Marianne Kapinos -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.



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FORM 9 -- EMERGENCY RULE QUESTIONNAIRE (Page 1)

AGENCY Health Care Authority

RULE TYPE Legislative AMENDMENT TO EXISTING RULE **No** TITLE-SERIES **65-33**

RULE NAME Exemption for Kidney Disease Treatment Centers

CITE AUTHORITY §16-2D-4(a)and(6)m 16-2D-11-(22) and 16-29B-8(a)(1)

PRIMARY CONTACT

Marianne Kapinos
100 Dee Drive

Charleston, STATE ZIP

Marianne Kapinos -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.



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FORM 9 -- EMERGENCY RULE QUESTIONNAIRE (Page 2)

AGENCY **Health Care Authority**
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RULE NAME **Exemption for Kidney Disease Treatment Centers**

CITE AUTHORITY **§16-2D-4(a)and(6)m 16-2D-11-(22) and 16-29B-8(a)(1)**

DATE OF FILING
Tuesday, August 16, 2016

STATUTORY AUTHORITY FOR PROMULGATING EMERGENCY RULE
WV Code §16-2D-4(a)and (6), 16-2D-11(22) and 16-29B-8(a)(1)

DATE OF FILING OF PROPOSED LEGISLATIVE RULE
Tuesday, August 16, 2016

DOES THE EMERGENCY RULE ADOPT NEW LANGUAGE OR DOES IT AMEND OR APPEAL A
CURRENT LEGISLATIVE RULE?

HAS THE SAME OR SIMILAR EMERGENCY RULE PREVIOUSLY BEEN FILED AND EXPIRED?
No

STATE, WITH PARTICULARITY, THOSE FACTS AND CIRCUMSTANCES WHICH MAKE THE
EMERGENCY RULE NECESSARY FOR THE IMMEDIATE PRESERVATION OF PUBLIC PEACE,
HEALTH, SAFETY OR WELFARE.

**HB4365 mandates the Authority to promulgate emergency rules prior to 12-31-16 to implement the
provisions of this legislation. This is one of the rules required by this legislation.**

**Marianne Kapinos -- By my signature, I certify that I am the person authorized to file legislative rules, in
accordance with West Virginia Code §29A-3-11 and §39A-3-2.**



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FORM 9 -- EMERGENCY RULE QUESTIONNAIRE (Page 3)

AGENCY **Health Care Authority**

RULE TYPE **Legislative** AMENDMENT TO EXISTING RULE No TITLE-SERIES **65-33**

RULE NAME **Exemption for Kidney Disease Treatment Centers**

CITE AUTHORITY **§16-2D-4(a)and(6)m 16-2D-11-(22) and 16-29B-8(a)(1)**

IF THE EMERGENCY RULE WAS PROMULGATED IN ORDER TO COMPLY WITH A TIME LIMIT ESTABLISHED BY THE CODE OR FEDERAL STATUTE OR REGULATION, CITE THE CODE PROVISION, FEDERAL STATUTE OR REGULATION AND TIME LIMIT ESTABLISHED THEREIN.

see above

STATE, WITH PARTICULARITY, THOSE FACTS AND CIRCUMSTANCES WHICH MAKE THE EMERGENCY RULE NECESSARY TO PREVENT SUBSTANTIAL HARM TO THE PUBLIC INTEREST.

see above

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENTS ARE TRUE AND CORRECT.

Yes

Marianne Kapinos -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.



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FORM 11 -- FISCAL NOTE FOR PROPOSED RULES (Page 1)

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CITE AUTHORITY **§16-2D-4(a)and(6)m 16-2D-11-(22) and 16-29B-8(a)(1)**

PRIMARY CONTACT

Marianne Kapinos
100 Dee Drive

Charleston, STATE ZIP

SECONDARY CONTACT

Cynthia Dellinger
100 Dee Drive

Charleston, STATE SECONDARY ZIP SECONDARY

Marianne Kapinos -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.



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RULE TYPE Legislative AMENDMENT TO EXISTING RULE **No** TITLE-SERIES **65-33**

RULE NAME Exemption for Kidney Disease Treatment Centers

CITE AUTHORITY §16-2D-4(a)and(6)m 16-2D-11-(22) and 16-29B-8(a)(1)

SUMMARIZE IN A CLEAR AND CONCISE MANNER WHAT IMPACT THIS MEASURE WILL HAVE ON COSTS AND REVENUES OF STATE GOVERNMENT.

