

**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.