

## SUMMARY OF COMMENTS RECEIVED AND CHANGES MADE TO TITLE 65, SERIES 32, CERTIFICATE OF NEED RULE

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

Both the WVHA and the HCA objected to the use of the word “exemption” and the listing of the requirements pertaining to exemption contained throughout the rule. These references have been eliminated and the appropriate language inserted into the pertinent exemption rules.

Goodwin and Goodwin requested that the definition of private office practice be amended to include a provision for management agreements. This amendment has been made in section 2.10.e.

CAMC and WVHA objected to the requirement that an “electronic copy on compact disc” of the application be filed with the Authority. This requirement has been eliminated.

The WVHA 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. This requirement, at their request, had been modified in the exemption process. However in regard to a full CON application this is not a new requirement. Since CON applications are more detailed, involve larger projects and have more public scrutiny, it is important that the Authority be assured that the applicant’s board is fully aware of the project and has committed to fund and support it.

The WVHA also requested that several other of the requirements contained in section 4 of the rule be removed. These include 1) policies for patient admission and uncompensated care – this is a longstanding requirement for CON applications and is important because the Authority needs this information to make one of the required findings in its decision. This required finding is that the project meets the needs of the medically underserved population, see WV Code §16-2D-12 (c); 2) copies of policies regarding employment of staff, etc.- this requirement has been removed; 3) impact of the construction on the applicant’s cost of providing health services – this requirement has been eliminated.

Both the WVHA and the HCA objected to the inclusion of “exemption” in section 5. This reference has been deleted.

The WVHA requested that the 15 day time period previously referenced in section 8.7 be reduced to 10 days. The Authority has adopted this suggestion and made the changes to the rule. In addition the Authority reduced the 180 day time period to 90 days.

The WVHA objected to the language in section 8.11 regarding the Authority’s ability to hold a hearing on its own initiative. This language has been removed as the authority to do so is in statute. Also, in 8.12, the language has been changed from “timeframe order” to “hearing order” to be consistent with the statute. Finally, the typographical error noted by the HCA in 8.9 has been corrected.

Both the HCA and the WVHA objected to the language in 9.2 and 9.3. This is standard language which has been in the CON rule for many years and is not a change. The automatic approval provision in

the new CON law requires that the Authority deny the application if these circumstances exist because there is no allowance for extending the review period beyond the stated 15 days, at the request of the applicant. Without this provision, the Authority would be forced to allow an application to be approved that did not merit approval. The HCA suggests that the Authority put the application on hold, however this is not permissible under the new time frames in the statute.

The HCA objected to the language in section 10 regarding the appropriate date for calculating notice. This date is governed by statute and begins with the date of the decision, therefore the HCA's suggestions are not feasible. However, the Authority did remove subsection 10.6 to avoid confusion. The Authority also reduced the time period in subsection 10.7 to 90 days, as opposed to one year, for the refiling of a denied application.

The Authority has adopted most of the suggested changes to sections 11 and 12 made by both the WVHA and the HCA regarding good cause, time periods and affected parties. The Authority retained the provision which permits it to participate in appeals as it is a party to the proceedings once the matter is appealed.

References to exemptions have been removed from sections 13, 14 and 16 as requested by the HCA and the WVHA.

Finally, the WVHA requested that the time period be reduced for issuing a determination of reviewability pursuant to section 18. This has been reduced from 60 days to 45 days contingent upon the requesting party supplying all of the necessary information in a timely manner.

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 65CSR32, CERTIFICATE OF NEED RULE**

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 65CSR32, Certificate of Need Rule**. We appreciate the Authority's swift action in filing the emergency rule pertaining to programmatic changes within the CON program and welcome the opportunity to now share our specific recommendations.

**§65-32-3. Certificate of Need Requirements.**

3.1. We recommend removing the sentence "If a new health service is exempt from certificate of need review by statute or rule, the Authority shall issue an exemption before the new health service is acquired, offered, or developed." WV Code §16-2D-10 provides for three exemptions that do not require "obtaining a certificate of need or applying to the authority for approval."

3.2. We recommend adding the words "or exemption, if required" at the end of this sentence before the words "from the Authority." WV Code §16-2D-11 requires application and approval for a number of exemptions that should fall under this prohibition.

**§65-32-4. Certificate of Need Application.**

4.1. We are in full support of an electronic submission option for certificate of need applications. However, the requirement that each application be submitted with an "electronic copy on compact disc" creates a technologic issue for several of our members. Many of our computers throughout our facilities lack the capability to "burn" information to a compact disc. Therefore, we would advocate for an online electronic submission option.

4.2.b. 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.

4.2.f. We suggest removing the requirement to include “policies for patient admission and provision of fully or partially uncompensated care” from the application. We believe this requirement would be over burdensome, and in many cases impractical. Furthermore, we do not believe this information is relevant to the certificate of need application.

4.2.i. We suggest removing the requirement to include “copies of existing or proposed policies with respect to employment of facility staff and, where applicable, admission to medical staff membership” from the application. We believe this requirement would be over burdensome, and in many cases impractical. Furthermore, we do not believe this information is relevant to the certificate of need application.

4.2.n. We suggest removing the requirement to include “the probable impact of the proposed construction on the applicant’s cost of providing health services” from the application. We believe this requirement would be over burdensome, and in many cases impractical. Furthermore, we do not believe this information is relevant to the certificate of need application.

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

We recommend removing the words “or request for exemption” from this section. All exemptions are subject to the Authority’s new proposed rule 65CSR29, Exemption From Certificate of Need. The access contemplated in this section would confuse, and perhaps exceed, the legislative authority relating to exemptions found at WV Code §16-2D-11. The scope of required information to be submitted for an exemption much more narrow than what is contemplated under this section.

#### **§65-32-8. Application Review Procedure.**

8.6. This subsection relates to WV Code §16-2D-13. To prevent misunderstanding and/or confusion we suggest including all applicable timelines and notification requirements found at WV Code §16-2D-13 in this subsection.

8.7. This subsection also relates to WV Code §16-2D-13. We recommend merging this subsection with 8.6 to prevent confusion. In addition, we believe the 15 day time limit for the Authority to determine completeness after additional information is submitted is unreasonably long. The original time limit to determine completeness is 10 days; we do not believe the determination of completeness after additional information is submitted would warrant an extra five days to make this determination.

8.11. This subsection permits the Authority to hold a public hearing on its own initiative. We do not believe the authority to initiate its own public hearing on a certificate of need application is contained in Article 2D of Chapter 16 of WV Code.

8.12. We would recommend replacing “timeframe order” with “hearing order” to be consistent with WV Code and prevent confusion.

**§65-32-9. Extensions of Review Periods.**

9.2. We recommend the removal of this subsection in its entirety. This would allow for a hypothetical determination to be made by the Authority on a certificate of need application, not contemplated in WV Code.

9.3.b. For the same reason as 9.2, we would recommend the removal of this subsection in its entirety.

9.3.c. This subsection references circumstances listed in section 8.6 as justification to deny a certificate of need application. We recommend moving this provision to section 8.6 for consistency and to avoid confusion.

**§65-32-10. Decision.**

10.7. We recommend narrowing the scope of this provision to only bar reapplication for a previously denied application in certain circumstances. For example, subsection 9.2 creates an ambiguous standard for the Authority to deny any application. As currently drafted, if the Authority decides that due to weather conditions it is impracticable to complete the review of a certificate of need application, it may deny the application. When that provision is read in conjunction with this subsection, an applicant could be barred from applying for a certificate of need for a new health service because a previous application was denied due to weather conditions.

