

WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION

Form #1

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1991 JUN 17 PM 4:05

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF PUBLIC HEARING ON A PROPOSED RULE

AGENCY: Health Care Cost Review Authority TITLE NUMBER: 65
RULE TYPE: Legislative; CITE AUTHORITY Code §§ 16-29B-11, 16-2D-1 et seq
AMENDMENT TO AN EXISTING RULE: YES NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED: _____

IF NO, SERIES NUMBER OF NEW RULE BEING PROPOSED: 7

TITLE OF RULE BEING PROPOSED: Certificate of Need Rule

DATE OF PUBLIC HEARING: July 18, 1991 TIME: 9:30 a.m.

LOCATION OF PUBLIC HEARING: Health Care Cost Review Authority

Large Conference Room

100 Dee Drive, Suite 201

Charleston, West Virginia 25311

COMMENTS LIMITED TO: ORAL , WRITTEN , BOTH

COMMENTS MAY ALSO BE MAILED TO THE FOLLOWING ADDRESS: Health Care Cost Review Authority

100 Dee Drive, Suite 201

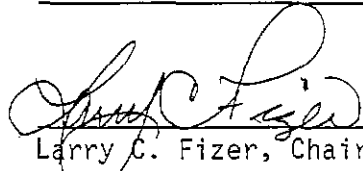
Charleston, WV 25311

ATTN: Marianne Stonestreet

The Department requests that persons wishing to make comments at the hearing make an effort to submit written comments in order to facilitate the review of these comments.

The issues to be heard shall be limited to the proposed rule.

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL


Larry C. Fizer, Chairman

4/1/00

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

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1991 JUN 17 PM 4: 16

Rule Title: Certificate of Need Rule

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

Type of Rule: X Legislative Interpretive Procedural

Agency Health Care Cost Review Authority Address 100 Dee Drive, Suite 201
Charleston, West Virginia 25311

| 1. Effect of Proposed Rule | ANNUAL | | FISCAL YEAR | | |
|----------------------------|-----------|----------|-------------|-----------|------------|
| | Increase | Decrease | Current | Next | Thereafter |
| Estimated Total Cost | \$ 30,795 | \$ | \$ | \$ 30,795 | \$ 30,795 |
| Personal Services | 24,636 | | | 24,636 | 24,636 |
| Current Expense | 6,159 | | | 6,159 | 6,159 |
| Repairs and Alterations | | | | | |
| Equipment | | | | | |
| Other | | | | | |

2. Explanation of above estimates.

Personal Services - 1 FTE Health Care Financial Analyst
Current Expenses - Fringe Benefits @ 25%

3. Objectives of these rules:

To implement, consolidate and update the requirements for certificate of need review.

4. Explanation of Overall Economic Impact of Proposed Rule.

A. Economic Impact on State Government.

N/A - The agency is funded by special revenues.

B. Economic Impact on Political Subdivisions; Specific Industries;
Specific groups of citizens.

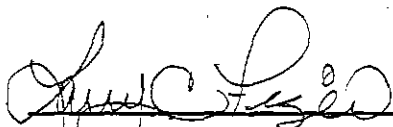
The funding for the additional health care financial analyst has been appropriated by the legislature. Funding is provided by assessments paid by West Virginia hospitals.

C. Economic Impact on Citizens/Public at Large.

The expanded certificate of need review provided by this rule will increase the agency's authority to review health care projects and assist it in containing health care costs in West Virginia.

Date June 17, 1991

Signature of Agency Head or Authorized Representative



Larry C. Fizer, Chairman

TITLE 65
EMERGENCY

WEST VIRGINIA LEGISLATIVE RULE
HEALTH CARE COST REVIEW AUTHORITY

SERIES 7

Title: CERTIFICATE OF NEED RULE

\$65-7-1

General

1.1. Scope - This legislative rule implements the provisions of the Certificate of Need program found at West Virginia Code §§16-2D-1 et seq. as administered by the West Virginia Health Care Cost Review Authority. This rule further repeals and replaces legislative rule "Certificate of Need (CON)" \$65 C.S.R. 7 (1983) and legislative rule "Exemptions From Certificate of Need Review," \$65 C.S.R. 11 (1988).

1.2. Authority - W. Va. Code §§16-2D-1, et seq., and 16-29B-11.

1.3. Filing Date - June 17, 1991.

1.4. Effective Date - _____.

1.5. This legislative rule repeals and replaces legislative rule "Certificate of Need (CON)," §65 C.S.R. 7 (1983) and legislative rule "Exemptions From Certificate of Need Review," §65 C.S.R. 11 (1988).

§65-7-2 Definitions

As used in this legislative rule, all terms that are defined in the Act at section 2 thereof have those same meanings which are in some cases further clarified herein. 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 or comparable arrangement a health care facility's assets used in the provision of health services, including the transfer of a health care facility from a subsidiary corporation to its parent or vice versa and/or including a change or transfer of the licensee of the health care facility.

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

2.3. "Batching" means the consideration of completed certificate of need applications which pertain to similar types of services, facilities or equipment affecting the same health service area.

2.4. "Batching Category" means any one of the groupings in section 10 of this rule.

2.5. "Board" means the West Virginia Health Care Cost Review 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.

2.6. "Certificate of Need" means a document issued by the board which indicates that a proposed new institutional 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 institutional health service.

2.7. "Consistent With The State Health Plan" means a determination made by the board, after considering and weighing all the evidence presented regarding an application, 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 this rule.

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

2.9. "Expenditure Minimum for Annual Operating Costs" means three hundred thousand dollars for each twelve month period following the date upon which a new institutional health service is acquired, offered or developed and for each twelve (12) month period thereafter.

2.10. "Health Care Facility" has the same meaning as contained in W. Va. Code §16-2D-2(i), but does not include personal care homes as defined in Code §16-5C-2, state homes for qualified veterans as defined in Code §9A-2-1, or any institution operated by or on behalf of the West Virginia Division of Corrections.

2.11. "Parties" means the applicant and, if a hearing is held, the person requesting the hearing and all persons designated by the board as parties to the hearing.

2.12. "Potentially Unnecessarily Duplicative," used as a term to describe applications, means those applications in the same review cycle which propose new institutional health services to serve the same or similar health needs of the same or potentially the same population.

2.13. "Project" means a proposed new institutional health service.

2.14. "Proposed New Institutional Health Service"

means:

(a) The construction, development, acquisition or other establishment of a new health care facility or health maintenance organization 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 has been so operated in the past;

(b) The partial or total closure of a health care facility or health maintenance organization with which a capital expenditure is associated;

(c) Any obligation for a capital expenditure incurred by or on behalf of a health care facility, except as exempted by this rule, or health maintenance organization 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:

(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, the contract is the result of arms length negotiations, the

board concludes that the contract was not undertaken as a means of technically complying with the requirement that a capital expenditure be incurred, but was entered into with the actual intent to proceed timely towards the completion of the project, and the contract contains a fixed starting date and completion date;

(2) When the governing board of 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; and the resolution contains a fixed starting date and completion date; or

(3) In the case of donated property, on the date on which the gift is completed under state law;

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

(e) The addition of health services which are offered by or on behalf of a health care facility or health maintenance organization and which were not offered on a regular basis by or on behalf of such health care facility or health maintenance organization within the twelve-month period prior to the time such services would be offered;

(f) The deletion of one or more health services, previously offered on a regular basis by or on behalf of a health care facility or health maintenance organization, which deletion is associated with a capital expenditure;

(g) 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;

(h) 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, computed tomography (CT) equipment or lithotripters.

(i) The acquisition of major medical equipment; and

(j) A substantial change in an approved new institutional health service for which a certificate of need is in effect.

2.15. "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 institutional health service for its intended purpose.

