

**SUMMARY OF COMMENTS RECEIVED AND CHANGES MADE TO TITLE 65, SERIES 29, EXEMPTION FROM  
CERTIFICATE OF NEED REVIEW**

The Health Care Authority (Authority) received three comments on this proposed rule. Comments were received from the West Virginia Hospital Association (WVHA), the West Virginia Health Care Association (HCA) and Charleston Area Medical Center (CAMC).

All three entities objected to the requirement that 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” be included in the application. Although this is a longstanding requirement for Certificate of Need (CON) applications and many exemptions, the Authority realizes that with the increased number of exemptions available under the new legislation, this could be burdensome if the board was required to adopt a resolution for every application. Therefore, the Authority has altered the language so that the board only has to authorize the CEO or his or her designee to sign the application and to act on its behalf. One board resolution will suffice for all applications unless or until the board elects to authorize a different individual.

The WVHA also objected to the inclusion of a capital expenditure in the exemption application. This requirement has been eliminated.

The WVHA objected to the requirement that a timetable for implementation of the project, including the capital expenditure be included in the application. The Authority has eliminated the capital expenditure requirement but still requires a timetable. Since the scope of exemptions has been greatly expanded by the new legislation, many large projects are now eligible for this process. Often large projects take several years to complete and it is important for the Authority to be aware of this timetable.

The WVHA noted that there was not a detailed process for declaring an exemption complete. This language and process has been eliminated.

Both the HCA and the WVHA objected to a substantial compliance review for exemptions. This process has been eliminated and a “Notification of Completion of Project” section, §8, has been added. This section simply requires the applicant to notify the Authority upon the completion of the project, as opposed to filing a progress report and undergoing substantial compliance review.

The HCA also requested that all references to exemptions should be placed in Series 29 as opposed to Series 32, which previously contained several references to exemptions. This has been done.



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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 65CSR29, EXEMPTION FROM CERTIFICATE OF NEED**

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 65CSR29, Exemption from Certificate of Need**. We appreciate the Authority's swift action in filing the emergency rule pertaining to Exemptions and welcome the opportunity to now share our specific recommendations.

**§65-29-3. 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.f: We suggest removing the requirement that an applicant for an exemption submit “a timetable for implementation of the project, including the obligation for any capital expenditure” for the same reasons as outlined above at 3.1.4.a.

**§65-29-5. Review Process.**

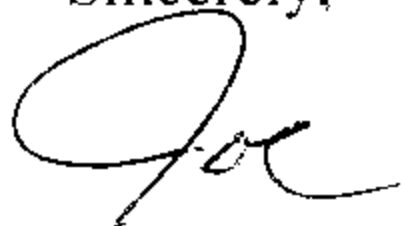
5.2: Under the new exemption section found at WV Code §16-2D-11, there is no mention of a determination of completeness as it relates to submitted applications. The Code provides that “the authority has forty-five days to review the exemption request.” In addition, this subsection of the rule does not 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.

**§65-29-7. 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 “Exemption Review Procedure.”

The Exemptions contemplated with the passage of Enrolled House Bill 4365 are intended to promote efficiency and access within the healthcare delivery system, while at the same time streamline the Certificate of Need activities of the Authority and reduce regulatory burden for providers. 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 11, 2016

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

Re: WVCSR 65-32-1 et.seq.  
WVCSR 65-29-1 et.seq.

Dear Ms. Kapinos:

The purpose of this letter is to provide comments with respect to the rules referenced above that the West Virginia Health Care Authority recently promulgated.

### **WVCSR 65-32-1**

#### 65-32-2. Definitions

You may want to consider defining the term “exemption” in this rule. It is used extensively throughout the rule.

#### 65-32-5. Access to Information and Facilities

The purpose of the exemption process is to streamline the CON process and make it less cumbersome. This section authorizes the Authority to “have access to any information, records, meetings, sites and/or facilities ... pertinent to a request for exemption.” Access to such information should not be necessary for an

exemption request. Filing the exemption application is simply a notice requirement and should not entail a lengthy process. The requirement should be eliminated.

#### 65-32-8.9. Application Review Procedure

A typographical error appears in the third sentence. The word “shall” appears twice.