**§65-32-11. Appeal of the Certificate of Need Decision.**

11.9. We suggest limiting the continuance authority to the Office of Judges judicial discretion, as opposed to setting a one year time limit on the continuance. We also suggest adding "Upon a showing of good cause." to the beginning of the first sentence to read "Upon a showing of good cause, the Office of Judges may grant a continuance of a hearing."

**§65-32-12. Judicial Review.**

12.1. We suggest removing the word "Authority's" at the end of the second sentence and replacing it with "Office of Judges."

12.2. The phrase "any party adversely affected by the Office of Judges review has standing to file an appeal" seems to create confusion. We suggest limiting this provision to only allow for affected persons party to the original hearing to have standing to file an appeal. Allowing "any party" at this stage in the process seems unfair and would frustrate the process. We would also oppose the Authority having standing to request an appeal at this stage. The point of the appeal to the Office of Judges is to review a decision that one of the parties to the original hearing disagreed with. By allowing the Authority to appeal the Office of Judges decision all but assures the Authority appealing decisions to overturn its original decision to Circuit Court. This will unnecessarily delay the application review process.

**§65-32-13. Progress Reports/Extension of Certificate of Need.**

13.1. This subsection, and accompanying subdivisions, should be amended to not include exemptions. Any provisions relating to exemptions should be contained in the Authority's new legislative rule 65CSR29, Exemption From Certificate of Need. The progress report contemplated in this section is not applicable to exemptions.

13.2. We suggest narrowing the language "any additional information" by adding "relating to the certificate of need." Also, we would recommend removing "or exemption" from this subsection and inserting an equivalent provision in the Authority's new legislative rule 65CSR29.

13.5. We would oppose the Authority deciding future applications completeness based on a failure to submit a progress report on a different certificate of need application. There is a separate process set up for the Authority to make a completeness determination on an application. Each application should be reviewed and decided on its own merits.

13.6. We would suggest removing mention of exemptions in this subsection and moving any applicable provision relating to exemptions to the Authority's new legislative rule 65CSR29, Exemption From Certificate of Need.

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

14.1. We would suggest removing "or exemption" from this subsection as the requirements for an exemption and a certificate of need are not analogous.

**§65-32-18. Declaratory Ruling or Ruling of Reviewability.**

18.4. We recommend reducing the time frame for the Authority to issue its ruling from the proposed 60 days, down to 30 days. For comparison, the Authority only has 45 days to review an exemption application and render a decision. We believe 30 days is ample time to determine reviewability.

The programmatic changes contemplated with the passage of Enrolled House Bill 4365 are 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

Charleston Area  
Medical Center

July 6, 2016

Marianne Kapinos  
General Counsel  
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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.

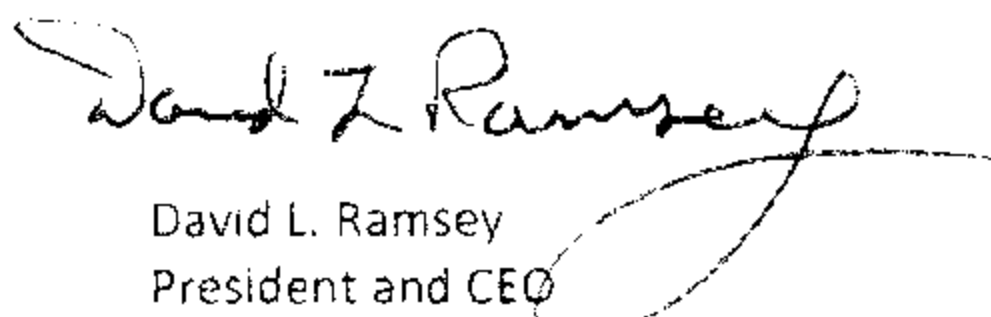
**Emergency Exemption Rule 65-29**

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

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.

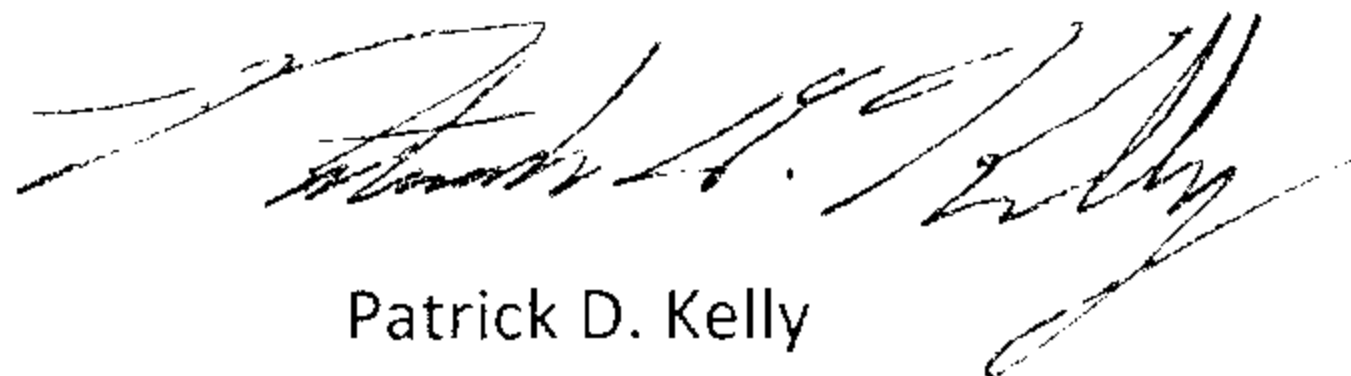
The Act does not require an applicant for exemption to proceed through a substantial review process. These additional steps add unnecessary costs.

#### **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



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July 11, 2016

Marianne Kapinos  
 General Counsel  
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 Charleston, WV 25311-1600

**Re: Comments Regarding Proposed Certificate of  
 Need Rule 65 C.S.R. 32**

Dear Ms. Kapinos:

MedExpress Urgent Care, Inc. – West Virginia (“MedExpress”) submits the following comments regarding Proposed Certificate of Need Rule 65 C.S.R. 32. MedExpress is a physician-owned practice and operates urgent care centers throughout West Virginia. Like many other physician-owned practices, MedExpress has a contractual relationship with a management services organization (“MSO”), Urgent Care MSO, LLC, for the provision of certain administrative services. MedExpress’ comments relate to the definition of “private office practice” as applied to a practice’s contractual arrangement with an MSO.

Under current law, a private office practice is exempt from Certificate of Need (“CON”) review. *See* W. Va. Code § 16-2D-10(1). To qualify as a “private office practice,” the practice must be an independent practice of one or more health professionals that “is not *controlled* directly or indirectly, in whole or in part, by any third person or entity.” W. Va. C.S.R. § 65-7-2.14.c (emphasis added). Pursuant to the rule, such “control can be manifested in one or more of the following ways”:

- 2.14.c.1.** The ability of a third person or entity to nominate, appoint, elect, or remove one or more members of the practice’s governing board or committee, or the ability of a third person or entity to exercise the voting power of one or more members of the governing board or committee by means of a voting trust, a voting agreement, proxy, or any other arrangement;



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**2.14.c.2.** The ability of a third person or entity to require its approval of an action that would otherwise be within the sole purview of the practice's governing board or committee, or the ability of a third person or entity to veto an action that would otherwise be within the sole purview of the governing board or committee, regardless of whether the approval or veto power is granted by the practice's organizational documents (partnership agreement, articles of incorporation, articles of organization, bylaws, policies, etc.), by contract, or by any other means;

**2.14.c.3.** The ability of a third person or entity to require the practice's governing board or committee to amend or restate its organizational documents; to incur or refinance indebtedness; to assign, sell, lease, mortgage, encumber, or otherwise transfer interests in the practice's assets; to merge, consolidate, or dissolve the practice; or to otherwise direct or require any other significant action that would otherwise be within the sole purview of the practice's governing board or committee; or

**2.14.c.4.** The agreement of any third person or entity (other than the lender or an insurer) to guarantee, pay, or otherwise discharge any indebtedness, liability, or other financial obligation of the practice.