§65-7-3

Certificate of Need Requirements

3.1. No new institutional health service may be acquired, offered or developed within this state unless a certificate of need has been issued for the new institutional health service by the board. If a new institutional health service is exempt from certificate of need review by statute or this rule, the board shall, upon a determination of said exemption, issue a certificate of need before the new institutional health service is offered or developed.

3.2. No person or health care facility may knowingly charge or bill for any health service associated with a new institutional health service knowingly acquired, offered or developed without first obtaining a certificate of need from the board.

3.3. Any charge or bill for health services associated with a new institutional health service for which a certificate of need has not been issued by the board shall be void and legally unenforceable.

3.4. Donations of equipment or facilities to a health care facility which, if acquired directly, would be considered a new institutional health service subject to review by the board shall require the issuance of a certificate of need before services associated with the equipment or facilities may be offered or developed.

3.5. A transfer of equipment or facilities for less than fair market value shall be considered a new institutional health service if a transfer of the equipment or facilities at fair market value would be subject to review by the board.

3.6. A series of expenditures, each less than the expenditure minimum, which, when taken together, are in excess of the expenditure minimum, may be determined by the board to be a single expenditure subject to the review of the board. In making such a determination, the board will consider the following:

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

(b) Whether the expenditures are to be made over a two-year period and are directed towards the accomplishment of a single goal within the health care facility's long-range plan; or

(c) Whether the expenditures are to be made within a two-year period within a single department such that they constitute a significant modernization of the department.

\$65-7-4

Certificate of Need Application

4.1. An application for a certificate of need shall be on forms approved by the board. The original and three (3) copies of the application must be submitted to the board. The application shall be verified under oath by the Chief Executive Officer.

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

- (a) The identification of the applicant;
- (b) A copy of the governing body's approval of the proposal and its written authorization empowering specified individual(s) to sign the application and to act on its behalf;
- (c) A description of the project;
- (d) A timetable for implementation of the project, including the projected date(s) for incurring the obligation for any capital expenditure;

(e) 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;

(f) Policies for patient admission and provision of fully or partially uncompensated care;

(g) Documented analysis of alternatives considered by the applicant;

(h) 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;

(i) An analysis of the relationship of the proposal to the applicant's long-range plan on file with the board;

(j) Documented analysis of the proposal's relationship to the state health plan;

(k) An analysis of the extent to which competition allocates services of the type being proposed and promotes quality assurance, cost effectiveness and accessibility;

(l) 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 thereof as may be required by the board;

(m) Documentation of the availability of resources, including health care providers, management personnel and funds for capital and operating needs;

(n) Copies of existing or proposed policies with respect to employment of facility staff and, where applicable, admission to medical staff membership;

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

(p) Documentation of existing or proposed mechanisms for soliciting consumer input into the applicant's decision-making process;

(q) In the case of construction projects, a documented analysis of the cost and methods of the proposed construction, including provisions for energy conservation and the probable impact of the proposed construction on the applicant's cost of providing health services;

(r) If applicable, documented analysis of the needs or circumstances of entities such as health professional schools, multi-disciplinary clinics and specialty centers which provide a substantial portion of their services to individuals not residing in the health service area in which they are located or in adjacent health service areas;

(s) If applicable, documented analysis of the needs and circumstances of research projects; and

(t) If applicable, documented analysis of the need and circumstances of health maintenance organizations.

5.1. Any person or health care facility may file a certificate of need application for expedited review, upon forms approved by the board, for those projects which would create a minimal impact upon the scope, quality or cost of health services to be provided by the health care facility. Such projects may include, but are not limited to, the following:

(a) Changes required of a facility or organization in order to comply with applicable building and fire codes and other laws, regulations and standards designed to preserve life and safety;

(b) Capital expenditures which do not involve the renovation, replacement or a substantial change to bed capacity, or a substantial change to the health services of the facility;

(c) The replacement of equipment;

(d) The acquisition of health care facilities;

(e) A substantial change to a new institutional health service for which a certificate of need is in effect;

(f) New institutional health services proposed to eliminate or alleviate emergency circumstances that pose a threat to public health; and

(g) Applications from ambulatory health care facilities, home health agencies, ambulatory surgical facilities and health maintenance organizations.

(h) Applications from health care facilities for projects that could be undertaken without a certificate of need by persons that are not health care facilities, i.e., projects for parking buildings and medical office buildings proposed by hospitals or the provision of personal care services by intermediate care facilities; or

(i) Any other application within the discretion of the board when there are no letters of intent on file for projects that may be potentially unnecessarily duplicative.

\$65-7-6

Long-Range Plans

6.1. Every hospital proposing a new institutional service subject to the standard batch review must submit to the board a long-range plan, adopted by the governing body of the hospital as its official long-range plan, which shall consist of the overall plan for the health care facility proposing the new

institutional service for at least the next five (5) years. The long-range plan shall, at a minimum, contain the following:

(a) A description of the organization and its purpose and structure;

(b) A statement of the goals and objectives of the organization as they relate to construction, new service development, equipment purchases, sharing or merger arrangements and staff recruitment;

(c) An analysis of the resources necessary and available to accomplish the goals and objectives;

(d) A description of the assumptions and rationale which form the basis for the goals and objectives; and

(e) The proposed annual capital expenditure budget for each of the five years.

§65-7-7

Access To Information And Facilities

Upon proper notice, and as is reasonable and necessary in the performance of the board's responsibilities in administering the certificate of need program, the board shall have access to any information, records, meetings, sites and/or facilities pertinent

to an application or request for exemption under review by the board.

§65-7-8 Additional Information or Amendments to Application

8.1. After the review of an application has begun, the board 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 board may:

(a) Extend the review cycle pursuant to the provisions of section 13 of this rule;

(b) Enter an order closing the file ten (10) days from the entry of such order; or

(c) Withdraw the application from review.

8.2. The board may examine the extent of additional information provided or any amendment made by the applicant regarding the application currently under consideration by the board and its impact on the new institutional health service, and determine the application to be a new proposal subject to a new

review cycle. The board shall notify the applicant of any such determination, in writing, and further advise the applicant of the dates in the new review cycle. A notice shall also be published by the board pursuant to section 11.6 of this rule.

§65-7-9

Application Withdrawal

9.1. An application under consideration by the board may be withdrawn by the applicant at any time prior to the issuance of a final decision and written findings. The withdrawal of such application shall be without prejudice.

9.2. A written notice withdrawing the application must be filed with the board before the issuance of a final decision.

§65-7-10

Batching of Applications

10.1. All applications which pertain to similar types of services, facilities or equipment affecting the same health service area shall be batched into the following categories and considered in relation to each other:

(a) Medical/surgical beds or facilities: Beds, health services or capital expenditures in excess of the applicable expenditure minimum;

(b) Behavioral health/psychiatric/chemical dependency/group homes for mental health/mental retardation/developmentally disabled: Beds, facilities, health services or capital expenditures in excess of the applicable expenditure minimum;

(c) Specialized acute care: Obstetric, pediatric or intensive care beds, health services or capital expenditures in excess of the applicable expenditure minimum;

(d) Medical rehabilitation: Beds, health services or capital expenditures in excess of the applicable expenditure minimum;

(e) Nursing facility (NF)/skilled nursing facility (SNF): Long-term care beds, health services or capital expenditures in excess of the applicable expenditure minimum;

(f) Major medical equipment: Capital expenditures in excess of the applicable expenditure minimum;

(g) Any proposed new institutional health service that does not fall in batching categories (a) through (f) of this subsection but which directly relate to beds, major medical equipment or health services associated with a capital expenditure in excess of the expenditure minimum; and

(h) Other proposed new institutional health services.

10.2. If any application is broader in scope than a single batching category, the components of the application shall be included by the board within each appropriate category.

10.3. Standard applications which fall within batching categories (a) through (g) of section 11.1 of this rule shall be reviewed in four annual cycles. On the first Friday of the months of February, May, August and November, the board shall collect by batching categories all applications determined to be complete since the previous cycle. The board shall then establish a ninety (90) day review cycle for each category. For consideration in any batch cycle, the application must be submitted no later than fifteen (15) days prior to the beginning of the batch.

