

SUMMARY OF COMMENTS RECEIVED AND CHANGES MADE TO TITLE 65, SERIES 33, EXEMPTION FOR KIDNEY DISEASE TREATMENT CENTERS

The Health Care Authority received two comments on this proposed rule. The comment received from Fresenius Kidney Care, Bio-Medical Applications of West Virginia, Inc., requested that “option to lease” be added to section 4.5.a. This change was made.

The West Virginia Hospital Association made comments regarding the exemption process generally and not specifically related to kidney disease treatment centers. Therefore, these comments are addressed in the Summary of Comments for Series 29, Exemption from Certificate of Need.



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July 11, 2016

Marianne Kapinos, General Counsel
West Virginia Health Care Authority
100 Dee Drive
Charleston, WV 25311

Dear Ms. Kapinos:

RE: NEW LEGISLATIVE RULE 65CSR33, EXEMPTION FOR KIDNEY DISEASE TREATMENT CENTERS

On behalf of the West Virginia Hospital Association (WVHA) and its 66 member hospitals and health systems, we respectfully submit this letter to provide public comments in response to the above referenced **New Legislative Rule 65CSR33, Exemption For Kidney Disease Treatment Centers**. We appreciate the Authority's swift action in filing the emergency rule pertaining to this change within the CON program and welcome the opportunity to now share our specific recommendations.

§65-33-3. Application.

3.1.3. We suggest removing the requirement to include "a copy of the governing body's approval of the proposal and its written authorization empowering specified individuals to sign the application and to act on its behalf" from the application. We believe this requirement would be over burdensome, and in many cases impractical.

3.1.4.a. We suggest removing the requirement to include "the capital expenditure" associated with the project as part of the exemption application. Many of the exemptions found at §16-2D-11 contain no mention of a capital expenditure threshold as a qualification for the listed exemption. As such, we are of the opinion this information is not relevant in the decision making process of whether to grant an exemption or not, and may exceed the statutory authority of the Authority. Furthermore, §65-29-7 of this rule references a substantial compliance review process that may be used to "withdraw the certificate or exemption and the board may direct that any license to operate the new service be revoked or denied." (WV Legislative Rule 65CSR7 §65-7-23. Substantial Compliance Review.) Therefore, if an exemption application includes a requirement to include "the capital expenditure" associated with the project, and then there is a substantial compliance review performed on that application, if during that substantial compliance review it is found the capital expenditure listed in the original application has been exceeded then the Authority may use the "Substantial Compliance Review" process to revoke the exemption. This action by the Authority is not contemplated in WV Code §16-2D-11.

3.1.4.h. We suggest removing the requirement to “include the obligation of any capital expenditure” from this paragraph for the same reasons listed above at 3.1.4.a.

§65-33-5. Review Process.

5.2. Under the new exemption section found at WV Code §16-2D-11, there is no mention of a determination of completeness as it relates to submitted applications. The Code provides that “the authority has forty-five days to review the exemption request.” In addition, this subsection of the rule does not provide a time table for the determination of completeness, and it is unclear if during this determination time the forty-five day review process time will toll.

§65-33-8. Substantial Compliance Review.

We discovered an incorrect cross reference in this section. WV CSR §65-7-23 relates to “Substantial Compliance Review.” The listed WV CSR reference in the rule directs the reader to the “Exemption Review Procedure.”

This exemption change contemplated with the passage of Enrolled House Bill 4365 is intended to reduce regulatory burden for providers, promote efficiency and access within the healthcare delivery system and streamline the administration of the Certificate of Need program in general. We respectfully request that you modify these emergency rules to achieve a rational balance of these core factors in order to ensure hospitals and healthcare providers efficiently meet the clinical needs of their patients without further regulatory burden.

Sincerely,



Joseph M. Letnaunchyn
President and CEO

JML/kw



July 14, 2016

Tim Adkins, Director
Certificate of Need
West Virginia Health Care Authority
100 Dee Drive, Suite 201
Charleston, West Virginia 25311-1600

RE: Exemption for End Stage Renal Disease; W.Va. Code R. § 65-33-1, *et seq.*
Comments from Bio-Medical Applications of West Virginia, Inc.

2016 JUL 14 10:03 AM
WEST VIRGINIA HEALTH CARE AUTHORITY

Mr. Adkins:

Bio-Medical Applications of West Virginia, Inc. ("BMA") thanks you for the opportunity to provide written comments regarding the Exemption for Kidney Disease Treatment Centers (the "ESRD Exemption") that was accepted by the West Virginia Secretary of State and became effective on June 17, 2016. BMA and its parent organization, Fresenius Medical Care, are providers of dialysis services. Currently, BMA provides in-center and home dialysis services to patients throughout West Virginia through a state-wide network of end stage renal disease treatment facilities.

BMA is pleased with the new, streamlined exemption procedure in Article 33 of the West Virginia Code of State Rules, with one small exception. Section 65-33-3, which includes the minimum contents of an exemption application under the proposed new regulations, requires the "address of the proposed facility and a copy of the executed lease or option to purchase agreement for the facility..." Practically, it would benefit BMA and other providers if the language required, instead, 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..." This small change would allow applicants under the ESRD Exemption to obtain an option agreement related to a proposed lease space, rather than executing a lease, prior to seeking approval from the West Virginia Health Care Authority. This small addition would have huge practical implications for applicants under the ESRD Exemption.

In conclusion, BMA appreciates the opportunity to participate in the process to review and comment on the ESRD Exemption. As we review any additional written comments filed by others, we would appreciate the opportunity to supplement this initial response.

If you have any questions, or if I can be of further assistance, please call me.

Sincerely,

Jim Swann
Director, Certificate of Need