W. Va. C.S.R. §§ 65-7-2.14.c.1 thru c.4. The proposed regulation does not alter this definition. *See* W. Va. C.S.R. § 65-32-2.10.c.

On several occasions, the West Virginia Health Care Authority (the "Authority") has approved of MedExpress' organizational structure. In 2008, the Authority concluded that MedExpress qualifies as a private office practice and is exempt from CON review:

MedExpress Urgent Care, PLLC – Wheeling has demonstrated that it [] meets the criteria as the private practice of one or more health professionals licensed to practice in this State. The Authority further determines that there has been no violation of CON law.

*In re: MedExpress Urgent Care, PLLC-Wheeling*, May 28, 2008 Decision on Possible Violation. CON File # 08-10-8679-PV. at p. 6.

In late 2010, in response to press coverage surrounding a new investment by General Atlantic and Sequoia Capital, the Authority once again requested information regarding MedExpress' corporate structure and its continued exemption from CON review. *See In re: MedExpress Urgent Care*, December 22, 2010 Letter, CON File # 11-WV-9352-PV. Following this second investigation, the Authority again ruled that the CON requirements simply did not apply:



Based upon a review of the relevant documents, the Authority has determined that MedExpress remains wholly owned by physicians and the affiliated organizations within the corporate structure do not exercise any type of control that would divest MedExpress of its status as a private office practice.

*In re: MedExpress Urgent Care*, March 22, 2011 Letter, CON File # 11-WV-9352-PV.

In 2011, the Authority promulgated regulations that provided some illustrative examples of the manner in which such “control” may manifest itself. *Compare* W. Va. C.S.R. § 65-7-2.14 (Mar. 29, 2007), *with* W. Va. C.S.R. § 65-7-2.14 (Apr. 13, 2011). As discussed above, these illustrative examples remain unaltered in the proposed rule. After the promulgation of the 2011 rules, the Authority again found that MedExpress qualified as a “private office practice” and that MedExpress’ management services agreement with Urgent Care MSO, LLC, did not divest MedExpress of control over its practice:

MedExpress has entered into a contract for administrative services and has not divested itself of control of its private office practice, either directly or indirectly, by engaging in this agreement. The main provision at issue is related to the MSO funding MedExpress in the event of a shortfall. This loan provision does not divest MedExpress of control but rather is a form of raising money to cover expenses that MedExpress may utilize. MedExpress may avert this provision by maintaining proper levels of liquidity in their accounts or seeking other sources of funding.

*In re: MedExpress Urgent Care, Inc. – West Virginia, and Optum Clinics Intermediate Holdings, Inc.*, November 20, 2015 Order, CON File # 11-WV-10493-PV, at pp. 8-9.

It is clear from the Authority’s precedent that MedExpress’ MSO arrangement satisfies the definition of “private office practice.” Despite the settled nature of this question, hospitals and MedExpress’ competitors continue to challenge MedExpress’ status as a private office practice. Accordingly, MedExpress proposes the Authority promulgate the following language to put an end to these incessant challenges:

Notwithstanding anything to the contrary, a management services organization’s provision of administrative services to a practice shall not constitute control, either direct or indirect, of the practice.

In the alternative, if the Authority does not wish to issue a broad statement regarding MSO arrangements, MedExpress proposes the Authority add the language set forth in Exhibit A, which is a codification of the Authority’s prior precedent concerning MSO arrangements. Again, MedExpress appreciates the opportunity to provide comments



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on the Proposed Rule. If you have any questions or require additional information, please feel free to contact me at 304-346-7000.

Sincerely,

Carte P. Goodwin

CPG/SLB

cc w/encl.: Frank W. Alderman, M.D., CEO (Via E-Mail)

TITLE 65  
LEGISLATIVE RULE  
HEALTH CARE AUTHORITY

SERIES 32  
CERTIFICATE OF NEED RULE



**§65-32-1. General.**

1.1. Scope. -- This legislative rule implements the provisions of the Certificate of Need program found at W. Va. Code §16-2D-1 et seq. as administered by the West Virginia Health Care Authority.

1.2. Authority. -- W. Va. Code §§16-2D-4(a)(1), (4), (7) and (8), 16-29B-8(a)(1) and 16-29B-11.

1.3. Filing Date. --

1.4. Effective Date. --

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

**§65-32-2. 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 section. Terms not defined in the Act have the following meanings unless the context expressly requires otherwise.

2.1. "Acquire a Health Care Facility" means to obtain by purchase, donation, lease, stock transfer or comparable arrangement a health care facility's assets used in the provision of health services or a majority of stock, including the transfer of a health care facility from a subsidiary corporation to its parent corporation or vice versa or including a change or transfer of the licensee of the health care facility.

2.2. "Act" means the certificate of need act, W. Va. Code §16-2D-1 et seq.

2.3. "Batching" means the consideration of completed certificate of need applications which are grouped by the date they are deemed complete. There are two batches each month: one on the fifteenth day of the month and one on the last day of the month. If either of these dates fall on a Saturday, Sunday or legal holiday, the applications will be batched on the next business day.

2.4. "Authority" means the West Virginia Health Care Authority established pursuant to W. Va. Code §16-29B-5 and which is designated to administer the certificate of need program by W. Va. Code §16-29B-11.

2.5. "Certificate of Need" means a document issued by the Authority which indicates that a proposed new health service is in compliance with the intent, purposes and provisions of W. Va. Code §16-2D-1 et seq., and that a need exists for the proposed new health service.

2.6. "Consistent With The State Health Plan" means a determination made by the Authority that the preponderance of the evidence supports the achievement of the applicable provisions of the State Health

Plan unless the Plan is in conflict with any statute or rule.

2.7. "Diagnostic services" means, the offering or development of laboratory or imaging services including but not limited to, radiology, ultrasound, mammography, fluoroscopy, nuclear imaging, densitometry, and computerized tomography

2.8. "Emergency Circumstances That Pose A Threat To Public Health" means those circumstances proclaimed by the Secretary of the Department of Health and Human Resources to be an emergency which pose a threat to public health or those circumstances upon which a state of emergency is declared pursuant to W. Va. Code §15-5-6.

2.9. "Health Care Facility" has the same meaning as contained in W. Va. Code §16-2D-2(16), but does not include state homes for qualified veterans as defined in W. Va. Code §9A-2-1, or any institution operated by or on behalf of the West Virginia Division of Corrections.

