



WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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9/28/2020 4:13:58 PM

Office of West Virginia
Secretary Of State

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

AGENCY: Health Care Authority TITLE-SERIES: 65-29
RULE TYPE: Legislative Amendment to Existing Rule: Yes Repeal of existing rule: No
RULE NAME: 65-29 Exemption from Certificate of Need

PRIMARY CONTACT

NAME: April L Robertson
ADDRESS: One Davis Square
Suite 100 East
Charleston, WV 25301
EMAIL: april.l.robertson@wv.gov
PHONE NUMBER: 304-558-9149

CITE STATUTORY AUTHORITY: 16-2D-4(a)(2), 16-2D-11 and 16-29B-8(a)(1)

EXPLANATION OF THE STATUTORY AUTHORITY FOR THE LEGISLATIVE RULE, INCLUDING A DETAILED SUMMARY OF THE EFFECT OF EACH PROVISION OF THE LEGISLATIVE RULE WITH CITATION TO THE SPECIFIC STATUTORY PROVISION WHICH EMPOWERS THE AGENCY TO ENACT SUCH RULE PROVISION:

Amendments are necessary due to the passage of HB 4108 which eliminated the application fee.

IS THIS FILING SOLELY FOR THE SUNSET PROVISION REQUIREMENTS IN W. VA. CODE §29A-3-19(e)? No

IF YES, DO YOU CERTIFY THAT THE ONLY CHANGES TO THE RULE ARE THE FILING DATE, EFFECTIVE DATE AND AN EXTENSION OF THE SUNSET DATE? No

DATE eFiled FOR NOTICE OF HEARING OR PUBLIC COMMENT PERIOD: 8/24/2020

DATE OF PUBLIC HEARING(S) OR PUBLIC COMMENT PERIOD ENDED: 9/23/2020

COMMENTS RECEIVED: Yes

(IF YES, PLEASE UPLOAD IN THE COMMENTS RECEIVED FIELD COMMENTS RECEIVED AND RESPONSES TO COMMENTS)

PUBLIC HEARING: No

(IF YES, PLEASE UPLOAD IN THE PUBLIC HEARING FIELD PERSONS WHO APPEARED AT THE HEARING(S) AND TRANSCRIPTS)

RELEVANT FEDERAL STATUTES OR REGULATIONS: No

WHAT OTHER NOTICE, INCLUDING ADVERTISING, DID YOU GIVE OF THE HEARING?

Posted on the Health Care Authority website.

SUMMARY OF THE CONTENT OF THE LEGISLATIVE RULE, AND A DETAILED DESCRIPTION OF THE RULE'S PURPOSE AND ALL PROPOSED CHANGES TO THE RULE:

This rule establishes the general criteria and procedures for applying for an exemption from Certificate of Need.

STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE RULE:

Passage of HB 4108 during the 2020 Regular Session of the Legislature which eliminated the \$1,000 application fee.

SUMMARIZE IN A CLEAR AND CONCISE MANNER THE OVERALL ECONOMIC IMPACT OF THE PROPOSED LEGISLATIVE RULE:

A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:

DHHR estimates a fiscal impact of an average of \$95,000 due to elimination of the filing fee associated with Certificate of Need exemption applications submitted to the Health Care Authority

B. ECONOMIC IMPACT ON SPECIAL REVENUE ACCOUNTS:

n/a

C. ECONOMIC IMPACT OF THE LEGISLATIVE RULE ON THE STATE OR ITS RESIDENTS:

na/

D. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year		
	2020 Increase/Decrease (use "-")	2021 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost			
Personal Services			
Current Expenses			
Repairs and Alterations			
Assets			
Other			
2. Estimated Total Revenues			-95,000.00

E. EXPLANATION OF ABOVE ESTIMATES (INCLUDING LONG-RANGE EFFECT):

The amount of revenue received from these fees in 2018 was \$112,000 and in 2019 was \$78,000 resulting in an average net loss of \$95,000 upon implementation.

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.

Yes

April L Robertson -- 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 65
LEGISLATIVE RULE
HEALTH CARE AUTHORITY

SERIES 29
EXEMPTION FROM CERTIFICATE OF NEED

§65-29-1. General.

1.1. Scope. -- This legislative rule establishes the general criteria and procedures for applying for an exemption from Certificate of Need.