10.4. Any standard application submitted to the board which falls entirely within batching category (h) shall be reviewed in cycles beginning each month. On the last working day of each month the board shall collect those standard applications determined to be complete during that month and which fall entirely within batching category (h), and establish a sixty-five (65) day review cycle for those applications.

10.5. Expedited applications shall be reviewed in cycles beginning each month. On the last working day of each month the board shall collect by batching categories those expedited applications determined to be complete during that month and establish a sixty-five (65) day review cycle for those applications.

10.6. In considering standard or expedited applications in relation to each other, the board shall consider to what extent the proposed new institutional health service within each batching category and review cycle are potentially unnecessarily duplicative. Where the potential for unnecessary duplication exists, the board shall conduct its review of the applications in such a way as to compare the potentially unnecessarily duplicative portions of the various applications. If one or more of the applicants are granted a certificate of need, the board shall, in its final decision, include a comparative analysis of the potentially unnecessarily duplicative services.

10.7 Standard and expedited applications reviewed pursuant to sections 11.4 and 11.5 may be batched together by the board if it determines that the applications pertain to similar types of services, facilities or equipment affecting the same health service area.

10.8. Any application submitted to the board for a new institutional health service proposed solely to eliminate or prevent imminent safety hazards, as defined by federal, state or local fire, building or life safety codes or regulations, or to comply with licensure, accreditation or certification standards, shall begin the review process on a weekly basis. On the last working day of each week the board shall collect the applications which fall into this category determined to be complete and establish the appropriate review cycle for those applications.

\$65-7-11

Application Review Procedure

11.1. This section shall apply to the review of standard and expedited applications.

11.2. An application for a certificate of need must be submitted and approved by the board before any new institutional health service is offered or developed in this state, unless exempted from certificate of need review by section 15 of this rule.

11.3. Any person proposing a new institutional health service must file with the board a letter of intent to do so at least fifteen (15) days before the submission of a formal application. The letter of intent shall contain sufficient

information to advise the board of the nature, scope, cost and timing of the project, as well as the location and name of the proposed applicant. Letters of intent shall be effective for one year from the date of their filing.

11.4. Upon receipt of a certificate of need application, the board shall determine whether the application is complete or whether additional information will be required. A declaration by the board that an application is complete means that there is sufficient information contained in the application for the board 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, an application shall not be declared complete if:

(a) A long-range plan with a sufficient level of detail acceptable to the board and adopted by the applicant within the preceding five (5) years is not on file with the board;

(b) 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 board all reports, records, data or other information required therein.

11.5. A determination of completeness must be made by the board within fifteen (15) days of its receipt of the application. If the board determines that the application is not complete, it shall request additional information or ask additional questions. Upon receipt of the additional information, the board shall have 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 shall be deemed withdrawn. If the applicant later desires to pursue the project, a new letter of intent and application must be filed.

11.6. Upon a determination by the board that an application is complete, the board shall publish a notice declaring its completeness in the Saturday Charleston newspapers, and the State Register. The notice shall, at a minimum, contain the following:

- (a) The name of the applicant;
- (b) A description of the proposed project;
- (c) The date the review cycle begins;
- (d) The last date for an affected person to request a public hearing;

(e) The file closing date if no public hearing is requested;

(f) The date upon which a decision will be issued by the board; and

(g) If applicable, that the application has been deemed potentially unnecessarily duplicative of other applications under review.

If the application is one for expedited review, the notice shall also identify the last date for an affected person to present reasons why the applicant should complete a standard application.

11.7. If the application is one for expedited review and the required notice of completeness has been published, any affected person may present reasons why the applicant should be required to proceed with the project only upon the filing of a standard application. The reasons must be submitted in writing within ten (10) days of the date the review cycle begins. The board shall then determine whether cause exists to require the applicant to use the standard application process. If the board determines that the standard application process should be utilized, the review of the expedited application shall be immediately terminated.

11.8. Once a determination of completeness has been made by the board and the appropriate notice published or mailed, the board shall provide a minimum of thirty (30) days from the beginning of the review period for affected persons to request a public hearing. A request for a public hearing must be in writing and shall be addressed to: General Counsel, West Virginia Health Care Cost Review Authority, Certificate of Need Program, 100 Dee Drive, Suite 201, Charleston, West Virginia 25311.

11.9. The board shall hold a public hearing on an application if requested to do so by any affected person. The board may also hold a public hearing upon its own initiative.

11.10. If a public hearing is held on an application, and other applications have been determined to be potentially unnecessarily duplicative thereof, the public hearing shall be held on the application and all other applications that are potentially unnecessarily duplicative.

11.11. When a public hearing is scheduled to be conducted upon an application, the board shall, prior to the hearing, provide notice to all parties and publish notice in the Saturday Charleston newspapers and the State Register. The notice shall, at a minimum, contain the following:

- (a) The name of the applicant;

- (b) A description of the proposed project;
- (c) The date of the public hearing;
- (d) The date of any prehearing conference; and

The hearing shall be conducted in accordance with the requirements for administrative hearings found in W. Va. Code §29A-5-1 et seq.

11.12. Whenever a public hearing is scheduled upon any application, the board 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. Affected persons may be designated as parties thereafter only for good cause shown.

11.13. All prehearing motions must be filed with the board prior to the prehearing conference. Motions shall be taken up for consideration and argument at the prehearing conference.

11.14. A list of all exhibits and witnesses to be presented or introduced at a public hearing must be exchanged with all other parties to the hearing and filed with the board during or prior to the prehearing conference unless a different date is

established by the board. Failure to comply with this section shall be sufficient grounds to disallow the testimony of a proposed witness or disallow the introduction of any exhibit.

11.15. The original and two copies of all communications concerning a pending application shall be filed with the board. 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 board. Failure to comply with this section shall be sufficient grounds for striking the written communication from the record.

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

11.17. 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.

11.18. Every subpoena or subpoena duces tecum issued at the request of a party shall be served at least five (5) days before the return date thereof, 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.

11.19. Fees for the attendance of witnesses shall be 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.

11.20. In any case of disobedience or neglect of any subpoena or subpoena duces tecum issued by the board, or any refusal of a witness to testify to any matter regarding which he or she may be lawfully interrogated, the board 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 said circuit.

11.21. If an order is first obtained from the board or a hearing examiner appointed by it, the parties may engage in

discovery as provided by the West Virginia Rules of Civil Procedure. The scope of any discovery, however, shall be limited to relevant and admissible evidence.

11.22. 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.

11.23. All witnesses who testify during a hearing shall first be subject to oath or affirmation.

11.24. The board shall maintain a verbatim record of the public hearing.

11.25. After the commencement of a public hearing on an application, and before a decision is rendered by the board, 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 board or any of its employees or agents who exercise any responsibility regarding the application.

11.26. A public hearing on an application may be continued by the board, and the board may elect to hold a rehearing on any application at its sole discretion.

11.27. If a public hearing is not conducted during the review of a standard application in batching categories (a) through (g) of section 10.1 of this rule, the review file shall be closed by the board on the seventy-fifth day of the review. The file closing date may be extended by the board pursuant to section 13 of this rule.

11.28. If a public hearing is not conducted during the review of an expedited application or an application falling within batching category (h) of section 10.1 of this rule, the review file shall be closed by the board on the thirty-first day of the review. The file closing date may be extended by the board pursuant to section 13 of this rule.

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

11.30. The board may, after the publication of a legal notice in the Saturday Charleston newspapers, and allowing thirty (30) days after the publication for public comment, adopt population projections for use in certificate of need decisions. In evaluating health needs and resources for the purpose of a project review, the board shall utilize, where available, data

projections for the fifth year following the calendar year in which the certificate of need decision is rendered.