#### 65-32-9.2 and 9.3. Extensions of Review Periods.

This provision of the rule gives the Authority unfettered ability to deny an application. It is unclear whether the denial is with or without prejudice. It also is unclear whether an applicant has to pay filing fees again if it refiles the application.

Instead of denying an application, the Authority should place the application on hold until the applicant provides the required information or weather conditions improve. The phrase “include, but not limited to” provides too much discretion for denying an application.

#### 65-32-10.6. Decision.

The rule states that notice of the Authority’s decision begins on “the date upon which legal notice of the decision appears” on the Authority’s website. A party to a proceeding may not be aware of the decision until it receives the decision in the mail. If sent by certified mail, that could take several days. If the Authority wants the date of notice to begin upon publication to its website, it should notify the parties or their legal representative by e-mail of the publication.

#### 65-32-11. Appeal of Certificate of Need Decision.

#### 65-32-12. Judicial Review.

The Authority should clarify in this rule whether an affected person who was not designated at the hearing can appeal a decision to the Office of Judges or Circuit Court. It appears that any entity that meets the definition of “affected person” can intervene at any time. That’s unfair.

The following language illustrates the ambiguity: “The Office of Judges, West Virginia Offices of the Insurance Commissioner shall review a final decision of the Authority relating to the issuance, denial or withdrawal of a certificate of need, upon request by an affected person.” The rule does not limit the request to an affected person designated at the hearing.

The rule authorizes the Office of Judges to grant a general continuance. We have no objection to that. Potential mischief lies in the sentence that states: “If the continuance continues for more than one (1) year, the review is withdrawn with prejudice.” Too many unusual circumstances could occur – weather, health issues of any party, backlog of cases, etc. - that could contribute to the delay. Could an opposing party manipulate the situation to cause a dismissal with prejudice? Some discretion, for good cause shown, should be given to the judge.

#### 65-32-13. Progress/Extension of Certificate of Need.

The Act does not state that entities receiving an exemption must file progress reports. The Act states that to obtain an exemption, a person shall: (1) File an exemption application; (2) Pay the \$1,000 application fee; and (3) Provide a statement detailing which exemption applies and the circumstances justifying the approval of the exemption.” Nowhere in the exemption section does it discuss progress reports. Additionally, the Act does not authorize the Authority to require “any additional information requested by the Authority.” The objective of the exemption was to reduce the burden and costs associated with CON review. Adding progress reports and unlimited reporting requirements defeats that objective.

#### 65-32-14. Substantial Changes to Project After Issuance of Certificate of Need.

This section should apply only to certificates of need and not exemptions. Some of the stated requirements are not applicable to exemptions. For example, the rule states that a capital expenditure in excess of 10 percent of the approved capital expenditure on major medical equipment or a 20 percent change in the total cost of the project are prima facie evidence of substantial changes. If the 10 percent increase in equipment or the 20 percent increase in the project are still within the limits of the exemption provisions, why would a new CON or any further review be required?

65-32-16. Substantial Compliance Review.

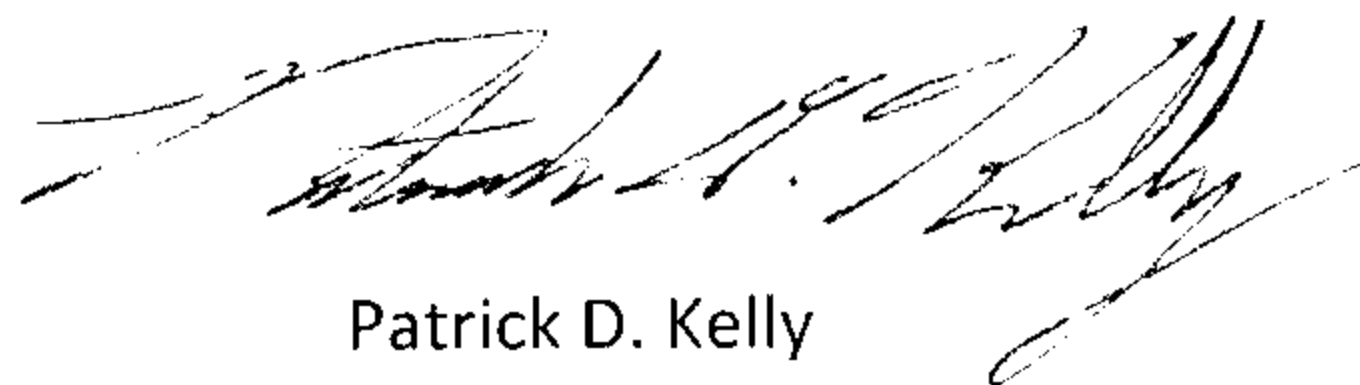
The Act does not require an applicant for exemption to proceed through a substantial review process. These additional steps add unnecessary costs.

