WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION

Form #3

Do Not Mark In this Box

NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE
AND
FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

AGENCY: WEST VIRGINIA HEALTH CARE AUTHORITY TITLE NUMBER: 65

CITE AUTHORITY W. VA. CODE §16-2D-3(b)(5), 7(u) and 8

AMENDMENT TO AN EXISTING RULE: YES X NO ___

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 7

TITLE OF RULE BEING AMENDED: CERTIFICATE OF NEED RULE

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

TITLE OF RULE BEING PROPOSED: ___

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE MAKING REVIEW COMMITTEE FOR THEIR REVIEW.

D. Parker Holliday

Authorized Signature

$20.00

QUESTIONNAIRE

(Please include a copy of this form with each filing of your rule: Notice of Public Hearing or Comment Period; Proposed Rule, and if needed, Emergency and Modified Rule.)

DATE: AUGUST 6, 1999

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: (Agency Name, Address & Phone No.) WEST VIRGINIA HEALTH CARE AUTHORITY
100 DEE DRIVE, SUITE 201
CHARLESTON, WEST VIRGINIA 25311-1600
(304) 558-7000

LEGISLATIVE RULE TITLE: THE CERTIFICATE OF NEED RULE

1. Authorizing statute(s) citation W. VA. CODE §16-2D-3(b)(5), 7(u) and 8

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:

JUNE 30, 1999

b. What other notice, including advertising, did you give of the hearing?

AGENCY NEWSLETTER

c. Date of Public Hearing(s) ***or*** Public Comment Period ended:

JULY 30, 1999

d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

Attached X No comments received ____

e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing: (be exact)
AUGUST 6, 1999

f. **Name, title, address and phone/fax/e-mail numbers** of agency person(s) to receive all *written correspondence* regarding this rule: (Please type)

MARIANNE K. STONESTREET, GENERAL COUNSEL

WEST VIRGINIA HEALTH CARE AUTHORITY

100 DEE DRIVE, SUITE 201

CHARLESTON, WEST VIRGINIA 25311-1600

(304) 558-7000 - PHONE; (304) 558-7001 - FAX

g. ***IF DIFFERENT*** **FROM ITEM 'f'**, please give **Name, title, address and phone number(s)** of agency person(s) who wrote and/or has responsibility for the contents of this rule: (Please type)

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

a. Give the date upon which you filed in the State Register a notice of the time and place of a

hearing for the taking of evidence and a general description of the issues to be decided.

N/A

b. Date of hearing or comment period:

N/A

c. On what date did you file in the State Register the findings and determinations required together with the reasons therefor?

N/A

d. Attach findings and determinations and reasons:

Attached N/A

CERTIFICATE OF NEED RULE

TITLE 65
LEGISLATIVE RULE
HEALTH CARE AUTHORITY

SERIES 7
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 W. Va. Code §16-2D-1 et seq. as administered by the West Virginia Health Care Authority.

1.2. Authority. -- W. Va. Code §§16-2D-3(b)(5), 7(u) and 8(c).

1.3. Filing Date. --

1.4. Effective Date. --

1.5. This legislative rule repeals and replaces W. Va. 65 CSR 7, "Certificate of Need Rule" filed April 10, 1992 and effective April 10, 1992.

§65-7-2. Definitions.

As used in this legislative rule, all terms that are defined in section 2 of the Act have those same meanings which are in some cases further clarified in this section. Terms not defined in the Act have the following meanings unless the context expressly requires otherwise.

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

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

2.3. "Batching" means the consideration of completed certificate of need applications which 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 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. "Diagnostic Services" means, as referenced in subdivision 28.1.b. of this rule, laboratory or imaging services for which the total cost of all the equipment required to provide these services exceeds $2,000,000.00. In determining whether the medical equipment exceeds $2,000,000.00, the cost of studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the acquisition of the equipment shall be included. If the equipment is acquired for less than fair market value, the term "cost" includes fair market value.

2.9. "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 to be an emergency which poses a threat to public health or those circumstances upon which a state of emergency is declared pursuant to W. Va. Code §15-5-6.

2.10. "Health Care Facility" has the same meaning as contained in W. Va. Code §16-2D-2(j), but does not include personal care homes as defined in Code §16-5D-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. "Non-health Related Project" is a project that exceeds the expenditure minimum for capital expenditures but the expenditure is for a non-health related purpose. Examples of a non-health related project are a telephone system, a heating and cooling system, a parking garage, etc.

2.12. "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.

2.13. "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.

2.14. "Private office practice" means the independent practice of a health professional licensed pursuant to the provisions of W. Va. Code §30-1-1 et seq. which is not controlled directly or indirectly by a health care facility or a health care facility's related organization.

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

2.16. "Proposed New Institutional Health Service" means:

2.16.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 which has been so operated in the past;

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

2.16.c. Any obligation for a capital expenditure incurred by or on behalf of a health care facility, or health maintenance organization, except as exempted by this rule, in excess of the expenditure minimum or any obligation for a capital expenditure incurred by any person to acquire a health care facility. An obligation for a capital expenditure is considered to be incurred by or on behalf of a health care facility:

2.16.c.1. When a contract, enforceable under state law, is entered into by or on behalf of the health care facility for the construction, acquisition, lease or financing of a capital asset, the contract is the result of arms length negotiations; and, the board determines 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. The contract must also contain a fixed starting date and completion date;

2.16.c.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

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

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

2.16.e. The addition of any health service specified in section 28 of this rule offered by or on behalf of a health care facility or health maintenance organization and which was not offered on a regular basis by or on behalf of the health care facility or health maintenance organization within the twelve-month period prior to the time such services would be offered;

2.16.f. The addition of ventilator services for any nursing facility bed by any health care facility or health maintenance organization:

2.16.g. 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;

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

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

2.16.j. The acquisition of major medical equipment;

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

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

2.17. "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.