§65-7-12

Review Criteria

12.1. Except for health maintenance organizations or ambulatory care facilities or health care facilities controlled directly or indirectly by a health maintenance organization or combination of health maintenance organizations, the board shall, at a minimum, consider the following criteria, if applicable, when making its determination to grant or deny a certificate of need.

(a) The relationship of the proposed new institutional health service to the State Health Plan and whether the proposed new institutional health service is in compliance with the State Health Plan, unless the State Health Plan is in conflict with this rule or the Act;

(b) The relationship of services reviewed to the long-range development plan of the applicant providing or proposing the service;

(c) The availability of less costly or more effective alternative methods of providing the service or services to be offered, expanded, reduced, relocated or eliminated and the

extent to which the development of such alternatives by the applicant or others appear practicable;

(d) The immediate and long-term financial feasibility of the proposal as well as the probable impact of the proposal on the costs of and charges for providing health services by the applicant proposing the new institutional health service;

(e) The relationship of the services proposed to the existing health care system in the area where the services are proposed to be provided;

(f) In the case of health services proposed to be provided, the availability of resources, including health care providers, management personnel and funds for capital and operating needs, for the provision of the services proposed to be provided and the need for alternative uses of these resources as identified by the State Health Plan;

(g) The appropriate and nondiscriminatory utilization of existing and available health care providers;

(h) The relationship, including the organizational relationship, of the health services proposed to be provided to ancillary or support services;

(i) Special needs and circumstances of those entities which provide a substantial portion of their services or resources, or both, to individuals not residing in the health service areas in which the entities are located or in adjacent health service areas. These entities may include medical and other health professional schools, multidisciplinary clinics and specialty centers.

(j) The special needs and circumstances of biomedical and behavioral research projects which are designed to meet a national need and for which local conditions offer special advantages;

(k) In the case of a construction project:

(1) The cost and methods of the proposed construction, including the costs and methods of energy provision; and

(2) The probable impact of the construction project reviewed on the costs of providing health services by the applicant proposing such construction project and on the costs and charges to the public of providing health services by other persons;

(l) In the case of health services proposed to be provided, the effect of the means proposed for the delivery of proposed health services on the clinical needs of health professional training programs in the area in which the services are to be provided;

(m) In the case of health services proposed to be provided, if the services are to be available in a limited number of facilities, the extent to which the schools in the area for health professions will have access to the services for training purposes;

(n) In the case of health services proposed to be provided, the extent to which the proposed services will be accessible to all the residents of the area to be served by the services;

(o) The factors influencing the effect of competition on the supply of the health services being reviewed;

(p) Improvements or innovations in the financing and delivery of health services which foster competition and serve to promote quality assurance and cost effectiveness;

(q) In the case of health services or facilities proposed to be provided, the efficiency and appropriateness of the use of existing services and facilities similar to those proposed;

(r) In the case of existing services or facilities, the quality of care provided by such services or facilities in the past;

(s) In the case where the application is by an osteopathic or allopathic facility for a certificate of need to construct, expand or modernize a health care facility, acquire major medical equipment, or add services, the need for that construction, expansion, modernization, acquisition of equipment, or addition of service, shall be considered on the basis of the need for and the availability in the community of services and facilities for osteopathic and allopathic physicians and their patients. The board will consider the application in terms of its impact on existing and proposed institutional training programs for doctors of osteopathy and medicine at the student, internship and residency training levels;

(t) The special circumstances of health care facilities with respect to the need for conserving energy;

(u) The existence of a mechanism for soliciting consumer input into the health care facility's decision-making process; and

(v) In the case of any proposed new institutional health service, and after consideration of the appropriateness of the use of existing facilities providing services similar to those being proposed, that;

(1) Superior alternatives to such services in terms of cost, efficiency and appropriateness do not exist and the development of such alternatives is not practicable;

(2) Existing facilities providing services similar to those proposed are being used in an appropriate and efficient manner;

(3) In the case of new construction, alternatives to new construction, such as modernization or sharing arrangements, have been considered and have been implemented to the maximum extent possible;

(4) Patients will experience serious problems in obtaining care of the type proposed in the absence of the proposed new service; and

(5) 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.

12.2. If the board determines that a substantially competitive market exists or may occur for a new institutional health service, the board may give minimal consideration to review criteria (b), (c), (d), (e), (f), (h), (k), (q), (r) and (u) of subsection 12.1 of this rule that tends to compensate for the absence of market controls in a noncompetitive market.

12.3. If the application is for a certificate of need for a health maintenance organization or ambulatory care facilities or health care facilities controlled directly or indirectly by a health maintenance organization or a combination of health maintenance organizations, the board shall consider only the special needs and circumstances of health maintenance organization or group of organizations. These needs and circumstances will be limited to the following:

(a) The needs of enrolled members and reasonably anticipated new members of the health maintenance organization for

the health services proposed to be provided by the organization;
and

(b) The availability of the new health services from nonhealth maintenance organization providers or other health maintenance organizations in a reasonable and cost effective manner which is consistent with the basic method of operation of the health maintenance organization. In assessing the availability of these health services from these providers, the agency shall consider only whether the services from these providers:

(1) Would be available under a contract of at least five (5) years duration;

(2) Would be available and conveniently accessible through physicians and other health professionals associated with the health maintenance organization;

(3) Would cost no more than if the services were provided by the health maintenance organization; and

(4) Would be available in a manner which is administratively feasible to the health maintenance organization.

12.4. The board shall, in its consideration of an application, give significant consideration to criteria (o) and (p)

of section 12.1 of this rule. Where supply of a health service is, or upon approval would be, within an acceptable range of supply for that service, the board may give significant consideration to whether the applicant has suitably demonstrated that approval of the application will, through the implementation of improvements or innovations in financing, reimbursement, service delivery arrangements or other means, strengthen the effect of competition on the service by creating incentives for the market to respond to the quality of services delivered or prices charged, or by placing the applicant at greater financial risk. Depending upon the circumstances, such innovations may include prepayment provider contracts with potential patients for the delivery of the service, arrangements for more reliance upon private payment for services where appropriate or provider-insurer risk contracts with clearly established limits on prices or such a contract with effective utilization controls.

12.5. The board may develop and utilize standards relating to any review criteria which the board finds relevant and appropriate.

\$65-7-13

Stays and Extensions of Review Periods

13.1. At any time during the board's review of an application, the board may grant the applicant's request that the running of the review period be stayed. An application under

review and stayed at the request of the applicant for a total period exceeding one hundred eighty (180) days during any review period shall be considered withdrawn, and a new letter of intent and application must be filed if the applicant desires to pursue the project. Standard applications in batching categories (a) through (g) of section 10.1 of this rule may not be stayed without the agreement of all applicants with applications in those batching categories that are in the same review cycle and batch as the application for which the hold is requested.

13.2. Upon a finding by the board that it would not be practicable to complete the review of an application within the time provided by this rule, the board may extend the review process for up to an additional thirty (30) days. If the review process is extended for an application in one of batching categories (a) through (g) of section 10.1 of this rule, then all applications within that batching category that are in the same review cycle shall be similarly extended.

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

(a) A project is of such a comprehensive nature that to review it within the time provided by this rule would not

do justice to the applicant or to the population which the proposed project would serve;

(b) Additional information has been requested from the applicant and the applicant has failed to provide the information to the board in the time frame directed by the board; and

(c) Weather conditions or other natural disasters have prevented the review process from taking place in a timely manner.

13.4. If the board grants a stay or issues an extension of the review period, it may also extend the file closing date. If the file closing date has already passed when the stay is imposed or the review is extended, the board may reopen the file and reestablish the file closing date.

13.5. If a public hearing is rescheduled, a file closing date is extended or reestablished, or a stay or extension is placed on a review, the board shall notify all affected persons of the reasons therefor.

