



WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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12/20/2021 3:40:18 PM

Office of West Virginia
Secretary Of State

NOTICE OF RULE MODIFICATION OF A PROPOSED RULE

AGENCY: Health Care Authority

RULE TYPE: Legislative

TITLE-SERIES: 65-32

RULE NAME: Certificate of Need

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

The above proposed Legislative rules, following review by the Legislative Rule Making Review Committee, is hereby modified as a result of review and comment by the Legislative Rule Making Review Committee. The attached modifications are filed with the Secretary of State.

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

Yes

Michelle L Bradley -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

TITLE 65
LEGISLATIVE RULE
HEALTH CARE AUTHORITY

SERIES 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), and §16-29B-8(a)(1) and ~~16-29B-11~~.

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

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

1.5. Sunset Date. -- This rule shall terminate and have no further force or effect ~~on June 1, 2022~~
August 1, 2027.

§65-32-2. Definitions.

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

2.1.a. "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.

2.1.b. "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~~ 16-2D-3(a)(1).

2.1.c. "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.

2.1.d. "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.

2.1.e. "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.

2.1.f. "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.

2.1.g. "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.

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

2.1.h.1. 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:

2.1.h.1.A. 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;

2.1.h.1.B. 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;

2.1.h.1.C. As a professional corporation duly registered with or certified by the appropriate health professional licensure board; or

2.1.h.1.D. As a professional limited liability company duly registered with or certified by the appropriate health professional licensure board.

2.1.h.2. Practice composition:

2.1.h.2.A. 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.

2.1.h.2.B. 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.

2.1.h.2.C. 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.

2.1.h.3. 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:

2.1.h.3.A. 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;

2.1.h.3.B. 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;

2.1.h.3.C. 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; or

2.1.h.3.D. 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.

2.1.h.4. 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".

2.1.h.5. 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.

2.1.h.6. 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 Statute; provided there has been no material change in the facts and circumstances provided in the original request for determination of reviewability.

2.1.i. "Project" means a proposed new health service.

2.1.j. "Proposed New Health Service" means:

2.1.j.1. 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;

2.1.j.2. The partial or total closure of a health care facility with which a capital expenditure is associated;

2.1.j.3. 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:

2.1.j.3.A. 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;

2.1.j.3.B. 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

2.1.j.3.C. In the case of donated property, on the date on which the gift is completed under state law;

2.1.j.4. A substantial change to the bed capacity of a health care facility with which a capital expenditure is associated;

2.1.j.5. 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;

2.1.j.6. The addition of ventilator services by a hospital;

2.1.j.7. 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;

2.1.j.8. 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;

2.1.j.9. 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;

2.1.j.10. The acquisition of major medical equipment;

2.1.j.11. A substantial change in an approved new health service for which a certificate of need is in effect;

2.1.j.12. 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

2.1.j.13. 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.

2.1.k. "Statute" means the certificate of need statute, W. Va. Code §16-2D-1 *et seq.*

2.1.l. "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.

2.1.m. "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.

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 forms may be located on the Authority's website, www.hca.wv.gov. The applicant shall submit the original and one paper copy to the Authority. The applicant may also submit the application electronically. The application shall have a verification signed by the Chief Executive Officer and the person or persons who prepared the application. Any application received after ~~5:00~~ 4:30 p.m., Eastern Standard Time, on a business day or on a weekend or holiday shall be deemed received on the next business day.

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 also a written authorization empowering specified individuals to sign the application and to act on its behalf. One authorization is sufficient for multiple applications provided the individual empowered to sign the application and to act

on the applicant's behalf has not changed. This must be clearly stated in the written authorization and a copy provided in each application;

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. 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; and.

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

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

5.1. 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 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 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 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 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~~ §16-29B-24, *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 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 10 days within which to determine if the application is complete. If the applicant fails to respond within ~~ninety (90)~~ 45 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 15th 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, 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 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 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 hearing order shall be entered by the Authority within 15 days from the last date an affected person may request an administrative hearing on a certificate of need application.

8.13. The hearing 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 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 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 days before the return date, either by personal service by a person over 18 years of age or by registered or certified mail, return receipt requested. If service is by mail, the five-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 unless the file closing date is extended by the Authority.

8.31. The Authority shall review an uncontested certificate of need application within 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 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 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 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; Denials.

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 15 days.

9.2. If the Authority issues an extension of the review period, or for good cause, it may extend the file closing date.

9.3. 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.

9.4. 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:

9.4.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;

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

9.4.c. Any of the circumstances listed in Section 8.6 of this rule.

§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 Statute or any rule promulgated by the Authority. Conditions may be imposed upon the operations of the applicant for a period not exceeding three 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. 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 90 days 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 Statute, 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 upon a showing of good cause. 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. The Office of Judges may dismiss the appeal with prejudice if the continuance continues for an unreasonable period of time and for good cause shown.~~

11.1. Decisions issued by the Authority prior to June 30, 2022, relating to the issuance, denial, or withdrawal of a certificate of need, shall be appealed by an affected person to the Office of Judges, West Virginia Office of the Insurance Commissioner. 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.

11.2. 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.

11.3. 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.

11.4. The person requesting a review of the Authority decision shall, as part of the request, include assignment(s) of error.

11.5. 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.

11.6. 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.

11.7. 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 of rulings of the Authority have been reversed or revised.

11.8. The Office of Judges may grant a continuance of a hearing upon a showing of good cause. 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. The Office of Judges may dismiss the appeal with prejudice if the continuance continues for an unreasonable period of time and for good cause shown.

§65-32-12. Judicial Review.

~~12.1. Any final decision of the Office of Judges granting, denying or withdrawing a certificate of need 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 Office of Judges' 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 Statute and participated in the Office of Judges proceedings.~~

~~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.~~

12.1. Decisions issued by the Authority after June 30, 2022, relating to the issuance, denial, or withdrawal of a certificate of need, shall be appealed by an affected person to the West Virginia Intermediate Court of Appeals, pursuant to the provisions governing the judicial review of contested administrative cases found in W. Va. Code, §29A-5-1, et seq. Pursuant to W. Va. Code §51-11-7(b), all appeals shall be filed with the Clerk of the Supreme Court of Appeals.

12.2. 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.

12.3. The person requesting a review of the Authority decision shall, as part of the request, include assignment(s) of error.

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

13.1. Any person holding a certificate of need 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 45 days prior to the expiration of the certificate of need, 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 shall submit any additional information relating to the certificate of need 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 within 12 months of issuance of the certificate of need 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 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 12 months, the applicant shall incur the obligation for the first component within 12 months after the issuance of the certificate of need.

13.7. Upon good cause shown, the Authority may extend the duration of a certificate of need for up to six months. If the obligation required to be incurred by Subsection 13.6 of this rule is not incurred within 18 months of the issuance of the certificate of need, the certificate 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 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 10 percent 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 percent 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 percent 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 15 days of its receipt of the request from the applicant or, if additional information is requested by the Authority, within 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. No later than 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 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, the Authority may withdraw the certificate 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 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 Statute 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 Statute 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 Statute, 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 Statute or any rule promulgated under the Statute.

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 \$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 45 days of its receipt of the request if all of the necessary information has been

provided to the Authority in a timely manner. 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.

19.1. 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 Statute:

- 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.

21.1. 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.