2.10. "Private Office Practice" means the independent practice of one or more health professionals that meets the following requirements:

2.10.a. The independent practice of one or more health professionals consists of one profession and is licensed, authorized, or organized pursuant to the provisions of Chapter 30 of the West Virginia Code in one of the following ways:

2.10.a.1. As a sole proprietorship wholly owned and operated by a health professional who is duly licensed pursuant to the provisions of Chapter 30 of the West Virginia Code;

2.10.a.2. As a partnership wholly owned and operated by two or more health professionals who are duly licensed pursuant to the provisions of Chapter 30 of the West Virginia Code;

2.10.a.3. As a professional corporation duly registered with or certified by the appropriate health professional licensure board; or

2.10.a.4. As a professional limited liability company duly registered with or certified by the appropriate health professional licensure board.

2.10.b. Practice composition:

2.10.b.1. If the practice is a for-profit entity, the entity must be owned exclusively by health professionals, all of whom are duly licensed to practice in the State of West Virginia.

2.10.b.2. If the practice is a non-profit entity and has a membership, all of the members of the entity must be health professionals, all of whom are duly licensed to practice in the State of West Virginia.

2.10.b.3. If the practice is a non-profit entity and does not have a membership, the governing body of the entity must be composed exclusively of health professionals, all of whom are duly licensed to practice in the State of West Virginia.

2.10.c. The independent practice of health professionals is not controlled directly or indirectly, in whole or part, by any third person or entity. That control can be manifested in one or more of the

following ways:

2.10.c.1. The ability of a third person or entity to nominate, appoint, elect, or remove one or more members of the practice's governing Authority or committee, or the ability of a third person or entity to exercise the voting power of one or more members of the governing Authority or committee by means of a voting trust, a voting agreement, proxy, or any other arrangement;

2.10.c.2. The ability of a third person or entity to require its approval of an action that would otherwise be within the sole purview of the practice's governing Authority or committee, or the ability of a third person or entity to veto an action that would otherwise be within the sole purview of the governing Authority or committee, regardless of whether the approval or veto power is granted by the practice's organizational documents (partnership agreement, articles of incorporation, articles of organization, bylaws, policies, etc.), by contract, or by any other means; *Provided*, that the following agreements between a practice and a management services organization do not constitute control:

..... (a) an agreement for the practice to maintain certain levels of insurance and to name the management services organization as an additional insured;

..... (b) an agreement for the management services organization to prepare financial records, books, tax returns, and other administrative documents for the practice; and

..... (c) an agreement permitting the management services organization to withdraw funds from designated accounts of the practice;

2.10.c.3. The ability of a third person or entity to require the practice's governing Authority or committee to amend or restate its organizational documents; to incur or refinance indebtedness; to assign, sell, lease, mortgage, encumber, or otherwise transfer interests in the practice's assets; to merge, consolidate, or dissolve the practice; or to otherwise direct or require any other significant action that would otherwise be within the sole purview of the practice's governing Authority or committee; *Provided*, That an agreement between a practice and a management services organization for the deferral of the management services organization's fees and/or the advancement of third-party vendor fees does not constitute control; or

2.10.c.4. The agreement of any third person or entity (other than the lender or an insurer) to guarantee, pay, or otherwise discharge any indebtedness, liability, or other financial obligation of the practice; *Provided*, That an agreement between a practice and a management services organization for the advancement of third-party vendor fees does not constitute control.

2.10.d. For purposes of this definition, the term "third person or entity" shall not include any person who is a health professional duly licensed pursuant to the provisions of Chapter 30 of the West Virginia Code, and who is participating in the practice as either the owner of a sole proprietorship, a partner of a partnership, a shareholder of a proprietary professional corporation, a member of a nonprofit professional corporation or a professional limited liability company, or an employed provider of professional health services to patients of the practice. All other persons constitute a "third person or entity".

2.10.e. Notwithstanding anything in this subsection 2.10 to the contrary, any practice granted a determination of nonreviewability as a private office practice by the Authority on or before July 1, 2010 is and shall remain a private office practice under the Act; provided there has been no material change in

the facts and circumstances provided in the original request for determination of reviewability.

2.11. "Project" means a proposed new health service.

2.12. "Proposed New Health Service" means:

2.12.a. The construction, development, acquisition or other establishment of a new health care facility including the acquisition of a health care facility which is not currently in operation or is not currently being operated as a health care facility but which has been operated as one in the past;

2.12.b. The partial or total closure of a health care facility with which a capital expenditure is associated;

2.12.c. Any obligation for a capital expenditure incurred by or on behalf of a health care facility in excess of the expenditure minimum or any obligation for a capital expenditure incurred by any person to acquire a health care facility. An obligation for a capital expenditure is considered to be incurred by or on behalf of a health care facility:

2.12.c.1. When a contract, enforceable under state law, is entered into by or on behalf of the health care facility for the construction, acquisition, lease or financing of a capital asset;

2.12.c.2. When the health care facility takes formal action to commit its own funds for a construction project undertaken by the health care facility as its own contractor; or

2.12.c.3. In the case of donated property, on the date on which the gift is completed under state law;

2.12.d. A substantial change to the bed capacity of a health care facility with which a capital expenditure is associated;

2.12.e. The addition of any health service specified in section 20 of this rule and which was not offered on a regular basis within the twelve-month period prior to the time the services would be offered;

2.12.f. The addition of ventilator services by a hospital;

2.12.g. The elimination of one or more health services, previously offered on a regular basis by or on behalf of a health care facility when the elimination is associated with a capital expenditure;

2.12.h. A substantial change to the bed capacity or health services offered by or on behalf of a health care facility, whether or not the change is associated with a proposed capital expenditure, if the change is associated with a previous capital expenditure for which a certificate of need was issued and if the change will occur within two years after the date the activity which was associated with the previously approved capital expenditure was undertaken;

2.12.i. The expansion of any of the following health services, whether or not the expansion is associated with a capital expenditure: open heart surgery rooms, cardiac catheterization laboratories, radiation therapy equipment, magnetic resonance imaging (MRI) equipment or PET scanners;

2.12.j. The acquisition of major medical equipment;

2.12.k. A substantial change in an approved new health service for which a certificate of need is in effect;

2.12.l. An expansion of the service area for hospice or home health agency, regardless of the time period in which the expansion is contemplated or made; or

2.12.m. The addition of health services which were not offered on a regular basis by or on behalf of the health care facility within the twelve month period prior to the time the services would be offered.

2.13. "Undertaken," when used to describe an activity for which a certificate of need has been issued or for which an exemption was granted, means the first use of the new health service for its intended purpose.

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

### **§65-32-3. Certificate of Need Requirements.**

3.1. A new health service as defined by W. Va. Code §16-2D-8 may not be acquired, offered or developed within this state unless the Authority has issued a certificate of need for the new health service. If a new health service is exempt from certificate of need review by statute or rule, the Authority shall issue an exemption before the new health service is acquired, offered, or developed.

3.2. A person or health care facility may not knowingly charge or bill for a health service as defined by W. Va. Code §16-2D-8 without first obtaining a certificate of need from the Authority.

3.3. Any charge or bill for a defined health service for which a certificate of need has not been issued by the Authority is void and legally unenforceable.

3.4. A transfer of equipment or facilities for less than fair market value is a new health service if a transfer of the equipment or facilities at fair market value would be subject to review by the Authority.