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

(a) That the proposed new institutional health service is needed and, with the exception of emergency circumstances that pose a threat to the public health, that the new institutional health service is consistent with the State Health Plan. If the proposed new institutional health service is not discussed in the State Health Plan, the application shall not be disapproved by the board solely for that reason.

(b) That after considering the appropriateness of the use of existing facilities providing services similar to those being proposed, that:

(1) Superior alternatives to such services in terms of cost, efficiency and appropriateness do not exist and that the development of such alternatives is not practicable;

(2) Existing facilities providing similar services to those proposed are using those services in an appropriate and efficient manner;

(3) 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;

(4) Patients will experience serious problems in obtaining care of the type proposed in the absence of the proposed new service;

(5) 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; and

(6) The project will be accessible to the medically underserved.

14.2. In addition to the above findings, the board's written findings will also take into consideration the following:

(a) The current accessibility of the facility as a whole;

(b) The need that the population served or to be served by the new institutional service has or will have for the service proposed to be offered or expanded, and the extent to which all residents of the area, and in particular the medically underserved population, are likely to have access to the service;

(c) In the case of a reduction or elimination of a service, including the relocation of a facility or service, the degree that the population presently served has for the service, the degree to which that need will be adequately met by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of the medically underserved population to obtain needed health care; and

(d) The contribution of the proposed service in meeting the health related needs of members of medically underserved populations which have traditionally experienced difficulties in obtaining equal access to health services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the board shall consider:

(1) The extent to which medically underserved populations currently use the applicant's services in

comparison to the percentage of the population in the applicant's service area which is medically underserved, and the extent to which medically underserved populations are expected to use the proposed services if approved;

(2) The performance of the applicant in meeting its obligation, if any, under any applicable federal regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal financial assistance, including the existence of any civil rights access complaints against the applicant;

(3) The extent to which medicare, medicaid and medically indigent patients are served by the applicant; and

(4) The extent to which the applicant offers a range of means by which a person will have access to its services, including, but not limited to, outpatient services, admission by house staff and admission by personal physician.

14.3. The board shall not be required to consider the criteria in subsection 14.2 of this rule where:

(a) The proposed new institutional health service is one to eliminate or prevent certain imminent safety hazards or to comply with certain licensure or accreditation standards;

(b) The new institutional health service is a proposed capital expenditure not directly related to the provision of health services or to beds or major medical equipment; or

(c) The new institutional health service is proposed by or on behalf of a health care facility which is controlled, directly or indirectly, by a health maintenance organization.

14.4. If the applicant is a health maintenance organization or a combination of health maintenance organizations, the board shall only consider the following criteria in issuing its written findings:

(a) The needs of enrolled members and reasonably anticipated new members of the health maintenance organization for the health services proposed to be provided by the organization;

(b) The availability of the new health services from nonhealth maintenance organization providers or other health maintenance organizations in a reasonable and cost-effective manner which is consistent with the basic method of operation of the

health maintenance organization. In assessing the availability of these health services from these providers, the board shall consider only whether the services from these providers:

(1) Would be available under a contract of at least five years duration;

(2) Would be available and conveniently accessible through physicians and other health professionals associated with the health maintenance organization;

(3) Would cost no more than if the services were provided by the health maintenance organization; and

(4) Would be available in a manner which is administratively feasible to the health maintenance organization.

14.5. If a health care facility controlled directly or indirectly by a health maintenance organization or combination of health maintenance organizations is the applicant, the board shall approve the application if it finds that:

(a) Approval of the application is required to meet the needs of the members of the health maintenance organization or group of health maintenance organizations and of

the new members which the organization or organizations can reasonably be expected to enroll; and

(b) The health maintenance organization or combination of health maintenance organizations is unable to provide, through services or facilities which can reasonably be expected to be available to the organization or group of organizations, its institutional health services in a reasonable and cost-effective manner which is consistent with the basic method of operation of the organization or group of organizations and which makes such services available on a long-term basis through physicians and other health professionals associated with it or them.

14.6. If the board 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 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 board shall approve the application to the extent that the capital expenditures is required to eliminate such hazards or meet such standards of accreditation or certification.

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

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

14.9. The decision and written findings of the board shall be sent by certified mail to the applicant and to any party. The decision and written findings shall also be available to other persons upon request and on payment of the cost set out in the fee schedule adopted by the board. Notice of the decision shall also be published in the Saturday Charleston newspapers.

14.10. If the application is for an expedited review pursuant to section 8 of this rule, or if the application falls within batching category (h) of section 10.1 of this rule, the

board shall issue its final decision and written findings before the sixty-fifth (65) day of the review cycle unless extended pursuant to the provisions of section 13 of this rule.

14.11. For the purposes of this rule, the date upon which all parties receive notice of the board's decision shall mean the date upon which legal notice of the decision appears in the Saturday Charleston newspapers.

14.12. Any application for a new institutional health service for which a certificate of need has been denied by the board may not be refiled for a period of one year.

§65-7-15

Exemptions From Certificate Of Need Program

15.1. Except for the acquisition of major medical equipment which costs in excess of three hundred thousand dollars, the following shall not be subject to supervision, regulation or control by the board.

(a) Any private office practice of one or more health professionals licensed pursuant to the provisions of Chapter 30 of the W. Va. Code. This exemption does not exempt from review the acquisition, offering or development of one or more health services, including ambulatory surgical facilities or centers,

lithotripsy, magnetic resonance imaging, radiation therapy by one or more health professionals and as further defined in rules promulgated by the board.

(b) Any dispensary or first-aid station located within a business or industrial establishment and maintained solely for the use of employees. The facility may not contain inpatient or resident beds for patients or employees who generally remain in the facility for more than twenty-four hours.

(c) Any establishment, such as motels, hotels and boarding houses, which provide medical, nursing personnel and health related services.

(d) The remedial care or treatment of residents or patients in any home or institution conducted only for those who rely solely upon treatment by prayer or spiritual means in accordance with the creed or tenets of any recognized church or religious denomination.

15.2. A certificate of need shall not be required for the offering of an inpatient institutional health service, the acquisition of major medical equipment for the provision of an inpatient institutional health service, or the obligation of a capital expenditure for the provisions of an inpatient institutional health service by the following if, with respect to

such offering, acquisition or obligation the board has granted an exemption. The board shall grant an exemption if it determines that the applicable requirements of this section are met or will be met on the date the proposed activity for which an exemption is requested will be undertaken.

(a) A health maintenance organization or a combination of health maintenance organizations if:

(1) The organization or combination of organizations has, in the service area of the organization or the service areas of the combined organizations, an enrollment of at least fifty thousand individuals;

(2) The facility in which the service will be provided is or will be geographically located so that the service will be reasonably accessible to the enrolled individuals; and

(3) At least seventy-five percent of the patients who can reasonably be expected to receive the institutional health service will be individuals enrolled with the organization or group of organizations.

(b) A health care facility if:

(1) The facility primarily provides or will provide inpatient health services;

(2) The facility is or will be controlled, either directly or indirectly, by a health maintenance organization or group of health maintenance organizations which has, in the service area of the organization or service areas of the combined organizations, an enrollment of at least fifty thousand individuals;

(3) The facility is or will be geographically located so that the service will be reasonably accessible to the enrolled individuals; and

(4) At least seventy-five percent of the patients who can reasonably be expected to receive the institutional health service will be individuals enrolled with the organization or group of organizations.

(c) A health care facility, or portion thereof, if:

(1) The facility is or will be leased by a health maintenance organization or group of health maintenance organizations which has, in the service area of the organization or service areas of the combined organizations, an enrollment of at

least fifty thousand individuals and at least fifteen years remain in the term of the lease;

(2) The facility is or will be geographically located so that the service will be reasonably accessible to the enrolled individuals; and

(3) At least seventy-five percent of the patients who can reasonably be expected to receive the new institutional health service will be individuals enrolled with the organization or group of organizations.