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

§65-7-3. Certificate of Need Requirements.

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

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

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

3.6.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

3.6.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 applicant must submit the original and three (3) copies of the application to the board. The application must have a verification signed by the Chief Executive Officer and the person or persons who prepared the application.

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

4.2.a. The identification of the applicant;

4.2.b. A copy of the governing body's approval of the proposal and its written authorization empowering specified individual(s) to sign the application and to act on its behalf;

4.2.c. A description of the project;

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

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

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

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

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

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

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

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

4.2.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;

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

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

4.2.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;

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

4.2.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;

4.2.r. If applicable, a 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;

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

4.2.t. If applicable, a documented analysis of the need and circumstances of health maintenance organizations.

§65-7-5. Expedited Applications.

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:

5.1. 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 or new institutional health services proposed to eliminate or alleviate emergency circumstances that pose a threat to public health;

5.2. Capital expenditures which do not involve the renovation or replacement of beds or a substantial change to bed capacity, or a substantial change to the health services of the facility;

5.3. The replacement of equipment;

5.4. The acquisition of health care facilities;

5.5. A substantial change to a new institutional health service for which a certificate of need is in effect;

5.6. Applications from ambulatory health care facilities, home health agencies, ambulatory surgical facilities and health maintenance organizations;

5.7. Applications for non-health related projects;

5.8. 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.

Every hospital or other entity proposing a new institutional service must submit to the board a long-range plan, adopted by the governing body of the entity 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:

6.1. A description of the organization and its purpose and structure;

6.2. 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;

6.3. An analysis of the resources necessary and available to accomplish the goals and objectives;

6.4. A description of the assumptions and rationale which form the basis for the goals and objectives; and

6.5. The proposed annual capital expenditure budget for each of the next three 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 applicant may not submit additional information unless it is requested by the board. If 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:

8.1.a. Extend the review cycle pursuant to the provisions of section 13 of this rule;

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

8.1.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. The board shall also publish a notice pursuant to subsection 11.6 of this rule.

§65-7-9. Application Withdrawal.

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

9.2. The applicant must file with the board a written notice withdrawing the application before the issuance of a final written decision.

§65-7-10. Batching of Applications.

10.1. The board shall batch all applications which pertain to similar types of services, facilities or equipment affecting the same health service area into the following categories and shall consider the applications in relation to each other:

10.1.a. Medical/surgical beds or acute care facilities: Beds, health services or capital expenditures in excess of the applicable expenditure minimum;

10.1.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;

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

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

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

10.1.f. Major medical equipment: Capital expenditures in excess of the applicable expenditure minimum;

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

10.1.h. Other proposed new institutional health services.

10.2. If any application is broader in scope than a single batching category, the board may include the components of the application within each appropriate category.

10.3. The board shall review standard applications which fall within batching categories (a) through (g) of subsection 10.1 of this rule 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 applicant must submit the application no later than fifteen (15) days prior to the beginning of the batch.

10.4. The board shall review expedited applications which fall within subsection 5.7 of this rule in cycles beginning each month. On the last working day of each month the board shall collect those applications filed pursuant to subsection 5.7 of this rule and determined to be complete during that month and establish a forty-five (45) day review cycle for those applications.

10.5. The board shall begin the review process for 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, on a weekly basis. On the last working day of each week the board shall collect the applications which fall into this category and are determined to be complete and establish the appropriate review cycle for those applications.

10.6. The board shall review all other expedited applications 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.

10.7. The board, in considering standard or expedited applications in relation to each other, shall consider to what extent the proposed new institutional health services 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.

10.8. The board may batch together standard and expedited applications reviewed if it determines that the applications pertain to similar types of services, facilities or equipment affecting the same health service area.

§65-7-11. Application Review Procedure.

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

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

11.3. Any person proposing a new institutional health service must file with the board a letter of intent at least fifteen (15) days before the submission of an 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 are 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 is required. Additional information may only be filed by an applicant at the request of the board. 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, the board shall not

declare an application complete if:

11.4.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;

11.4.b. The applicant is a health care facility subject to the financial disclosure or rate review 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 by the Code and the rules promulgated pursuant thereto.

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

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

11.6.a. The name of the applicant;

11.6.b. A description of the proposed project;

11.6.c. The date the review cycle begins;

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

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

11.6.f. The date upon which the board will issue a decision;

11.6.g. If applicable, a statement that the board has determined that the application is potentially unnecessarily duplicative of other applications under review; and

11.6.h. 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 board has published the required notice of completeness, any affected person may present reasons why the board should require the applicant to proceed with the project only upon the filing of a standard application. The affected person must submit the reasons 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, it shall immediately terminate the review of the expedited application.

11.8. When a determination of completeness is made by the board and the notice specified in subsection 11.6 of this rule is published, affected persons may request a public hearing within thirty (30) days from the beginning of the review period. A request for a public hearing must be in writing and shall be addressed to: General Counsel, West Virginia Health Care Authority, Certificate of Need Program, 100 Dee Drive, Suite 201, Charleston, West Virginia 25311.

11.9. The board shall hold a public hearing on an application if it is requested within the time period specified by subsection 11.8 of this rule 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 the board has determined other applications to be potentially unnecessarily duplicative thereof, the board shall hold the public hearing 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:

11.11.a. The name of the applicant;

11.11.b. A description of the proposed project;

11.11.c. The date of the public hearing; and,

11.11.d. The date of any prehearing conference.

The board shall conduct the hearing 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. The board may designate affected persons as parties after the prehearing conference only for good cause shown.