There is no effect.

Marianne Kapinos -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.



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FORM 11 -- FISCAL NOTE FOR PROPOSED RULES (Page 2)

AGENCY **Health Care Authority**
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RULE NAME **Exemption for Kidney Disease Treatment Centers**

CITE AUTHORITY **§16-2D-4(a)and(6)m 16-2D-11-(22) and 16-29B-8(a)(1)**

FISCAL NOTE DETAIL -- SHOW OVER-ALL EFFECT IN ITEM 1 AND 2 AND, IN ITEM 3, GIVE AN EXPLANATION OF BREAKDOWN BY FISCAL YEAR, INCLUDING LONG-RANGE EFFECT.

Effect Of Proposal	Current Increase/Decrease (use ' - ')	Next Increase/Decrease (use ' - ')	Fiscal Year (Upon Full Implementation)
ESTIMATED TOTAL COST	0	0	0
PERSONAL SERVICES	0	0	0
CURRENT EXPENSES	0	0	0
REPAIRS AND ALTERATIONS	0	0	0
ASSETS	0	0	0
OTHER	0	0	0
ESTIMATED TOTAL REVENUES	0	0	0

Marianne Kapinos -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.



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FORM 11 -- FISCAL NOTE FOR PROPOSED RULES (Page 3)

AGENCY Health Care Authority

RULE TYPE Legislative AMENDMENT TO EXISTING RULE No TITLE-SERIES 65-33

RULE NAME Exemption for Kidney Disease Treatment Centers

CITE AUTHORITY §16-2D-4(a)and(6)m 16-2D-11-(22) and 16-29B-8(a)(1)

3. EXPLANATION OF ABOVE ESTIMATES (INCLUDING LONG-RANGE EFFECT). PLEASE INCLUDE ANY INCREASE OR DECREASE IN FEES IN YOUR ESTIMATED TOTAL REVENUES.

There is no effect

Marianne Kapinos -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.



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FORM 11 -- FISCAL NOTE FOR PROPOSED RULES (Page 4)

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RULE NAME **Exemption for Kidney Disease Treatment Centers**

CITE AUTHORITY **§16-2D-4(a)and(6)m 16-2D-11-(22) and 16-29B-8(a)(1)**

PLEASE IDENTIFY ANY AREAS OF VAGUENESS, TECHNICAL DEFECTS, REASONS THE PROPOSED RULE WOULD NOT HAVE A FISCAL IMPACT, AND OR ANY SPECIAL ISSUES NOT CAPTURED ELSEWHERE ON THIS FORM.

There are none

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENTS ARE TRUE AND CORRECT.

Marianne Kapinos -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.



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FORM 12 -- BRIEF SUMMARY AND STATEMENT OF CIRCUMSTANCES (Page 1)

AGENCY **Health Care Authority**
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RULE NAME **Exemption for Kidney Disease Treatment Centers**

CITE AUTHORITY **§16-2D-4(a)and(6)m 16-2D-11-(22) and 16-29B-8(a)(1)**

SUMMARIZE IN A CLEAR AND CONCISE MANNER CONTENTS OF CHANGES IN RULE AND STATEMENT OF CIRCUMSTANCES REQUIRING THE RULE.

HB 4365, effective June 10, 2016, directs the Health Care Authority to promulgate emergency rules by December 31, 2016 to effectuate the purposes of this legislation. This is one of the rules required by this legislation

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENTS ARE TRUE AND CORRECT.

Yes
Marianne Kapinos -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.



Title-Series: 65-33



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TITLE 65
LEGISLATIVE RULE
HEALTH CARE AUTHORITY

SERIES 33
EXEMPTION FOR KIDNEY DISEASE TREATMENT CENTERS

§65-33-1. General.

1.1. Scope. -- This legislative rule establishes an exemption from Certificate of Need for kidney disease treatment centers located in an area designated by the Authority as a medically underserved population.

1.2. Authority. -- W. Va. Code §§16-2D-4(a)(2) and (6), §16-2D-11(c)(22) and 16-29B-8(a)(1).

1.3. Filing Date. --

1.4. Effective Date. --

§65-33-2. Definitions.