15.3. A health maintenance organization, combination of health maintenance organizations or other health care facility shall not be exempt from obtaining a certificate of need unless:

(a) It has submitted to the board, at such time as the board may prescribe, an application for the exemption;

(b) The application contains such information respecting the organization, combination of organizations, facility, proposed offering, acquisition or obligation as the board may require to determine whether the organization or combination meets the requirements of section 15.2 of this rule or that the facility meets or will meet the requirements; and

(c) The application is approved by the board.

15.4. No health care facility, part thereof, or medical equipment for which an exemption has been granted under sections 16.2 and 16.3 may be sold or leased unless:

(a) The board issues a certificate of need approving the sale, lease, acquisition or use; or

(b) The board determines, upon proper application, that the entity to which the facility or equipment is proposed to be sold or leased is:

(1) A health maintenance organization or a combination of health maintenance organizations with an enrollment of at least fifty thousand individuals and, with respect to the facility or equipment to be acquired or leased, the entity meets the accessibility and patient enrollment requirements of subsections 16.2(a) (2) and (3) of this rule; or

(2) A health care facility which meets the inpatient, enrollment and accessibility requirements of subsections 16.2(b)(1), (2) and (3) of this rule and, with respect to its patients, meets the enrollment requirements of subsection 15.2(b)(4).

15.5. A controlling interest in a health care facility, or part thereof, in medical equipment, or in a lease of such facility or equipment for which an exemption has been granted pursuant to section 15 of this rule, may not be acquired unless:

(a) The board issues a certificate of need approving the acquisition or use; or

(b) The board determines, upon proper application, that the entity acquiring interest in the facility, equipment or lease is:

(1) A health maintenance organization or a combination of health maintenance organizations with an enrollment of at least fifty thousand individuals and, with respect to the facility, equipment or lease for which a controlling interest is to be acquired, the entity meets the accessibility and patient enrollment requirements of subsections 16.2(a)(2) and (3) of this rule; or

(2) A health care facility which meets the inpatient, enrollment and accessibility requirements of subsections 16.2(b)(1), (2) and (3) of this rule and, with respect to its patients, meets the enrollment requirements of subsection 15.2(b)(4).

15.6. A health care facility granted on exemption pursuant to subsection 15.2(c) of this rule may not be used by any person other than the lessee originally granted the exemption unless:

(a) The board issues a certificate of need approving the acquisition of the facility or lease; or

(b) The board determines, upon proper application, that the entity acquiring the facility or lease is:

(1) A health maintenance organization or a combination of health maintenance organizations with an enrollment of at least fifty thousand individuals and, with respect to the facility to be acquired, the entity meets the accessibility and patient enrollment requirements of subsections 16.2(a)(2) and (3) of this rule; or

(2) A health care facility which meets the inpatient, enrollment and accessibility requirements of subsections 16.2(b)(1), (2) and (3) of this rule and, with respect to its patients, meets the enrollment requirements of subsection 15.2(b)(4).

15.7. Health maintenance organizations or ambulatory care facilities or health care facilities controlled

directly or indirectly by a health maintenance organization or combination of health maintenance organizations must obtain a certificate of need only if offering inpatient institutional health services, acquiring major medical equipment, or obligating capital expenditures for the offering of inpatient institutional health services. A certificate of need is required only for those offerings, acquisitions or obligations not exempt from such requirement pursuant to §16.2 of this rule.

15.8. The board shall grant or deny an application for exemption filed pursuant to section 15.3 of this rule within forty-five (45) days of the receipt of all information requested by the board. Failure to provide all information requested by the board within the period of time designated by the board shall result in the summary denial of the application.

15.9. A health care facility shall be exempt from the certificate of need requirements for the acquisition of major medical equipment to be used solely for research, the addition of health services to be offered solely for research, or the obligation of a capital expenditure to be made solely for research, if the facility notifies the board in writing of its intent and the use to be made of the medical equipment, health service or capital expenditure, and the board does not find, within sixty (60) days after it receives the notice, that the acquisition, offering or obligation will:

(a) Affect the charges of the facility for the provision of medical or other patient care services other than the services which are included in the research;

(b) Result in a substantial change to the bed capacity of the facility; or

(c) Result in a substantial change to the health services of the facility.

For the purposes of this section, the phrase "solely for research" also includes patient care provided on an occasional and irregular basis and not as part of a research program.

15.10. If major medical equipment is acquired, a health service is offered, or a capital expenditure is obligated solely for research, and a certificate of need is not required for the acquisition, offering or obligation, then the equipment, service or facility so acquired may not be used for another purpose unless the board issues a certificate of need approving the different use or purpose.

15.11. The board may exempt from certificate of need review the addition of the following health services not associated with a capital expenditure and which have projected annual operating costs less than the expenditure minimum: chemical

dependency beds or units, ICU/CCU beds, birthing centers, obstetric units, emergency rooms, discrete psychiatric units, pediatric beds or units, home health services, hospice services and computed tomography (CT) services. The board shall determine whether the proposed health service is likely to be substantially expanded during the next five (5) years without being subject to certificate of need review and, if such expansion is likely, whether the expansion is consistent with the state health plan. The board may grant an exemption if:

(a) The addition of the proposed health service is not associated with capital expenditure and is projected to entail annual operating costs less than the expenditure minimum for annual operating costs; and

(b) The application for the addition of the health service is consistent with the State Health Plan.

15.12. If a health service granted an exemption pursuant to section 15.11 of this rule does not exceed the expenditure minimum for annual operating costs for a period of five (5) years after the service is undertaken, it shall not be subject to future certificate of need review.

15.13. The board may exempt from certificate of need review the obligation of a capital expenditure to acquire, either

by purchase or under lease or comparable arrangement, an existing health care facility with a fair market value less than seven-hundred fifty thousand dollars (\$750,000.00) if:

(a) The board finds, within thirty (30) days of the date it receives a notice required by subsection (b) of this section, that the services or bed capacity of the facility will not be changed by reason of the acquisition; and

(b) Before the person enters into a contractual arrangement to acquire an existing health care facility, whether or not contingent upon the receipt of an exemption, a notification of such intent is sent to the board in writing at least thirty (30) days before contractual arrangements are entered into to acquire the facility, which notifies the board of the services to be offered in the facility and its bed capacity; and

(c) The board finds that the acquisition is financially feasible and that the applicant has adequate resources to ensure the viability of the project.

15.14. No person shall enter into a contractual arrangement to acquire an existing health care facility, whether or not contingent upon the receipt of an exemption, without first

providing written notice to the board as required by section 15.12 of this rule.

15.15. The board may exempt from certificate of need review the acquisition of major medical equipment which will not be owned by or located in a health care facility if the proposed use of the equipment is to provide temporary services to hospital inpatients under the following circumstances:

(a) In the event of a temporary emergency that poses a threat to the public health;

(b) If an inpatient is in imminent danger of death or permanent injury and the proposed equipment could, on a temporary basis, aid in the reduction of the danger; or

(c) If the hospital to be served by the equipment on a temporary basis has been denied a certificate of need for the same or similar equipment as that proposed, and to transport the inpatient to another facility with equipment similar to that proposed would present a greater risk to the patient than the risk of providing the service by use of the proposed equipment.

15.16. All health care facilities or persons granted an exemption from certificate of need review shall report the progress toward completion of the exempt project to the board not

less than forty-five (45) days prior to the anniversary date of the exemption or at such other time as the board may require in writing. Any failure to report the progress of the exempted project when required to do so, or to report a substantial change in the scope of the exempted project, shall be sufficient cause for the board to withdraw the exemption or determine that there has been a substantial change to the project requiring certificate of need review. If the board withdraws a previously granted exemption, the health care facility must obtain a certificate of need before proceeding with the project.