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

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

11.15. The party shall file the original and two copies of all communications concerning a pending application 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 is sufficient grounds for the board or its designee to strike the written communication from the record.

11.16. The board may subpoena witnesses, papers, records, documents and any other information or data it considers necessary for its determination. The board shall issue all subpoenas and subpoenas duces tecum in the name of the board. Any party requesting a subpoena or subpoena duces tecum is responsible for seeing that they are properly served. Service of subpoenas or subpoenas duces tecum issued at the instance of the board is 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 by the party 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 are the same as for witnesses before the circuit court of this State and shall be paid by the party requesting the issuance of the subpoena or subpoena duces tecum.

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 Kanawha County Circuit Court.

11.21. The parties may engage in discovery as provided by the West Virginia Rules of Civil Procedure. The scope of discovery is limited to relevant and admissible evidence. Parties engaging in discovery are required to file a copy of the certificate of service attached to the discovery request or response thereto with the board. Discovery requests and responses are not to be filed with the board.

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 are first 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. The board or its designee may continue a public hearing on an application 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 subsection 10.1 of this rule, the board shall close the file on the seventy-fifth day of the review. The board may extend the file closing date 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 subsection 10.1 of this rule, the board shall close the file on the thirty-first day of the review. The board may extend the file closing date 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 the 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.

§65-7-12. Review Criteria.

12.1. A certificate of need may only be issued if the proposed new institutional health service is:

12.1.a. Found to be needed; and

12.1.b. Except in emergency circumstances that pose a threat to public health, consistent with the State Health Plan.

12.2. In the case of any proposed new institutional health service, the board shall not grant a certificate of need unless, after consideration of the appropriateness of the use of existing facilities providing services similar to those being proposed, the board makes the following findings:

12.2.a. Superior alternatives to such services in terms of cost, efficiency and appropriateness do not exist and the development of such alternatives is not practicable;

12.2.b. Existing facilities providing services similar to those proposed are being used in an appropriate and efficient manner;

12.2.c. 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;

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

12.2.e. 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.

12.3. The board shall, at a minimum, consider the following criteria, if applicable, when making its determination to grant or deny a certificate of need.

12.3.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;

12.3.b. The relationship of services reviewed to the long-range development plan of the applicant providing or proposing the services;

12.3.c. The need that the population served or to be served by such services has for such services proposed to be offered or expanded, and the extent to which all residents of the area, and in particular low income persons, racial and ethnic minorities, women, handicapped persons, other medically underserved populations, and the elderly, are likely to have access to those services;

12.3.d. The availability of less costly or more effective alternative methods of providing the service or services to be offered, expanded, reduced, relocated or eliminated;

12.3.e. 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;

12.3.f. The relationship of the services proposed to the existing health care system in the area where the services are proposed to be provided;

12.3.g. 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 and other applicable plans;

12.3.h. The appropriate and nondiscriminatory utilization of existing and available health care providers;

12.3.i. The relationship, including the organizational relationship, of the health services proposed to be provided to ancillary or support services;

12.3.j. The 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.

12.3.k. In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the need that the population presently served has for the service, the extent to which that need will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, other medically underserved populations, and the elderly, to obtain needed health care;

12.3.l. In the case of a construction project:

12.3.l.1. The cost and methods of the proposed construction, including the costs and methods of energy provision; and

12.3.l.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;

12.3.m. 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;

12.3.n. 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;

12.3.o. 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;

12.3.p. The factors influencing the effect of competition on the supply of the health services being reviewed;

12.3.q. Improvements or innovations in the financing and delivery of health services which foster competition and serve to promote quality assurance and cost effectiveness;

12.3.r. 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;

12.3.s. In the case of existing services or facilities, the quality of care provided by such services or facilities in the past;

12.3.t. 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 services 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 shall 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;

12.3.u. The special circumstances of health care facilities with respect to the need for conserving energy;

12.3.v. The existence of a mechanism for soliciting consumer input into the health care facility's decision-making process; and

12.3.w.The accessibility of the project to the medically underserved;

12.4. If the applicant proposes to provide ventilator services for a nursing facility bed which have not been previously provided, the board shall consider the application in terms of the need for the service and whether the cost exceeds the level of current medicaid services. An applicant may not provide a higher level of service for a nursing facility bed without demonstrating that the change in level of service by the provision of the additional ventilator services will result in no additional fiscal burden to the state.

12.5. If the applicant proposes to provide personal care services, the board shall consider the application in terms of the need for service and whether the cost exceeds the level of the cost of current medicaid services. No applicant may provide personal care services to be billed for medicaid reimbursement without demonstrating that the provision of the personal care service will result in no additional fiscal burden to the state.

12.6. 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 is considered withdrawn, and the applicant must file a new letter of intent and an application if the applicant desires to pursue the project.

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.

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:

13.3.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;

13.3.b. The board has requested additional information from the applicant and the applicant has failed to provide the information to the board in the time frame directed by the board; and

13.3.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 for the action.

§65-7-14. Decision.

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:

14.1.a. That the proposed new institutional health service is needed;

14.1.b. 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 board shall not disapprove the application solely for that reason;

14.1.c. That 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;

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

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

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

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

14.2. 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 expenditure is required to eliminate such hazards or meet such standards of accreditation or certification.

14.3. 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.

14.4. 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 board may only issue a certificate of need with conditions if the conditions directly relate to the criteria found in the Act or any rule promulgated by the board. Conditions may be imposed upon the operations of the applicant for a period not exceeding three (3) years.

14.5. The board shall send its decision by certified mail to the applicant and to any affected party. The board shall also make the decision available to other persons upon request and on payment of the cost set out in the fee schedule adopted by the board. The board shall also publish notice of the decision in the Saturday Charleston newspapers.