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

1.3. Filing Date. -- ~~June 1, 2017~~

1.4. Effective Date. -- ~~June 1, 2017~~

1.5 Sunset Date. -- This rule shall terminate and have no further force or effect ~~on June 1, 2022.~~
upon the expiration of five years from its effective date.

§65-29-2. Definitions.

As used in this legislative rule, all terms that are defined in ~~section 2 of the statute~~ W. Va. Code §16-2D-2 have those same meanings which are in some cases further clarified in this rule. All terms not defined in ~~the statute~~ W. Va. Code §16-2D-2 have the following meanings unless the context expressly requires otherwise.

2.1.a. "Authority" means the West Virginia Health Care Authority which is designated to administer the Certificate of Need program by W. Va. Code ~~§16-29B-11~~§16-2D-3(a)(1).

2.1.b. "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 fewer than 50,000 residents is deemed to be a medically underserved population if there is no kidney disease treatment center located less than six driving miles from the location provided in the exemption application.

2.1.c. "Statute" means the West Virginia Health Care Authority Certificate of Need statute, W. Va. Code §16-2D-1 *et seq.*

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

§65-29-3. 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~~ an exemption application has been submitted to the Authority and the Authority has acknowledged in writing that the proposed health service is exempt from certificate of need review.

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~~ submitting an exemption application to the Authority and receiving an acknowledgement in writing from the Authority that the proposed health service is exempt from certificate of need review.

§65-29-4. Application.

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

- 4.1.a. Name, address, and contact information for the applicant;
- 4.1.b. Name, address, and contact information for the person making the application;
- 4.1.c. Verifications from the person making the application and the CEO of the applicant entity;
- 4.1.d. A copy of the governing body's written authorization empowering the CEO or his or her designee to authorize specified individuals to sign the application and to act on its behalf; and
- 4.1.e. A detailed description of the project, including but not limited to:
 - 4.1.e.1. The location of the proposal;
 - 4.1.e.2. A detailed statement of the services to be provided;
 - 4.1.e.3. The exemption for which the applicant is applying with the appropriate Code citation;
 - 4.1.e.4. A statement of the circumstances justifying approval of the exemption; and
 - 4.1.e.5. A timetable for implementation of the project. In the case of a kidney disease treatment center, the facility must be operational within one year of the approval or the exemption will expire after one year.
- 4.1.f. In the case of an exemption of a kidney disease treatment center, the application shall also contain:
 - 4.1.f.1. 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; and
 - 4.1.f.2. Evidence that there is adequate water and other utilities at the site to support the facility.

~~§65-29-5. 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.~~

§65-29-65. Review Process.

- ~~6.1.5.1.~~ 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 4 of this rule and meets the requirements of the exemption for which the applicant is applying. Failure to provide the required information or comply with the requirements of the exemption being sought is grounds for denial of the exemption application.

~~6.2.5.2.~~ Once the application is processed, the Authority will ~~provide notice to the public of its receipt of the application on its website~~ acknowledge in writing either that the proposed health service is exempt from certificate of need review or that the application is denied due to failure to provide the required information or comply with the terms of the exemption being sought.

5.3. The Authority will provide notice to the public on its website of its receipt of the application and either the acknowledgement of the exemption from certificate of need review or the denial of the exemption application.

~~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.~~

~~6.7.5.4.~~ In addition to the grounds listed in ~~sections 5 and 6.1~~ section 5.1 of this rule, the Authority may deny the application ~~if~~ if the applicant is not in compliance with any of the financial disclosure requirements contained in ~~WV Code § 16-5F-1 et seq.~~ W. Va. Code §16-29B-24 and 65CSR13; or is in violation of any of the provisions of ~~WV~~ W. Va. Code §16-2D-1 *et seq.* or §16-29B-1 *et seq.* or any of the rules promulgated pursuant to these Code sections.

§65-29-76. Expiration of Exemption.

If a kidney disease treatment 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.

§65-29-87. Appeals.

~~8.1.7.1.~~ An appeal of the Authority's decision may be filed with the Office of Judges in accordance with W.Va. Code §16-2D-16.

~~8.2.7.2.~~ In lieu of an appeal, the applicant may refile an application with the Authority.

§65-29-98. 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 the completion of the project and the date that the project became or will become operational.