\$65-7-16

Exemption Review Procedure

16.1. Any person seeking an exemption pursuant to sections 16.11 or 16.13 of this rule or pursuant to rules promulgated by the board must file with the board a letter of intent to do so at least fifteen (15) days before the submission of a formal request for exemption. The letter of intent shall contain sufficient information to advise the board of the nature of the exemption sought and outline the grounds for such exemption.

16.2. Upon receipt of the letter of intent, the board shall publish a notice of such receipt in the Saturday Charleston newspapers and the State Register. The notice shall identify the legal entity seeking an exemption and the grounds

alleged for such exemption. The notice shall also state the rights of affected parties to a hearing.

16.3. An exemption application must be filed with the board no sooner than the fifteenth day or later than the thirtieth day following the filing of a letter of intent. Upon receipt of the application, the board shall have fifteen (15) days in which to determine whether or not the application is complete. If the application is not complete, the board may request additional information. Upon receipt of the additional information, the board shall have fifteen (15) days to determine if the application is complete.

16.4. Upon determining that the application is complete, and after the date has passed in which an affected person may request a hearing, the board shall publish a notice in the Saturday Charleston newspapers and the State Register. The notice shall identify the legal entity seeking the exemption and the grounds alleged for the exemption. If a hearing has been requested, the notice shall also state the time, date and place of hearing.

16.5. If no hearing has been requested by an affected party, the board shall render its decision on the exemption request within ten (10) days of the publication required by section 16.4.

16.6. If a hearing has been requested by an affected party, the board shall hold a hearing within thirty (30) days of the request unless the board sets a later date upon a showing of good cause therefor. At the conclusion of the hearing, the parties may submit proposed findings of fact and conclusions of law or legal briefs within five (5) days of the receipt of the transcript and this period may be extended only with the consent of the applicant. The board shall then have ten (10) days from the receipt of these items, or the closure of the record if those items are not tendered, to render its written decision.

16.7. The board may conduct a prehearing conference in accordance with Rule 16 of the West Virginia Rule's of Civil Procedure. If an order is first obtained from the board or a hearing examiner appointed by the board, the parties may engage in discovery as provided by the West Virginia Rules of Civil Procedure. The scope of any discovery permitted by this section shall be limited to relevant and admissible evidence.

\$65-7-17

Reconsideration of Final Board Decision

17.1. Any person may request, in writing, a public hearing for the purposes of reconsideration of a decision rendered by the board on a certificate of need application. If the request for reconsideration establishes good cause for reconsideration, then a public hearing shall be granted.

17.2. A request for a reconsideration hearing shall be deemed to have shown good cause if, in a detailed statement, it:

(a) Presents significant, relevant information not previously considered by the board, and demonstrates that with reasonable diligence the information could not have been presented before the board made its decision;

(b) Demonstrates that there have been significant changes in factors or circumstances relied upon by the board in reaching its decision;

(c) Demonstrates that the board has materially failed to follow its adopted procedures in reaching its decision; or

(d) Provides such other bases for a public hearing as the board determines constitutes good cause.

17.3. A request for reconsideration must be received by the board within thirty (30) days after the date upon which all parties received notice of the board's decision. A request for reconsideration shall stay the running of the appeal period until a decision is rendered upon the reconsideration.

17.4. Any hearing upon a request for reconsideration shall be held within thirty (30) days of the board's receipt of the request. This time period may be extended for good cause.

17.5. Notification of a reconsideration hearing shall be sent, prior to the date of the hearing, to the person requesting the hearing, the applicant proposing the new institutional health service and to any other person upon request.

17.6. The public reconsideration hearing shall be held in accordance with the public hearing requirements of this rule.

17.7. The board shall issue its written findings which state the basis of its decision upon the request for reconsideration within forty-five (45) days after the conclusion of the hearing.

17.8. The decision of the board after a reconsideration hearing shall be considered the final decision of the board subject to appeal pursuant to the provisions of section 18 of this rule.

17.9. A request for reconsideration which does not establish good cause shall be denied.

18.1. A final decision of the board relating to the issuance, denial or withdrawal of a certificate of need shall, upon request by an affected person, be reviewed by the State Tax Department's Office of Hearings and Appeals. A request for review must be received by the Office of Hearings and Appeals within thirty (30) days after the date upon which all parties received notice of the board's decision.

18.2. Requests for a review hearing must be addressed or delivered to: Chief Hearing Examiner, Office of Hearings and Appeals, State Tax Department, 1001 Lee Street, Charleston, West Virginia 25301. A copy of the request must also be addressed or delivered to the board.

18.3. To the extent not inconsistent with section 10 of the Act, for the purpose of administrative review of the board's decision, the Office of Hearings and Appeals 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, notwithstanding the exceptions contained in Code §29A-5-4.

18.4. The board and the Office of Hearings and Appeals may stay the effect of the board's decision pending its review. Such a stay must be in writing and at the request of the person appealing the board's decision or the applicant seeking a certificate of need.

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

18.6. If a person requesting the review of the board's decision fails to appear at the date, time and place of the hearing, the review shall, unless good cause be shown, be dismissed.

18.7. The written findings of the Office of Hearings and Appeals shall be sent to the person who requested the review, the person proposing the new institutional health service and the board. The board shall make copies of the decision available to others upon request.

18.8. Unless remanded to the board for further action or consideration, the decision of the Office of Hearings and Appeals shall be considered the final decision of the board.

18.9. If the Office of Hearings and Appeals remands the matter to the board, the remand order may establish a date by which further action shall be completed by the board. The order shall also state whether any findings or rulings of the board have been reversed or revised.

18.11. The Office of Hearings and Appeals may grant a continuance of a hearing or hold a rehearing of a review request. If a request for a general continuance is requested, and neither the person requesting the review or the applicant seeking the certificate of need for a new institutional service object, the Office of Hearings and Appeals may grant the request for a general continuance. If the continuance continues for more than one (1) year, the review shall be considered withdrawn with prejudice.

\$65-7-19

Judicial Review

19.1. Any final decision of the Office of Hearings and Appeals granting, denying or withdrawing a certificate of need or exemption shall be appealable to the Circuit Court of Kanawha County or to the circuit court of the county in which the petitioner or any of the petitioners reside or do business. The appeal shall be filed within thirty (30) days after the date upon which all parties receive notice of the decision of the Office of Hearings and Appeals.

19.2. Any party adversely affected by the Office of Hearings and Appeals review shall have standing to file an appeal. For the purposes of this section, a "person adversely affected by the review" means the board, any person who meets the definition of "affected person" under section 2 of the Act, and any person who participated in the proceeding before the board.

19.3. For the purposes of this section, no decision of the board shall be deemed final until it is reviewed by the Office of Hearings and Appeals pursuant to section 18 of this rule or until the time for such an appeal has elapsed. No circuit court shall have jurisdiction to consider a decision of the board if the petitioner has failed to file a request for review with the Office of Hearings and Appeals within the time permitted under section 18 of this rule, or, if a request for review was filed, the person requesting the review has failed to pursue the review and it has been dismissed with prejudice.

\$65-7-20

Progress Reports/Extension of Certificate of
Need

20.1. Any person holding a certificate of need or who has been granted an exemption under section 16 of this rule shall submit to the board, 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 be verified under oath 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 such other time as directed by the board. The report shall include, at a minimum, the following:

(a) The current status of the project in relation to the timetable in the application;

(b) The projected date of completion;

(c) The cause or causes of any delays encountered;

(d) Changes in the project, including any proposed changes for which a request is made for the board to determine whether the proposed change is reviewable as a substantial change or that an exemption previously granted under section 16 of this rule should be withdrawn and the applicant required to obtain a certificate of need for failure to meet the requirements of the exemption;

(e) The projected total cost; and

(f) Compliance with any conditions of certification.

20.2. Any person holding a certificate of need or exemption under section 16 of this rule shall submit any additional information requested by the board.

20.3. The creation of shelled in space shall not be considered completion unless explicitly provided for in the board's decision granting the certificate of need.