14.6. 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 subsection 10.1 of this rule, the board shall issue its final decision before the sixty-fifth (65) day of the review cycle unless the review period is extended pursuant to the provisions of section 13 of this rule.

14.7. For the purposes of this rule, the date upon which the affected person filing the request for review received notice of the board's decision means the date upon which legal notice of the decision appears in the Saturday Charleston newspapers.

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

§65-7-15. Exemptions From Certificate Of Need Program.

15.1. Except for the acquisition of major medical equipment which costs in excess of two million dollars, the following projects are not subject to supervision, regulation or control by the board:

15.1.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 65 C.S.R. 17.

15.1.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.

15.1.c. Any establishment, such as a motel, hotel or boarding house, which provides medical, nursing personnel and health related services.

15.1.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.

15.1.e. The creation of new primary care services located in communities that are underserved with respect to primary care services. This exemption is limited to applicants that are community-based nonprofit organizations with community boards that provide or will provide primary care services to people without regard to ability to pay. This exemption is further defined in 65 CSR 23.

15.1.f. The creation of birthing center by nonprofit primary care centers that have a community board and provide primary care services to people in their community without regard to ability to pay, or by nonprofit hospitals with less than one hundred licensed acute care beds. This exemption is further defined in 65 CSR 24.

15.2.a. A health care facility is 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:

15.2.a.1. 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;

15.2.a.2. Result in a substantial change to the bed capacity of the facility; or

15.2.a.3. Result in a substantial change to the health services of the facility.

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

15.2.c. 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.

15.2.d. Prior to acquiring major medical equipment, offering a health service or obligating a capital expenditure solely for research, a health care facility shall notify the board in writing of its intent and the use to be made of the medical equipment, health service or capital expenditure.

15.3.a. 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 two million dollars if:

15.3.a.1. The board finds, within thirty (30) days of the date it receives a notice required by paragraph (2) of this subdivision, that the services or bed capacity of the facility will not be changed by reason of the acquisition; and

15.3.a.2. 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

15.3.a.3. The board finds that the acquisition is financially feasible and that the applicant has adequate resources to ensure the viability of the project.

15.3.b. 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 paragraph 15.3.a.2. of this rule.

15.4. An exemption from certificate of need review may be obtained by two or more acute care facilities for shared services which can reasonably be made mobile. This exemption is further defined in 65 CSR 16.

15.5. 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 one year 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, is 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 section 15 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 in the Saturday Charleston newspapers and the State Register. The notice shall identify the legal entity seeking an exemption, the type of exemption requested and a description of the proposal. The notice shall also state the rights of affected parties to a hearing.

16.3. The applicant must file an exemption application with the board no sooner than the fifteenth day or later than the thirtieth day following the filing of a letter of intent. The chief executive officer and the person or persons who prepared the application shall each sign a verification and attach it to the application. Upon receipt of the application, the board has 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. Additional information may only be submitted upon request of the board. Upon receipt of the additional information, the board has 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, the type of exemption requested and describe the proposal. 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 subsection 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. 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 the board may extend this period only with the consent of the applicant. The board then has 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. 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 is limited to relevant and admissible evidence. A copy of the certificate of service attached to the discovery request and the response must be filed with the board. Copies of the request and the response shall not be filed with the board.

16.8. Only an affected party may request a hearing and the affected party must file the request, in writing, with the board within ten (10) days of the publication of the notice in the Charleston Saturday newspapers as described in subsection 16.2 of this rule.

§65-7-17. Reconsideration of Final Board Decision.

17.1. Any person may request, in writing, 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 the board shall grant the request. Upon request, the board may grant a public hearing to consider the request for reconsideration.

17.2. A request for ~~a~~ reconsideration is considered to have shown good cause if, in a detailed statement, it:

17.2.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;

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

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

17.2.d. Provides such other basis for a public hearing as the board determines constitutes good cause.

17.3. The board must receive a request for reconsideration within thirty (30) days after the date of the board's decision.

17.4. The board or its designee shall hold any hearing upon a request for reconsideration within thirty (30) days of the board's receipt of the request. The board may extend this time period for good cause.

17.5. The board shall send notification of a reconsideration hearing 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 board shall hold the public reconsideration hearing 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. The board may extend this time period for good cause.

17.8. The decision of the board upon reconsideration is the final decision of the board subject to appeal pursuant to the provisions of section 18 of this rule.

17.9. The board shall deny a request for reconsideration which does not establish good cause.

17.10. If the board denies the request for reconsideration, the initial decision of the board is the final decision and the appeal period runs from the date of the order denying the reconsideration. If the board grants the request for reconsideration, the appeal period runs from the date of the decision upon reconsideration, which becomes the final order as specified in subsection 17.8 of this rule.

§65-7-18. Appeal of Certificate of Need Decision.

18.1. The Office of Judges, Bureau of Employment Programs shall review a final decision of the board relating to the issuance, denial or withdrawal of a certificate of need, upon request by an affected person. If a reconsideration request was not filed with the board by an affected person, a request for review must be received by the Office of Judges within thirty (30) days after the date upon which the affected person filing the request for review received notice of the board's decision. If a reconsideration request was filed with the board by an affected person, the time within which to file a request for review is governed by subsection 17.10 of this rule.

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

with the West Virginia Rules of Civil Procedure and the Local Rules for the Circuit Court of Kanawha County, and its review of appeals in accordance with the provisions governing the judicial review of contested administrative cases in W. Va. Code §29A-5-4.

18.4. The board may stay the effect of the board's decision pending 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 Office of Judges shall, unless good cause be shown, dismiss the request for review.