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

2.1. "Act" mean the West Virginia Health Care Authority Certificate of Need Act, W. Va. Code §16-2D-1 et seq.

2.2. "Authority" mean the West Virginia Health Care Authority which is designated to administer the Certificate of Need program by W. Va. Code §16-29B-11.

2.3. "Medically underserved population" is defined on a county by county basis. Applicants seeking an exemption for a proposed new end stage renal disease treatment facility under this rule shall identify the service area as the county where the new facility is proposed to be located. For purposes of this rule only, a county service area with less than 50,000 residents is deemed to be a medically underserved population if there is no kidney disease treatment center located less than six (6) driving miles from the location provided in the exemption application.

2.4. "Verification" means a statement made under oath before a notary public that the information is knowingly provided and is true and correct.

§65-33-3. General Requirements.

3.1. A health service exempt from certificate of need review by W.Va. Code § 16-2D-11 may not be acquired, offered or developed within this state unless the Authority has issued an exemption for the health service.

3.2. A person or health care facility may not knowingly charge or bill for a health service exempted from certificate of need review by W.Va. Code § 16-2D-11 without first obtaining an exemption from the

Authority.

§65-33-4. Application.

An application for an exemption shall, at a minimum, include the following:

- 4.1. Name, address and contact information for the applicant;
- 4.2. Name, address and contact information for the person making the application;
- 4.3. Verifications from the person making the application and the CEO of the applicant entity;
- 4.4. A copy of the governing body's authorization empowering the CEO or his or her designee to sign the application and to act on its behalf; and
- 4.5. A detailed description of the project, including but not limited to:
 - 4.5.a. The address of the proposed facility and a copy of the executed lease or option to lease or option to purchase agreement for the facility;
 - 4.5.b. Evidence that there is adequate water and other utilities at the site to support the facility.
 - 4.5.c. A detailed statement of the services to be provided;
 - 4.5.d. The name, address and contact information for the medical director of the facility.
 - 4.5.e. The exemption for which the applicant is applying with the appropriate Code citation;
 - 4.5.f. A statement of the circumstances justifying approval of the exemption; and
 - 4.5.g. A timetable for implementation of the project. The facility must be operational within one year of the approval or the exemption will expire.

§65-33-5. Fee.

The application must be accompanied by a nonrefundable fee of \$1,000. Failure to file the required fee with the application is grounds for denial of the exemption.

§65-33-6. Review Process.

- 6.1. Upon receipt of the exemption application and fee, the Authority shall review the application to determine if the application contains all of the information required by Section 3 of this rule. Failure to provide the required information is grounds for denial of the exemption application.
- 6.2. Once the application is processed, the Authority will provide notice to the public of its receipt of the application on its website.
- 6.3. An affected party may not file an objection to the exemption request.

6.4. The Authority may not conduct an administrative hearing to review the application.

6.5. The Authority must either approve or deny the application within forty five days, or sixty days if the time period is extended. The applicant may request or agree with the Authority to a fifteen day extension of this timeframe.

6.6. If the Authority does not approve or deny the application within forty-five days, or sixty days if the time period is extended, the exemption is deemed approved.

6.7. In addition to the grounds listed in sections 4 and 5.1 of this rule, the Authority may deny the application if the applicant is not in compliance with any of the financial disclosure requirements contained in WV Code §16-5F-1 et seq. and 65 CSR 13; or is in violation of any of the provisions of WV Code §16-2D-1 et seq. or §16-29B-1 et seq. or any of the rules promulgated pursuant to these Code sections.

§65-33-7. Expiration of Exemption.

If the facility is not operational within one year from the date of the decision on exemption, the exemption will expire unless good cause can be demonstrated.

§65-33-8. Appeals.

8.1. An appeal of the Authority's decision may be filed with the Office of Judges in accordance with W.Va. Code §16-2D-16.

8.2. In lieu of an appeal, the applicant may refile an application with the Authority.

§65-33-9. Notification of Completion of Project.

The applicant shall notify the Authority in writing upon the completion of the project. The notification shall contain a brief description of the project, the assigned case file number, the date of completion of the project and the date that the project became or will become operational.