



**WEST VIRGINIA  
SECRETARY OF STATE**

**NATALIE E. TENNANT**

**ADMINISTRATIVE LAW DIVISION**

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8/16/2016 4:48:45 PM

OFFICE OF  
WEST VIRGINIA SECRETARY OF STATE

**FORM 3 -- NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE AND FILING WITH THE  
LEGISLATIVE RULE-MAKING REVIEW COMMITTEE**

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)(2)and (6), 16-2D-11(c)(22), 16-29B-8(a)(1)**

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE FOR THEIR REVIEW.

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: 28814



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**FORM 10 -- LEGISLATIVE QUESTIONNAIRE (Page 1)**

AGENCY **Health Care Authority**

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**PRIMARY CONTACT**

Marianne Kapinos  
100 Dee Drive

Charleston, STATE ZIP

**SECONDARY CONTACT**

Cynthia Dellinger  
100 Dee Drive

Charleston, STATE SECONDARY ZIP SECONDARY

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

AUTHORIZING STATUTE(S) CITATION  
**WV Code§16-2D-4(a)and (6), 16-2D-11(c)(22) and 16-29B-8(a)(1)**

DATE FILED IN STATE REGISTER WITH NOTICE OF HEARING OR PUBLIC COMMENT PERIOD  
**Wednesday, June 08, 2016**

WHAT OTHER NOTICE, INCLUDING ADVERTISING, DID YOU GIVE OF THE HEARING?  
**agency website and agency newsletter**

DATE OF PUBLIC HEARING(S) OR PUBLIC COMMENT PERIOD ENDED  
**Monday, July 11, 2016**

**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 10 -- LEGISLATIVE QUESTIONNAIRE (Page 2)**

AGENCY **Health Care Authority**

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

ATTACH LIST OF PERSONS WHO APPEARED AT HEARING, COMMENTS RECEIVED,  
AMENDMENTS, REASONS FOR AMENDMENTS.

**Attached**

DATE YOU FILED IN STATE REGISTER THE AGENCY APPROVED PROPOSED LEGISLATIVE RULE  
FOLLOWING PUBLIC HEARING: (BE EXACT)

**Tuesday, August 16, 2016**

**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 10 -- LEGISLATIVE QUESTIONNAIRE (Page 3)**

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IF THE STATUTE UNDER WHICH YOU PROMULGATED THE SUBMITTED RULES REQUIRES CERTAIN FINDINGS AND DETERMINATIONS TO BE MADE AS A CONDITION PRECEDENT TO THE PROMULGATION. GIVE THE DATE UPON WHICH YOU FILED IN THE STATE REGISTER A NOTICE OF THE TIME AND PLACE OF A HEARING FOR THE TAKING OF EVIDENCE AND A GENERAL DESCRIPTION OF THE ISSUES TO BE DECIDED.

**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 10 -- LEGISLATIVE QUESTIONNAIRE (Page 4)

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

DATE OF HEARING OR COMMENT PERIOD

ON WHAT DATE DID YOU FILE IN THE STATE REGISTER THE FINDINGS AND DETERMINATIONS REQUIRED TOGETHER WITH THE REASONS THEREFOR?

ATTACH FINDINGS AND DETERMINATIONS AND REASONS

**Attached**

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

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

**CITE AUTHORITY §16-2D-4(a)(2)and (6), 16-2D-11(c)(22), 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)**

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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)(2)and (6), 16-2D-11(c)(22), 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**

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

**CITE AUTHORITY §16-2D-4(a)(2)and (6), 16-2D-11(c)(22), 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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CITE AUTHORITY **§16-2D-4(a)(2)and (6), 16-2D-11(c)(22), 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.

**Thee 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)(2)and (6), 16-2D-11(c)(22), 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 became effective on June 10, 2016. This legislation directs the Health Care Authority to promulgate emergency rules to effectuate the purposes of this legislation by December 31, 2016, This is one of the rules mandated 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. --

1.5. Sunset Date. -- This rule will sunset 5 years after the rule becomes effective.

**§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.