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

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

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

§65-7-19. Judicial Review.

19.1. Any final decision of the Office of Judges granting, denying or withdrawing a certificate of need or exemption may be appealed to the Circuit Court of Kanawha County or to the circuit court of the county in which the petitioner or any of the petitioners reside or do business. The appellant shall file an appeal within thirty (30) days after the date the appellant received notice of the decision of the Office of Judges.

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

19.3. For the purposes of this section, no decision of the board is considered final until it is reviewed by the Office of Judges pursuant to section 18 of this rule or until the time for such an appeal has elapsed. No circuit court has jurisdiction to consider a decision of the board if the petitioner has failed to file a request for review with the Office of Judges 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 The Office of Judges has dismissed the request for review 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 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 contain a verification signed by the Chief Executive Officer and must 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:

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

20.1.b. The projected date of completion;

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

20.1.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 should be withdrawn and the applicant be required to obtain a certificate of need for failure to meet the requirements of the exemption;

20.1.e. The projected total cost; and

20.1.f. Compliance with any conditions of certification.

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

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

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

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

20.6. The applicant shall incur an obligation for a capital expenditure associated with an approved project or exemption within twelve (12) months of issuance of the certificate of need or exemption unless the 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 applicant must incur the obligation for the first component 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 automatically expires.

20.8. If the obligation required to be incurred by subsection 20.6 of this rule is incurred within the prescribed time period, the applicant may request a renewal of the certificate of need in order to complete the project.

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

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

20.11. If a request for renewal of a certificate of need is not made before its expiration, the certificate automatically expires. For good cause shown, the board may waive the effect of this subsection and permit the extension of the certificate of need during the renewal 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 are substantial, the board shall consider the following as prima facie evidence of a substantial change.

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

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

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

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

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

21.1.f. The addition of health services;

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

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

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

§65-7-23. Substantial Compliance Review.

23.1. The board shall conduct a substantial compliance review of all new institutional health services for which it has issued a certificate of need or for which it has granted an exemption. No later than forty-five (45) days prior to licensure or the undertaking of the activity for which a certificate of need was issued or an exemption granted, the applicant shall request, in writing, that the board undertake a substantial compliance review. The request must contain a verification signed 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 board may withdraw the certificate or exemption 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 conditional notice of substantial compliance, authorizing the licensure or the undertaking of the activity, for up to twelve (12) months. The applicant must prepare and submit documented final cost figures within the time designated by the board in its notice of substantial compliance. Failure to submit the final cost figures within the time designated by the board may result in the withdrawal of the certificate of need by the board. The board may impose appropriate fines and seek an injunction against the further use or operation of the new service.

§65-7-24. Withdrawal of Certificate of Need.

24.1. The board may withdraw a certificate of need for any of the following reasons:

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

24.1.b. Noncompliance with any conditions of certification;

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

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

24.1.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 applicant may appeal the withdrawal of a certificate of need pursuant to section 18 of this rule.

§65-7-25. Declaratory Ruling or Ruling of Reviewability.

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. Persons who request a declaratory ruling or a ruling regarding reviewability shall make the request in writing. They shall address the request to: Chairman, West Virginia Health Care Authority, 100 Dee Drive, Suite 201, Charleston, West Virginia 25311. The request must contain a verification signed 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 board shall serve the ruling upon the person requesting the ruling and shall make the ruling available to any other person upon request and on payment of the cost set out in the fee schedule adopted by the board.

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

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 affected person shall make the request for reconsideration in writing and shall set forth with particularity the reasons for the request. The affected person shall address the request to: General Counsel, West Virginia Health Care Authority, 100 Dee Drive, Suite 201, Charleston, West Virginia 25311.

25.7. Upon receipt of a request for reconsideration, the board shall, within thirty (30) days, determine whether the request will be granted. If the board grants the request, it shall determine whether sufficient grounds are established to hold a public hearing or whether the reconsideration is upon the record and any written matters submitted to the board pursuant to the requirements of subsection 25.10 of this rule. The board shall serve notice of the board's decision regarding reconsideration upon all affected persons.

25.8. The board's determination of whether to hold a public hearing or to consider the request upon the record and other written matters submitted pursuant to section 25.10 is final and nonreviewable.

25.9. The board shall publish notice of its decision regarding reconsideration in the Saturday Charleston newspapers. 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.

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 proposed findings of fact and conclusions of law and/or legal briefs within the time established by the board. The board must issue a final ruling on or before the forty-fifth day after the submission of all written matters.

25.11. If the board determines that it should hold a hearing on the request for reconsideration, the hearing shall be held within thirty (30) days of the publication required by subsection 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. The parties may engage in discovery as provided by the West Virginia Rules of Civil Procedure. The scope of any discovery is limited to relevant and admissible evidence.

25.13. At the conclusion of any hearing, the parties shall submit proposed findings of fact and conclusions of law or legal briefs if required by the board. The board has forty-five (45) 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. The board shall make copies of any such applications or documents available to the public upon request. The board may charge its reasonable and customary fees for making such copies.

§65-7-27. Applicability.

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

§65-7-28. Addition of Health Services

28.1. The addition of the following health services offered by or on behalf of a health care facility or a health maintenance organization which were not offered on a regular basis within the twelve month period prior to the time the services would be offered is subject to certificate of need review pursuant to section 3(b)(5) of the Act:

28.1.a. Alcohol and other drug treatment and rehabilitation if offered in a discrete unit.

28.1.b. Ambulatory surgical facilities, ambulatory surgical centers and diagnostic services.

28.1.c. Cardiac catheterization.

28.1.d. Comprehensive medical rehabilitation on an inpatient basis.