20.4. New conditions which are unrelated to the representations made by the applicant may not be imposed by the board at the time of recertification.

20.5. Any failure to submit a complete and timely progress report shall be sufficient grounds for the board to determine that any future certificate of need application was not complete or for the board to refuse to approve any increase in rates.

20.6. An obligation for a capital expenditure associated with an approved project or exemption under section 16 of this rule shall be incurred within twelve (12) months of issuance of the certificate of need or exemption unless the board 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 board 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 obligation for the first component must be incurred within twelve (12) months after the issuance of the certificate of need or exemption.

20.7. Upon good cause shown, the board 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 20.6 of this rule is not incurred within eighteen (18) months of the issuance of the certificate of need or exemption, the certificate or exemption shall automatically expire.

20.8. If a renewal review is underway, the old certificate of need shall automatically be extended until the completion of the renewal review.

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

§65-7-21

Substantial Changes to Project After Issuance
of Certificate of Need

21.1. In determining whether changes proposed to an approved project for which a certificate of need or exemption has been issued is substantial, the following shall be considered by the board as prima facie evidence of a substantial change.

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

(b) A change in the service area of the approved project;

(c) A change in the location to a county that was not significantly impacted by the proposal when it was originally approved;

(d) An addition in the number of beds or a change in the types of beds;

(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;

(f) The addition of health services;

(g) The increase or decrease in square footage in excess of 10% of the originally approved footage or 1,000 square feet, whichever is greater; and

(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.

21.2. No proposed substantial change to a previously approved project may be undertaken by an applicant until a determination of the need for review has been made by the board. The board will issue its decision on whether a new certificate of need review is required. The board shall issue its decision within (a) fifteen (15) days of its receipt of the request from the applicant, or (b) if additional information is requested by the board, within fifteen (15) days of its receipt of the additional information.

21.3. Any failure to inform the board of a proposed substantial change to a previously approved project may result in the withdrawal of the certificate of need.

§65-7-22

Transferability

22.1. 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.

22.2. If the board finds that a certificate of need has been transferred, the certificate shall be withdrawn.

§65-7-23

Substantial Compliance Review

23.1. The board shall conduct a substantial compliance review of all new institutional health services for which a certificate of need has been issued or for which an exemption has been granted under section 16 of this rule. 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 under section 16 of this rule, the applicant shall request, in writing, that the board undertake a substantial compliance review. The request must be verified under oath by the Chief Executive Officer.

23.2. The board shall issue its findings as to substantial compliance within forty-five (45) days of its receipt

of a request for such review. If the board finds that the project is not in substantial compliance with its certificate of need or exemption, the certificate or exemption may be withdrawn by the board and the board may direct that any license to operate the new service be revoked or denied, or the board may impose appropriate fines and/or seek an injunction against the use or operation of the new service.

23.3. If the board 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 board may issue a notice of substantial compliance, authorizing the licensure or the undertaking of the activity, which is conditional, for up to twelve (12) months. The applicant must prepare and submit documented final cost figures within the time designated by the board when issuing its notice of substantial compliance. Failure to submit the final cost figures within the time designated by the board may result in the withdraw of the certificate of need. The board may impose appropriate fines and seek an injunction against the further use or operation of the new service.

24.1. A certificate of need may be withdrawn by the board for any of the following reasons:

(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;

(b) Noncompliance with any conditions of certification;

(c) A substantial change in an approved new institutional health service for which change a certificate of need has not been issued;

(d) A material misrepresentation by an applicant upon which the board relied in making its decision; or

(e) Other reasons contained in the Act or this rule.

24.2. After the commencement of a hearing on the board'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 board or its staff or agents who exercise responsibility respecting the withdrawal of the certificate.

24.3. In the case of a proposed withdrawal of a certificate, the board 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 reconsideration provisions, the conditional decision provisions and the notification of decision and findings provisions of the Act and this rule.

24.4. An appeal of the withdrawal of a certificate of need shall be made pursuant to section 18 of this rule.

§65-7-25

Declaratory Judgement or Ruling of
Nonreviewability

25.1. A health care facility, health care provider or health maintenance organization regulated by the Act, or any person planning to acquire, offer or develop any new institutional health service may apply to the board for a declaratory ruling on any matter regulated by the Act or any rule promulgated thereunder.

25.2. Any person acquiring, offering or developing an institutional health service may apply to the board for a ruling regarding reviewability of the proposed institutional health service.

25.3. Any request for a declaratory ruling or a ruling regarding reviewability shall be made in writing. The request shall be addressed to Director of Certificate of Need, West Virginia Health Care Cost Review Authority, 100 Dee Drive, Suite 201, Charleston, West Virginia 25311. The request must be verified under oath by the Chief Executive Officer.

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

25.5. The board shall publish notice of its declaratory ruling or ruling regarding reviewability in the Saturday Charleston newspapers and the State Register.

25.6. Any affected person may, within ten (10) days of the published notice, request a reconsideration of the board's

ruling regarding reviewability. The request for reconsideration shall be in writing and must set forth with particularity the reasons for the request. The request shall be addressed to General Counsel, West Virginia Health Care Cost Review Authority, 100 Dee Drive, Suite 201, Charleston, West Virginia 25311.

25.7. Upon receipt of a request for reconsideration, the board shall, within ten (10) days, determine whether the request will be granted. If the board determines that the request should be granted, it shall also determine whether sufficient grounds have been established to hold a public hearing or whether the reconsideration shall be upon the record and any written matters submitted to the board pursuant to the requirements of section 25.10 of this rule. Notice of the board's decision regarding reconsideration shall be served upon the affected person requesting the reconsideration and the person requesting the original ruling.

25.8. The board's determination on whether the reconsideration shall be by public hearing or upon the record and other written matters submitted pursuant to section 25.10 shall be final and nonreviewable.

25.9. If the board determines that reconsideration will be granted, notice of said decision shall be published in the Saturday Charleston newspapers and the State Register. The notice

shall identify the person or entity requesting the ruling, the nature of the original ruling, and the date, time and place of a public hearing on the matter if one is to be held, and if not, then the date by which written submissions for review must be filed with the board.

25.10. If the board determines that a review shall be upon the record, it shall establish a schedule for the submission of written matters. Any affected person may submit written testimony, proposed findings of fact and conclusions of law and/or legal briefs within the time established by the board, but the time so established shall not be more than twenty (20) days after the publication required by section 25.9. A final ruling by the board must be issued on or before the forty-fifth day after the publication required by section 25.9.

25.11. If the board determines that a hearing should be held upon the request for reconsideration, it shall be held within thirty (30) days of the publication required by section 25.9 unless the board, for good cause shown, sets a later date.

25.12. The board may conduct a prehearing conference in accordance with Rule 16 of the West Virginia Rules of Civil Procedure. If an order is first obtained from the board or a hearing examiner appointed by the board, the parties may engage in discovery as provided by the West Virginia Rules of Civil

Procedure. The scope of any discovery shall be limited to relevant and admissible evidence.

25.13. At the conclusion of any hearing, the parties may submit proposed findings of fact and conclusions of law or legal briefs within five (5) days of the receipt of the transcript and this period may be extended only with the consent of the person or entity originally requesting the ruling on reviewability. The board shall then have fifteen (15) days from the receipt of those items or the closure of the record if those items are not tendered to make its determination in writing.

\$65-7-26

Public Access To Information

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

§65-7-27

Applicability

Any application for which a review cycle has been established prior to the effective date of this rule shall be considered under the rules in effect at the time the review cycle was established.

§65-7-28

Severability

If any section or provision of these regulations is declared unconstitutional or void by any court of competent jurisdiction or the applicability thereof to any person or circumstance is held invalid, the constitutionality or validity of the remainder of the regulations and the applicability thereof to other persons and circumstances shall not be affected thereby, and to this end, the sections and provisions of these regulations are declared to be severable.