3.5. The Authority may determine a series of expenditures, each less than the expenditure minimum, which, when taken together, are in excess of the expenditure minimum, to be a single expenditure subject to the review of the Authority. In making that determination, the Authority shall consider the following:

3.5.a. Whether the expenditures are for components of a system which is required to accomplish a single purpose;

3.5.b. Whether the expenditures are to be made over a two-year period and are directed towards the accomplishment of a single goal; or

3.5.c. Whether the expenditures are to be made within a two-year period within a single department and constitute a significant modernization of the department.

### **§65-32-4. Certificate of Need Application.**

4.1. An application for a certificate of need shall be on forms approved by the Authority. The applicant

shall submit the original and one (1) paper copy and one (1) electronic copy on compact disc in Microsoft Word of the application to the Authority. The application shall have a verification signed by the Chief Executive Officer and the person or persons who prepared the application.

4.2. The application shall, at a minimum, include the following:

4.2.a. The identification of the applicant;

4.2.b. 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;

4.2.c. A description of the project;

4.2.d. A timetable for implementation of the project, including the projected date for incurring the obligation for any capital expenditure;

4.2.e. A documented analysis of the need of the population to be served by the project, including the medically underserved, and the extent to which the proposed service will be accessible to the population;

4.2.f. Policies for patient admission and provision of fully or partially uncompensated care;

4.2.g. A documented analysis of alternatives considered by the applicant;

4.2.h. A documented analysis of the proposal's relationship to the existing health care system, including providers of direct, ancillary, and support services and health professional training programs in the area in which services are to be provided, and, when applicable, the extent to which the proposal will meet the needs of those training programs;

4.2.i. A documented analysis of the proposal's relationship to the state health plan;

4.2.j. An analysis of the relationship of the proposal to the most recent statements of deficiencies and plans of corrections from surveys conducted by accreditation organizations and other federal, state and local inspection agencies, as well as copies of those survey reports or portions of the reports as may be required by the Authority;

4.2.k. Documentation of the availability of resources, including health care providers, management personnel and funds for capital and operating needs;

4.2.l. Copies of existing or proposed policies with respect to employment of facility staff and, where applicable, admission to medical staff membership;

4.2.m. A preliminary financial feasibility study which includes an analysis of historical and projected utilization, charges, sources of revenue, statements of revenues and expenses, a statement of changes in fund balance, a statement of cash flows, balance sheets, and a statement of the specific assumptions upon which the feasibility study was based;

4.2.n. In the case of construction projects, a documented analysis of the cost and methods of the proposed construction, including the probable impact of the proposed construction on the applicant's

cost of providing health services; and

4.2.o. If applicable, a documented analysis of the needs and circumstances of research projects.

**§65-32-5. Access to Information and Facilities.**

Upon proper notice, and when reasonable and necessary in the performance of the Authority's responsibilities in administering the certificate of need program, the Authority shall have access to any information, records, meetings, sites and/or facilities pertinent to an application or request for exemption under review by the Authority.

**§65-32-6. Additional Information or Amendments to Application.**

6.1. After the review of an application has begun, the Authority may require the applicant to submit additional information. If no hearing is requested upon the application, and the applicant fails to submit the information within the time directed or if the applicant submits a substantial amendment to its application, the Authority may extend the review cycle for fifteen days at the request of the applicant.

6.2. If the additional information requested is not sufficient to satisfy the Authority's request or not timely received, the Authority may deny the application.

6.3. The Authority may examine the extent of additional information provided or any amendment made by the applicant regarding the application currently under consideration by the Authority and determine the application to be a new proposal subject to a new review cycle. The Authority shall notify the applicant of the determination, in writing, and further advise the applicant of the dates in the new review cycle. The Authority shall also publish notice of its action on its website.

**§65-32-7. Application Withdrawal.**

7.1. An applicant may withdraw an application under consideration by the Authority at any time prior to the issuance of a final written decision. The withdrawal of the application is without prejudice.

7.2. The applicant shall file with the Authority a written notice withdrawing the application before the issuance of a final written decision.

**§65-32-8. Application Review Procedure.**

8.1. Any person proposing a new health service shall file with the Authority a letter of intent ten (10) days before the submission of an application. The letter of intent shall contain sufficient information to advise the Authority of the nature, scope, cost and timing of the project, as well as the location and name of the proposed applicant.

8.2. Notification of receipt of the letter of intent shall be published in a newspaper of general circulation in the area where the health service is being proposed. The newspaper notice shall contain a statement that further information regarding the application is on the Authority's website. The notification in the newspaper shall be provided within five (5) days of receipt of the letter of intent. A copy of the letter of intent shall be placed on the Authority's website.

8.3. A certificate of need application must be filed ten (10) days after the letter of intent.

8.4. The application must be accompanied by the appropriate fees as defined in W. Va. Code §16-2D-13(b)(2). An application will not be accepted without the appropriate fee.

8.5. A copy of the application must be submitted to the Director of the Office of Insurance Consumer Advocacy.

8.6. Upon receipt of a certificate of need application, the Authority shall determine whether the application is complete or whether additional information is required. A declaration by the Authority that an application is complete means that there is sufficient information contained in the application for the Authority to make an informed decision. It does not mean that the approval of the application is warranted. Except in emergency situations that pose a threat to the public health, the Authority shall not declare an application complete if:

8.6.a. The applicant is a health care facility subject to the financial disclosure provisions of W. Va. Code §16-5F-1 et seq. or W. Va. Code §16-29B-1 et seq., and the health care facility has failed to file with the Authority all reports, records, data or other information required by the Code and the rules promulgated pursuant to the Code.

8.6.b. Information provided in the application differs from information provided in the letter of intent; and

8.6.c. The application is not timely filed as provided in section 8.3 of this rule.

8.7. The Authority shall make a determination of completeness within ten (10) days of its receipt of the application. If the Authority determines that the application is not complete, it may request additional information or ask additional questions. Upon receipt of the additional information, the Authority has fifteen (15) days within which to determine if the application is complete. If the applicant fails to respond within one hundred eighty (180) days, the application is considered withdrawn. If the applicant later desires to pursue the project, the applicant shall file a new letter of intent and an application.

8.8. Upon a determination by the Authority that an application is complete, the Authority shall notify the applicant in writing.

8.9. The Authority may batch completed application for review on the fifteenth day of the month or the last day of the month in which the application was deemed complete. The Authority shall publish on its website a notice of review for each batch. The notice shall, at a minimum, shall contain the following:

8.9.a. The name of the applicant;

8.9.b. A description of the proposed project;

8.9.c. The date the review cycle begins;

8.9.d. The last date for an affected person to request a public hearing;

8.9.e. The file closing date if no public hearing is requested; and

8.9.f. The last date upon which the Authority will issue a decision;

8.10. When a determination of completeness is made by the Authority and the notice specified in subsection 8.9 of this rule is published, affected persons may request a public hearing within thirty (30) days from the batch date. A request for a public hearing shall be in writing and shall be addressed to: General Counsel, West Virginia Health Care Authority, Certificate of Need Program, 100 Dee Drive, Suite 201, Charleston, West Virginia 25311.

8.11. The Authority shall hold a public hearing on an application if it is requested within the time period specified by subsection 8.14 of this rule by any affected person. The Authority may also hold a public hearing upon its own initiative. The Authority shall conduct the public hearing in accordance with the requirements for administrative hearings found in W. Va. Code §29A-5-1 et seq.

8.12. A timeframe order shall be entered by the Authority within fifteen (15) days from the last date an affected person may request an administrative hearing on a certificate of need application.