28.1.e. End-stage renal dialysis stations and home training.

28.1.f. Intermediate care facilities for the mentally retarded (ICF-MR).

28.1.g. Discrete units for long term care nursing beds.

28.1.h. Lithotripsy.

28.1.i. Magnetic resonance imaging (MRI).

28.1.j. Medical or surgical beds.

28.1.k. Discrete obstetrical units.

28.1.l. Organ and tissue transplants.

28.1.m. Open heart surgery.

28.1.n. Discrete pediatric units.

28.1.o. Discrete inpatient psychiatric units.

28.1.p. Special care units for burns, intensive care, cardiac care, neonatal intensive care, neonatal intermediate care and pediatric intensive care.

28.1.q. Surgical services.

28.1.r. Radiation therapy.

28.1.s. Hospice.

28.1.t. Home health.

28.1.u. Positron emission tomography (PET).

28.1.v. In-home personal care services.

28.1.w. Outpatient behavioral health services.

28.2. The services listed in subsection 28.1 are subject to certificate of need review regardless of the expenditure associated with the proposal.

BRIEF SUMMARY OF THE RULE

CERTIFICATE OF NEED PROPOSED RULE

SUMMARY: This proposed legislative rule, the Certificate of Need Rule, outlines the process for obtaining a certificate of need or an exemption from certificate of need in West Virginia. Enrolled Senate Bill 492, which was passed by the legislature in 1999, directs the Health Care Authority (Authority) to develop this rule and to file it as an emergency rule.

This rule repeals and replaces former 65 CSR 7, "Certificate of Need Rule". The new rule increases the thresholds for major medical equipment and capital expenditures. It develops an expedited review process for non-health related services. In addition, the rule contains a list of health services which are subject to certificate of need review. Those services not on the list are not subject to review.

In summary, the proposed rule implements the provisions of Senate Bill 492 and updates the certificate of need rule to comply with current requirements. The Authority will administer and enforce the rule. For further information contact: Marianne K. Stonestreet, General Counsel, Health Care Authority, 100 Dee Drive, Suite 201, Charleston, West Virginia 25311-1600, telephone number (304) 558-7000; fax (304) 558-7001.

CERTIFICATE OF NEED RULE

TITLE 65
LEGISLATIVE RULE
HEALTH CARE COST REVIEW AUTHORITY

SERIES 7
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 W. Va. 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. – April 10, 1992

1.4. Effective Date. – April 10, 1992

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 section 2 of the Act have those same meanings which are in some cases further clarified in this section. Terms not defined in the Act have the following meanings unless the context expressly requires otherwise.

2.1. "Acquire a Health Care Facility" means to obtain by purchase, donation, lease 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 corporation 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, W. Va. 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 to be an emergency which poses a threat to public health or those circumstances upon which a state of emergency is declared pursuant to W. Va. Code §15-5-6.

2.9. "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 which 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, or health maintenance organization, except as exempted by this rule, 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; and, the board determines 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. The contract must also contain 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.

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

§65-7-3. Certificate of Need Requirements.

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

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 is 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 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 is 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. The board may determine a series of expenditures, each less than the expenditure minimum, which, when taken together, are in excess of the expenditure minimum, to be a single expenditure subject to the review of the 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 applicant must submit the original and three (3) copies of the application to the board. The application must have a verification signed by the Chief Executive Officer and the person or persons who prepared the application.

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

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

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

(g) A documented analysis of alternatives considered by the applicant;

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

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

(j) A 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, a 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, a documented analysis of the needs and circumstances of research projects; and

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

§65-7-5. Expedited Applications.

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, or replacement of beds 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;

(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 next three 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. The board shall also publish a notice pursuant to subsection 11.6 of this rule.

§65-7-9. Application Withdrawal.

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

9.2. The applicant must file with the board a written notice withdrawing the application before the issuance of a final written decision.

§65-7-10. Batching of Applications.

10.1. The board shall batch all applications which pertain to similar types of services, facilities or equipment affecting the same health service area into the following categories and shall consider the applications in relation to each other:

(a) Medical/surgical beds or acute care 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 board may include the components of the application within each appropriate category.

10.3. The board shall review standard applications which fall within batching categories (a) through (g) of subsection 10.1 of this rule 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 applicant must submit the application no later than fifteen (15) days prior to the beginning of the batch.

10.4. The board shall review any standard application submitted to the board which falls entirely within batching category (h) 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. The board shall review expedited applications 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. The board, in considering standard or expedited applications in relation to each other, the board shall consider to what extent the proposed new institutional health services 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. The board may batch together standard and expedited applications reviewed pursuant to subsections 10.4 and 10.5 if it determines that the applications pertain to similar types of services, facilities or equipment affecting the same health service area.

10.8. The board shall begin the review process for 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, on a weekly basis. On the last working day of each week the board shall collect the applications which fall into this category and are determined to be complete and establish the appropriate review cycle for those applications.

§65-7-11. Application Review Procedure.

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

11.2. An application for a certificate of need must be submitted to 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 at least fifteen (15) days before the submission of an 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 are 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 is 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, the board shall not declare an application 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 by the Code and the rules promulgated pursuant thereto.

11.5. The board must make a determination of completeness 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 has fifteen (15) days within which to determine if the application is complete. If the applicant fails to respond within one hundred eighty (180) days, the application is considered withdrawn. If the applicant later desires to pursue the project, the applicant must file a new letter of intent and an application.

11.6. Upon a determination by the board that an application is complete, the board shall publish a 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 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 the board will issue a decision;

(g) If applicable, a statement that the board has determined that the application is potentially unnecessarily duplicative of other applications under review; and

(h) 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 board has published the required notice of completeness, any affected person may present reasons why the board should require the applicant to proceed with the project only upon the filing of a standard application. The affected person must submit the reasons 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, it shall immediately terminate the review of the expedited application.