#### **WVCSR 65-29-1**

All of the requirements related to exemptions should be placed in this section so the public has a clear understanding of the obligations of an applicant. Incorporating the exemption provisions into the rules related to certificates of need is confusing, in some situations they are not applicable, and they will cause unintended consequences. This results in a greater burden on the Authority and health care providers.

Thank you for your consideration of these comments.

Very truly yours,

A handwritten signature in black ink, appearing to read "Patrick D. Kelly", written in a cursive style.

Patrick D. Kelly  
CEO

Charleston Area  
Medical Center

DAVID L. RAMSEY  
PRESIDENT & CEO

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July 6, 2016

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

Dear Ms. Kapinos:

I am writing to comment on the Emergency CON Rules and the Emergency Exemption Rules that were recently submitted to the West Virginia Secretary of State's Office by the Health Care Authority.

My comments are provided below:

**Emergency CON Rule 65-32**

The CON Rule 65-32 should define the Establishment of Operating Rooms as: "The development or addition of operating rooms at a new or existing health care facility; provided however, that an existing acute care hospital that contains existing operating rooms may add additional operating rooms per the exemption for renovations to acute care hospitals contained in Chapter 16-2D-11(c)10 of the West Virginia Code." This appears to be the intent of the legislation but clarification is needed and should be added to the definitions section of the Rule.

The Rules require an applicant to submit *an original, a copy and a digital copy on a CD* when a CON application is filed. This should be amended to *an original, a copy and a digital copy*. Emailing the digital copy or using another method of exchanging the digital file such as a thumb drive should be an acceptable means of transferring a digital copy of the file between the applicant and the Authority.

A correction is needed for the header of every other even numbered page of the document which references CSR Series 65-7 which this document replaces.

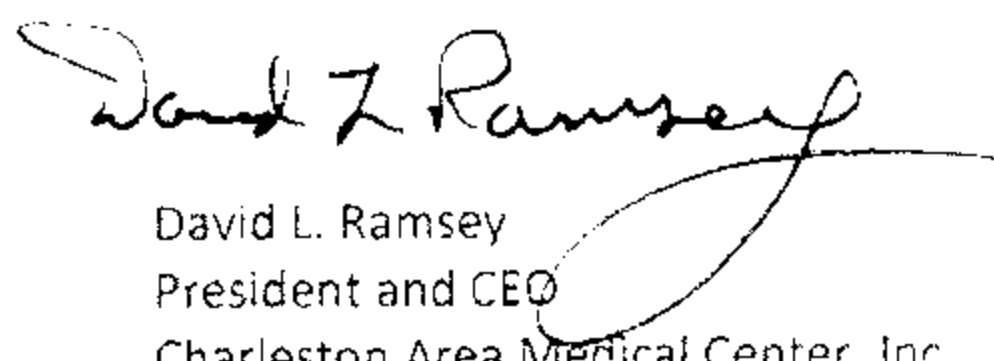
**Emergency Exemption Rule 65-29**

The CON process requires applicants to submit a board resolution approving the project, the contact person and who will sign the CON application for full CON review. This requirement has now been extended to the Exemption Process. Requiring a board resolution for projects that are "exempt" from CON review due to their minimal scope, nature and probable impact on the health care system should not require a board resolution.

The Emergency Exemption Rules reference substantial compliance for an exemption back to Series 65-7 which is being replaced by the Emergency CON Rules.

If you have questions, please contact me at (304) 388-7627.

Sincerely,



David L. Ramsey  
President and CEO  
Charleston Area Medical Center, Inc.