8.13. The timeframe order shall contain, at a minimum, the following:

8.13.a. The date of the hearing;

8.13.b. The date of the prehearing conference;

8.13.c. The last date to submit replacement pages;

8.13.d. The last date to file motions for discovery;

8.13.e. The completion date for discovery;

8.13.f. The last date to file all motions which must be a minimum of three (3) days prior to the prehearing conference; and

8.13.g. The last date to file requests for subpoenas and/or subpoenas duces tecum.

8.14. The hearing shall be conducted no later than three (3) months from the date the hearing order is entered by the Authority and in accordance with the administrative hearing requirements in W. Va. Code §29A-5-1, et. seq.

8.15. When a public hearing is scheduled to be conducted upon an application, the Authority shall, prior to the hearing, provide notice to all parties and publish notice on its website. The notice shall, at a minimum, contain the following:

8.15.a. The name of the applicant;

8.15.b. A description of the proposed project;

8.15.c. The date of the public hearing; and

8.15.d. The date of any prehearing conference.

8.16. Whenever a public hearing is scheduled upon any application, the Authority may direct the

parties to appear for a prehearing conference. The prehearing conference may be held before any member of the board or before a hearing examiner appointed by the board. The board or its designee shall designate parties to the public hearing at the prehearing conference. The Authority may designate affected persons as parties after the prehearing conference only for good cause shown.

8.17. Parties shall file all prehearing motions with the Authority a minimum of three days prior to the prehearing conference or in accordance with the date established by the time frame order entered in the case, whichever is sooner. The Authority or its designee may consider motions at the prehearing conference.

8.18. Parties shall exchange a list of all witnesses and copies of all documents to be presented or introduced at a public hearing with all other parties to the hearing. The witness lists and the copies of the documents shall be filed by the parties with the Authority or its designee during or prior to the prehearing conference unless a different date is established by the Authority or its designee. Failure to comply with this section is sufficient grounds for the Authority or its designee to disallow the testimony of a proposed witness or disallow the introduction of any exhibit.

8.19. Parties shall file the original and one copy of all communications concerning a pending application with the Authority. A standard certificate of service shall be attached to each written communication which shows that copies have been sent by the regular United States Mail, postage prepaid, to all other parties to the matter. A list of all parties to a matter may be obtained from the Authority. The Authority or its designee may strike a written communication from the record if it does not comply with the requirements of this section.

8.20. The Authority may subpoena witnesses, papers, records, documents and any other information or data it considers necessary for its determination. The Authority shall issue all subpoenas and subpoenas duces tecum in the name of the Authority. Any party requesting a subpoena or subpoena duces tecum is responsible for seeing that they are properly served. Service of subpoenas or subpoenas duces tecum issued at the instance of the Authority is the responsibility of the Authority.

8.21. All requests for subpoenas and subpoenas duces tecum shall be in writing and shall contain a statement acknowledging that the requesting party agrees to pay all fees for the attendance and travel of witnesses.

8.22. Every subpoena or subpoena duces tecum issued at the request of a party shall be served by the party at least five (5) days before the return date, either by personal service by a person over eighteen (18) years of age or by registered or certified mail, return receipt requested. If service is by mail, the five (5) day notice period shall not begin until the date the person or entity receives the subpoena or subpoena duces tecum.

8.23. Fees for the attendance of witnesses are the same as for witnesses before the circuit court of this State and shall be paid by the party requesting the issuance of the subpoena or subpoena duces tecum.

8.24. In any case of disobedience or neglect of any subpoena or subpoena duces tecum issued by the Authority, or any refusal of a witness to testify to any matter regarding which he or she may be lawfully interrogated, the Authority may apply to the Circuit Court of Kanawha County, and the court shall compel obedience through the same manner as a subpoena or subpoena duces tecum is enforced in Kanawha County Circuit Court.

8.25. The affected parties may engage in discovery as provided by the West Virginia Rules of Civil Procedure. The scope of discovery is limited to relevant and admissible evidence. Affected parties engaging in discovery are required to file a copy of the certificate of service attached to the discovery request or response with the Authority. Affected parties shall not file copies of the actual discovery and responses with the Authority.

8.26. In a public hearing, any party may be represented by counsel and may present oral or written arguments and evidence relevant to the matter which is the subject of the hearing. Any party may conduct reasonable cross-examination of persons who testify at the proceeding.

8.27. All witnesses who testify during a hearing are first subject to oath or affirmation.

8.28. The Authority shall maintain a verbatim record of the public hearing.

8.29. After the commencement of a public hearing on an application, and before a decision is rendered by the Authority, there shall be no ex parte contacts between the applicant, any person acting on behalf of the applicant or any person opposed to the application with the Authority or any of its employees or agents who exercise any responsibility regarding the application.

8.30. If a public hearing is not conducted during the review of an application, the Authority shall close the file on the thirty-fifth day after the batch date. After this date, no other factual information or evidence may be considered by the Authority.

8.31. The Authority shall review an uncontested certificate of need application within sixty (60) days from the date the application is batched. An uncontested application is deemed approved if the Authority does not issue a decision within this time period unless an extension, up to fifteen (15) days is requested by the applicant as provided in section 9 of this rule.

8.32. In the event a hearing is conducted on the certificate of need application, the Authority shall issue a decision within forty-five (45) days of the closing of the file in the administrative proceedings.

8.33. At any time prior to the file closing date, the Authority shall, upon request, provide a detailed itemization of the documents in the Authority's file on a proposed new health service.

8.34. The Authority may, after the publication of a notice on its website and allowing thirty (30) days after the publication for public comment, adopt population projections for use in certificate of need decisions.

#### **§65-32-9. Extensions of Review Periods.**

9.1. At any time during the Authority's review of an application, the Authority may grant the applicant's request that the running of the review period be extended for fifteen (15) days.

9.2. Upon a finding by the Authority that it would not be practicable to complete the review of an application within the time provided by this rule, the Authority may deny the application.

9.3. Situations which would make it impracticable for the Authority to complete its review within the time provided by this rule include, but are not limited to the following:

9.3.a. The Authority has requested additional information from the applicant and the applicant has failed to provide all of the information to the Authority in the time frame directed by the Authority;

9.3.b. Weather conditions or other natural disasters have prevented the review process from taking place in a timely manner; and

9.3.c. Any of the circumstances listed in section 8.6 of this rule.

9.4. If the Authority issues an extension of the review period, it may also extend the file closing date.

**§65-32-10. Decision.**

10.1. Except as provided later in this section, the Authority shall issue a certificate of need only if it makes the following written findings:

10.1.a. That the proposed new health service is needed;

10.1.b. With the exception of emergency circumstances that pose a threat to the public health, that the new health service is consistent with the State Health Plan. If the proposed new health service is not discussed in the State Health Plan, the Authority shall not disapprove the application solely for that reason;

10.1.c. That superior alternatives to the services in terms of cost, efficiency and appropriateness do not exist and that the development of alternatives is not practicable;

10.1.d. Existing facilities providing similar services to those proposed are using those services in an appropriate and efficient manner;

10.1.e. In the case of new construction, alternatives to new construction have been considered and have been implemented to the maximum extent possible, including modernization and sharing arrangements;

10.1.f. Patients will experience serious problems in obtaining care of the type proposed in the absence of the proposed new service; and

10.1.g. In the case of a proposal for the addition of beds for the provision of skilled nursing or intermediate care services, the addition will be consistent with the plans of other agencies of the state responsible for the provision and financing of long-term care facilities or services including home health services.