11.8. When a determination of completeness is made by the board and the notice specified in subsection 11.6 of this rule is published, affected persons may request a public hearing within thirty (30) days from the beginning of the review period. 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 it is requested within the time period specified by subsection 11.8 of this rule 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 the board has determined other applications to be potentially unnecessarily duplicative thereof, the board shall hold the public hearing 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; and,

(d) The date of any prehearing conference.

The board shall conduct the hearing 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. The board may designate affected persons as parties after the prehearing conference only for good cause shown.

11.13. Parties must file all prehearing motions with the board prior to the prehearing conference. The board or its designee shall consider motions at the prehearing conference.

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

11.15. The party shall file the original and two copies of all communications concerning a pending application 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 is sufficient grounds for the board or its designee to strike the written communication from the record.

11.16. The board may subpoena witnesses, papers, records, documents and any other information or data it considers necessary for its determination. The board shall issue all subpoenas and subpoenas duces tecum in the name of the board. Any party requesting a subpoena or subpoena duces tecum is responsible for seeing that they are properly served. Service of subpoenas or subpoenas duces tecum issued at the instance of the board are 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 by the party 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 are the same as for witnesses before the circuit court of this State and shall be paid by the party requesting the issuance of the subpoena or subpoena duces tecum.

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 Kanawha County Circuit Court.

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, is 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 are first 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. The board or its designee may continue a public hearing on an application 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 subsection 10.1 of this rule, the board shall close the file on the seventy-fifth day of the review. The board may extend the file closing date 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 subsection 10.1 of this rule, the board shall close the file on the thirty-first day of the review. The board may extend the file closing date 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 the 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 need that the population served or to be served by such services has for such services proposed to be offered or expanded, and the extent to which all residents of the area, and in particular low income persons, racial and ethnic minorities, women, handicapped persons, other medically underserved population, and the

elderly, are likely to have access to those services;

(d) 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;

(e) 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;

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

(g) 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;

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

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

(j) The 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.

(k) 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;

(l) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the need that the population presently served has for the service, the extent to which that need will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, other medically underserved population, and the elderly, to obtain needed health care;

(m) 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;

(n) 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;

(o) 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;

(p) 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;

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

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

(s) 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;

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

(u) 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;

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

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

(x) The accessibility of the project to the medically underserved;

(y) 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), (d), (e), (f), (g), (i), (m), (s), (t) and (w) 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 a group of organizations. These needs and circumstances are 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 board 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 (q) and (r) of subsection 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 is considered withdrawn, and the applicant must file a new letter of intent and an application if the applicant desires to pursue the project. The board may not stay standard applications in batching categories (a) through (g) of subsection 10.1 of this rule 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 stay 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 subsection 10.1 of this rule, then the board shall similarly extend all applications within that batching category that are in the same review cycle.

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) The board has requested additional information 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 for the action.

§65-7-14. Decision.

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,

(b) 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 board shall not disapprove the application shall not be solely for that reason; and

(c) 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. 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.

14.3. 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.

14.4. 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 board may only issue a certificate of need with conditions if the conditions directly relate to the criteria found in the Act or any rule promulgated by the board, and conditions upon the operations of the applicant for a period exceeding three (3) years.

14.5. The board shall send its decision by certified mail to the applicant and to any party. The board shall also make the decision available to other persons upon request and on payment of the cost set out in the fee schedule adopted by the board. The board shall also publish notice of the decision in the Saturday Charleston newspapers.

14.6. 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 subsection 10.1 of this rule, the board shall issue its final decision before the sixty-fifth (65) day of the review cycle unless the review period is extended pursuant to the provisions of section 13 of this rule.

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

14.8. An applicant shall not refile any application for a new institutional health service for which a certificate of need has been denied by the board 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 projects are not 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 65 C.S.R. 17.

(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 is not 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 is not 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 of organizations meets the requirements of subsection 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 subsections 15.2 and 15.3 may be sold or leased unless:

(a) The board issues a certificate of need approving its 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 15.2(a) (2) and (3) of this rule; or

(2) A health care facility which meets the inpatient, enrollment and accessibility requirements of subsections 15 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 the board has granted an exemption 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 15.2(a) (2) and (3) of this rule; or

(2) A health care facility which meets the inpatient, enrollment and accessibility requirements of subsections 15.2(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. Only the lessee which originally received an exemption pursuant to subsection 15.2(c) of this rule may use a health care facility unless:

(a) The board issues a certificate of need approving the acquisition or lease of the facility; 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 15.2(a) (2) and (3) of this rule; or

(2) A health care facility which meets the inpatient, enrollment and accessibility requirements of subsections 15.2(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 subsection 15.2 of this rule.

15.8. The board shall grant or deny an application for exemption filed pursuant to subsection 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 is 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 a 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 subsection 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 is not 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 15.13 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 one year 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, is 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 section 15 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 in the Saturday Charleston newspapers and the State Register. The notice shall identify the legal entity seeking an exemption, the type of exemption requested and a description of the proposal. The notice shall also state the rights of affected parties to a hearing.

16.3. The applicant must file an exemption application with the board no sooner than the fifteenth day or later than the thirtieth day following the filing of a letter of intent. The chief executive officer and the person or persons who prepared the application shall each sign a verification and attach it to the application. Upon receipt of the application, the board has 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 has 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, the type of exemption requested and describe the proposal. 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 subsection 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 the board may extend this period only with the consent of the applicant. The board then has 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 is limited to relevant and admissible evidence.