10.2. If the Authority finds that the facility or service with respect to which a capital expenditure is proposed by the applicant is required to eliminate or prevent imminent safety hazards as defined by federal, state or local fire, building or life safety codes or rules and regulations, to comply with state licensure requirements, or to comply with accreditation or certification standards, and that the obligation of the capital expenditure is consistent with the State Health Plan, then the Authority shall approve the application to the extent that the capital expenditure is required to eliminate the hazards or meet the standards of accreditation or certification.

10.3. If the Authority disapproves a proposed new health service for its failure to meet the needs of medically underserved populations, the finding shall be in writing.

10.4. The final decision of the Authority upon an application shall be in the form of an approval, a denial or an approval with conditions. If the approval is with conditions, the Authority shall not impose upon the applicant a new health service not originally proposed by the applicant. The Authority may only issue a certificate of need with conditions if the conditions directly relate to the criteria found in the Act or any rule promulgated by the Authority. Conditions may be imposed upon the operations of the applicant for a period not exceeding three (3) years.

10.5. The Authority shall send its decision by certified mail to the applicant and to any affected party. The Authority shall also make the decision available to other persons upon request. The Authority shall also publish notice on its website.

10.6. For the purposes of this rule, the date upon which the affected person filing the request for review received notice of the Authority's decision means the date upon which legal notice of the decision appears on its website.

10.7. An applicant shall not file any application for a new health service for which a certificate of need has been denied by the Authority for a period of one year from the date that the case has reached a final resolution. This prohibition does not apply if the State Health Plan standards relating to the new health service are amended after the date of the decision to the extent that an approval of the application would be required by the Authority.

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

11.1. 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. A request for review must be received by the Office of Judges within thirty (30) days after the date of the Authority's decision.

11.2. Affected persons shall address or deliver a request for review to: West Virginia Health Care Authority/Office of Judges, P.O. Box 3585, Charleston, West Virginia 25328. Affected persons shall also address or deliver a copy of the request to the Authority.

11.3. To the extent not inconsistent with section 16 of the Act, for the purpose of administrative review of the Authority's decision, the Office of Judges shall conduct its proceedings in conformance with the West Virginia Rules of Civil Procedure and the Local Rules for the Circuit Court of Kanawha County, and its review of appeals in accordance with the provisions governing the judicial review of contested administrative cases in W. Va. Code §29A-5-4.

11.4. The Authority may stay the effect of the Authority's decision pending review. The stay shall be in writing and at the request of the person appealing the Authority's decision or the applicant seeking a certificate of need.

11.5. The person requesting a review of the Authority's decision shall, as part of the request, include an assignment of errors.

11.6. If a person requesting the review of the Authority's decision fails to appear at the date, time

and place of the hearing, the Office of Judges shall, unless good cause is shown, dismiss the request for review.

11.7. The Office of Judges shall send its written findings to the person who requested the review, the person proposing the new health service, all other affected parties and the Authority. The Authority shall make copies of the decision available to others upon request.

11.8. If the Office of Judges remands the matter to the Authority, the remand order may establish a date by which the Authority shall complete further action. The order shall also state whether any findings or rulings of the Authority have been reversed or revised.

11.9. The Office of Judges may grant a continuance of a hearing. If a request for a general continuance is made, and neither the person requesting the review or the applicant seeking the certificate of need for a new health service object, the Office of Judges may grant the request for a general continuance. If the continuance continues for more than one (1) year, the review is withdrawn with prejudice.

#### **§65-32-12. Judicial Review.**

12.1. Any final decision of the Office of Judges granting, denying or withdrawing a certificate of need or exemption may be appealed to the Circuit Court of Kanawha County. The appellant shall file an appeal within thirty (30) days after the date of the Authority's decision.

12.2. Any party adversely affected by the Office of Judges review has standing to file an appeal. For the purposes of this section, a "person adversely affected by the review" means the Authority and any person who meets the definition of "affected person" under section 2 of the Act.

12.3. For the purposes of this section, no decision of the Authority is considered final until it is reviewed by the Office of Judges pursuant to section 11 of this rule or until the time for an appeal has elapsed. No circuit court has jurisdiction to consider a decision of the Authority if the petitioner has failed to file a request for review with the Office of Judges within the time permitted under section 11 of this rule, or, if a request for review was filed, the person requesting the review has failed to pursue the review and the Office of Judges has dismissed the request for review with prejudice.

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

13.1. Any person holding a certificate of need or who has been granted an exemption shall submit to the Authority, in writing, a report on the progress being made toward completion of the approved project according to the timetable contained in the application. The progress report must contain a verification signed by the Chief Executive Officer and shall be submitted at least forty-five (45) days prior to the expiration of the certificate of need or exemption, or at any other time directed by the Authority. The report shall include, at a minimum, the following:

13.1.a. The current status of the project in relation to the timetable in the application;

13.1.b. The projected date of completion;

13.1.c. The cause or causes of any delays encountered;

13.1.d. Changes in the project, including any proposed changes for which a request is made for

the Authority to determine whether the proposed change is reviewable as a substantial change or that an exemption previously granted should be withdrawn and the applicant be required to obtain a certificate of need for failure to meet the requirements of the exemption;

13.1.e. The projected total cost; and

13.1.f. Compliance with any conditions of certification.

13.2. Any person holding a certificate of need or exemption shall submit any additional information requested by the Authority.

13.3. The creation of shelled in space shall not be considered completion of the project unless explicitly permitted in the Authority's decision granting the certificate of need.

13.4. The Authority may not impose new conditions which are unrelated to the representations made by the applicant.

13.5. Any failure to submit a complete and timely progress report is sufficient grounds for the Authority to determine that any future certificate of need application is not complete.

13.6. The applicant shall incur an obligation for a capital expenditure associated with an approved project or exemption within twelve (12) months of issuance of the certificate of need or exemption, unless the Authority has approved a timetable for the obligation of a series of obligations for capital expenditures for discrete components to be incurred over a period longer than twelve (12) months. If the Authority has approved a timetable for the obligation of a series of obligations for capital expenditures for discrete components to be incurred over a period longer than twelve (12) months, the applicant shall incur the obligation for the first component within twelve (12) months after the issuance of the certificate of need or exemption.

13.7. Upon good cause shown, the Authority may extend the duration of a certificate of need or exemption for up to six (6) months. If the obligation required to be incurred by subsection 13.6 of this rule is not incurred within eighteen (18) months of the issuance of the certificate of need or exemption, the certificate or exemption automatically expires.

13.8. If the obligation required to be incurred by subsection 13.6 of this rule is incurred within the prescribed time period, the applicant may request a renewal of the certificate of need in order to complete the project.

13.9. If a renewal review is underway, the Authority shall automatically extend the old certificate of need until the completion of the renewal review.

13.10. The Authority may grant a renewal of the certificate of need for time periods that are determined appropriate.

13.11. If a request for renewal of a certificate of need is not made before its expiration, the certificate automatically expires. For good cause shown, the Authority may waive the effect of this subsection and permit the extension of the certificate of need during the renewal review period.

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

14.1. In determining whether changes proposed to an approved project for which a certificate of need or exemption has been issued are substantial, the Authority shall consider the following as prima facie evidence of a substantial change.

14.1.a. A change in the location of the approved project which reduces the accessibility of patients who otherwise have no alternative to the services reasonably available or the change in location would adversely affect or impact an existing health care facility;

14.1.b. A change in the service area of the approved project;

14.1.c. A change in the location of the approved project to a county that was not significantly impacted by the proposal when it was originally approved;

14.1.d. An addition in the number of beds or a change in the types of beds;

14.1.e. The acquisition of major medical equipment not described in the application as part of the project or a capital expenditure for major medical equipment in excess of ten percent (10%) over the approved capital expenditure for medical equipment;

14.1.f. The addition of health services;

14.1.g. An increase or decrease in square footage in excess of 10% of the originally approved footage or 1,000 square feet, whichever is greater; and

14.1.h. An unapproved capital expenditure, or an increase in the approved capital expenditure which is in excess of the expenditure minimum or in excess of 20% of the originally approved capital expenditure, whichever is less.

14.2. An applicant shall not make a proposed substantial change to a previously approved project until the Authority has made a determination of the need for review. The Authority shall issue its decision on whether a new certificate of need review is required. The Authority shall issue its decision within fifteen (15) days of its receipt of the request from the applicant or, if additional information is requested by the Authority, within fifteen (15) days of its receipt of the additional information.

14.3. Any failure to inform the Authority of a proposed substantial change to a previously approved project may result in the Authority withdrawing the certificate of need.

#### **§65-32-15. Transferability.**

15.1. A certificate of need is nontransferable. A transfer includes the sale, lease, transfer of stock or partnership shares, or other comparable arrangement which has the effect of transferring the control of the owner of the certificate of need.

15.2. If the Authority finds that a certificate of need has been transferred, the Authority shall withdraw the certificate.

#### **§65-32-16. Substantial Compliance Review.**

16.1. The Authority shall conduct a substantial compliance review of all new health services for which it has issued a certificate of need or for which it has granted an exemption. No later than forty-five (45) days prior to licensure or the undertaking of the activity for which a certificate of need was issued or an exemption granted, the applicant shall request, in writing, that the Authority undertake a substantial compliance review. The request shall contain a verification signed by the Chief Executive Officer.

16.2. The Authority shall issue its findings as to substantial compliance within forty-five (45) days of its receipt of a request for the review. If the Authority finds that the project is not in substantial compliance with its certificate of need or exemption, the Authority may withdraw the certificate or exemption and the Authority may direct that any license to operate the new service be revoked or denied, or the Authority may impose appropriate fines and/or seek an injunction against the use or operation of the new service.

16.3. If the Authority determines that it would be impracticable for the applicant to prepare and submit final cost figures for the project prior to the time the project is ready to be licensed or ready to undertake the activity for which a certificate of need was issued, the Authority may issue a conditional notice of substantial compliance, authorizing the licensure or the undertaking of the activity, for up to twelve (12) months. The applicant shall prepare and submit documented final cost figures within the time designated by the Authority in its notice of substantial compliance. The Authority may withdraw a certificate of need if the applicant fails to submit the final cost figures within the time designated by the Authority. The Authority may impose appropriate fines and seek an injunction against the further use or operation of the new service.

**§65-32-17. Withdrawal of Certificate of Need.**

17.1. The Authority may withdraw a certificate of need for any of the following reasons:

17.1.a. Insufficient progress in meeting the timetable specified in the approved application for the certificate and for not making a good faith effort to meet it in developing the project;

17.1.b. Noncompliance with any conditions of certification;

17.1.c. A substantial change in an approved new health service for which the Authority has not issued a certificate of need;

17.1.d. A material misrepresentation by an applicant upon which the Authority relied in making its decision; or

17.1.e. Other reasons contained in the Act or this rule.

17.2. After the commencement of a hearing on the Authority's proposal to withdraw a certificate of need, and before a final decision is issued, there may be no ex parte contacts between the holder of the certificate, any person acting on behalf of the holder, or any person in favor of or in opposition to the withdrawal of the certificate and any member of the Authority or its staff or agents who exercise responsibility respecting the withdrawal of the certificate.

17.3. In the case of a proposed withdrawal of a certificate, the Authority shall follow the notification of review provisions, the public hearing provisions, the notification of the status of review and finding provisions, the annual report provisions, the conditional decision provisions and the notification of

decision and findings provisions of the Act and this rule.

17.4. An applicant may appeal the withdrawal of a certificate of need pursuant to section 11 of this rule.

**§65-32-18. Declaratory Ruling or Ruling of Reviewability.**

18.1. A health care facility, health care provider or other entity regulated by the Act, or any person planning to acquire, offer or develop any new health service may apply to the Authority for a declaratory ruling on any matter regulated by the Act or any rule promulgated under the Act.

18.2. Any person acquiring, offering or developing a health service may apply to the Authority for a ruling regarding reviewability of the proposed health service. The request must be accompanied by a nonrefundable one hundred dollar (\$100) fee.

18.3. Persons who request a declaratory ruling or a ruling regarding reviewability shall make the request in writing. They shall address the request to: Chairman, West Virginia Health Care Authority, 100 Dee Drive, Suite 201, Charleston, West Virginia 25311. The request shall contain a verification signed by the Chief Executive Officer.

18.4. Upon receipt of a request for declaratory ruling or a ruling regarding reviewability, the Authority shall issue its ruling within sixty (60) days of its receipt of the request. The Authority shall serve the ruling upon the person requesting the ruling and shall make the ruling available to any other person upon request and on payment of the cost set out in the fee schedule adopted by the Authority.

18.5. The Authority shall publish notice of its declaratory ruling or ruling regarding reviewability on its website.

**§65-32-19. Public Access To Information.**

The Authority shall make available for public inspection and examination all applications filed with the Authority and all other pertinent written materials filed with the Authority and essential to its review process. The Authority shall make copies of the applications or documents available to the public upon request. The Authority may charge its reasonable and customary fees for making the copies.

**§65-32-20. Addition of Health Services.**

20.1. The following health services are subject to certificate of need review pursuant to section 8(b) of the Act:

20.1.a. Constructing, developing, acquiring or establishing of a birthing center;

20.1.b. Providing radiation therapy;

20.1.c. Providing computed tomography;

20.1.d. Providing positron emission tomography;

20.1.e. Providing cardiac surgery;

- 20.1.f. Providing fixed magnetic resonance imaging;
- 20.1.g. Providing comprehensive medical rehabilitation;
- 20.1.h. Establishing an ambulatory care center;
- 20.1.i. Establishing an ambulatory surgical center;
- 20.1.j. Providing diagnostic imaging;
- 20.1.k. Providing cardiac catheterization services;
- 20.1.l. Constructing, developing, acquiring or establishing of kidney disease treatment centers, including freestanding hemodialysis units;
- 20.1.m. Providing megavoltage radiation therapy;
- 20.1.n. Providing surgical services;
- 20.1.o. Establishing operating rooms;
- 20.1.p. Adding acute care beds;
- 20.1.q. Providing intellectual developmental disabilities services;
- 20.1.r. Providing organ and tissue transplants;
- 20.1.s. Establishing an intermediate care facility for individuals with intellectual disabilities;
- 20.1.t. Providing inpatient services;
- 20.1.u. Providing hospice services;
- 20.1.v. Establishing a home health agency; and
- 20.1.w. Providing personal care services.

20.2. The services listed in subsection 20.1 of this rule are subject to certificate of need review regardless of the expenditure associated with the proposal.

**§65-32-21. Applicability.**

The Authority shall consider any application for which a review cycle has been established prior to the effective date of this rule under the rules in effect at the time the review cycle was established.