16.8. Only an affected party may request a hearing and the affected party must file the request, in writing, with the board within ten (10) days of the publication of the notice in the

Charleston Saturday newspapers as described in subsection 16.2 of this rule.

§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 the board shall grant a public hearing.

17.2. A request for a reconsideration hearing is considered 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. The board must receive a request for reconsideration 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. The board or its designee hold any hearing upon a request for reconsideration within thirty (30) days of the board's receipt of the request. The board may extend this time period for good cause.

17.5. The board shall send notification of a reconsideration hearing 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 board shall hold 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. The board may extend this time period for good cause.

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

17.9. The board shall deny a request for reconsideration which does not establish good cause.

§65-7-18. Appeal of Certificate of Need Decision.

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

18.2. Affected persons must address or deliver requests for a review hearing to: Chief Hearing Examiner, Office of Hearings and Appeals, State Tax Department, 1001 Lee Street, Charleston, West Virginia 25301. Affected persons must also address or deliver a copy of the request 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 Office of Hearings and Appeals shall, unless good cause be shown, dismiss the request for review.

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

18.9. 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 is 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 is 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 appellant shall file an 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 has 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 is considered 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 has 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 The Office of Hearings and Appeals has dismissed the request for review 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 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 contain a verification signed by the Chief Executive Officer and must 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 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 shall submit any additional information requested by the board.

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

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

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

20.6. The applicant shall incur an obligation for a capital expenditure associated with an approved project or exemption within twelve (12) months of issuance of the certificate of need or exemption unless the 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 applicant must incur the obligation for the first component 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 automatically expires.

20.8. If the obligation required to be incurred by subsection 20.6 of this rule is incurred within the prescribed time period, the applicant may request a renewal of the certificate of need in order to complete the project.

20.9. If a renewal review is underway, the board shall automatically extend the old certificate of need extended until the completion of the renewal review.

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

20.11. If a request for renewal of a certificate of need is not made before its expiration, the certificate shall automatically expires. For good cause shown, the board may waive the effect of this subsection and permit the extension of the certificate of need during a the renewal 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 are substantial, the board shall consider the following as prima facie evidence of a substantial change.

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

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

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

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

(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. An applicant shall not make a proposed substantial change to a previously approved project until the board has made a determination of the need for review. 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 board withdrawing 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 board shall withdraw the certificate.

§65-7-23. Substantial Compliance Review.

23.1. The board shall conduct a substantial compliance review of all new institutional health services for which it has issued a certificate of need or for which it has granted an exemption. No later than forty-five (45) days prior to licensure or the undertaking of the activity for which a certificate of need was issued or an exemption granted, the applicant shall request, in writing, that the board undertake a substantial compliance review. The request must contain a verification signed 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 board may withdraw the certificate or exemption 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 conditional notice of substantial compliance, authorizing the licensure or the undertaking of the activity, for up to twelve (12) months. The applicant must prepare and submit documented final cost figures within the time designated by the board in its notice of substantial compliance. Failure to submit the final cost figures within the time designated by the board may result in the withdrawal of the certificate of need by the board. The board may impose appropriate fines and seek an injunction

against the further use or operation of the new service.

§65-7-24. Withdrawal of Certificate of Need.

24.1. The board may withdraw 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 the board has not issued a certificate of need;

(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 applicant may appeal the withdrawal of a certificate of need pursuant to section 18 of this rule.

§65-7-25. Declaratory Ruling or Ruling of Reviewability.

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. Persons who request a declaratory ruling or a ruling regarding reviewability shall make the request in writing. They shall address the request to: Chairman, West Virginia Health Care Cost Review Authority, 100 Dee Drive, Suite 201, Charleston, West Virginia 25311. The request must contain a verification signed 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 board shall serve the ruling upon the person requesting the ruling and shall make the ruling available to any other person upon request and on payment of the cost set out in the fee schedule adopted by the 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 affected person shall make the request for reconsideration shall be in writing and shall set forth with particularity the reasons for the request. The affected person shall address the request 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 thirty (30) days, determine whether the request will be granted. If the board grants the request, it shall determine whether sufficient grounds are established to hold a public hearing or whether the reconsideration is upon the record and any written matters submitted to the board pursuant to the requirements of subsection 25.10 of this rule. The board shall serve notice of the board's decision regarding reconsideration upon all affected persons.

25.8. The board's determination of whether to hold a public hearing or to consider the request upon the record and other written matters submitted pursuant to section 25.10 is final and nonreviewable.

25.9. The board shall publish notice of its decision regarding reconsideration 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.

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 proposed findings of fact and conclusions of law and/or legal briefs within the time established by the board. The board must issue a final ruling on or before the forty-fifth day after the submission of all written matters.

25.11. If the board determines that it should hold a hearing on the request for reconsideration, it the hearing shall be held within thirty (30) days of the publication required by subsection 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 is limited to relevant and admissible evidence.

25.13. At the conclusion of any hearing, the parties shall submit proposed findings of fact and conclusions of law or legal briefs if required by the board. The board has forty-five (45) 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. The board shall make copies of any such applications or documents available to the public upon request. The board may charge its reasonable and customary fees for making such copies.

§65-7-27. Applicability.

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

§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 is not affected thereby, and to this end, the sections and provisions of these regulations are severable.

STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE RULE TO BE FILED AS AN EMERGENCY

CERTIFICATE OF NEED PROPOSED RULE

The 1999 Legislature passed Enrolled Senate Bill 492 which directs the Health Care Authority (Authority) to file emergency rules to implement certain changes within the certificate of need law. W. Va. Code §§16-2D-3(b)(5), 7(u) and 8(c) give the agency the authority to file this rule as an emergency rule.

The purpose of this rule is to update the certificate of need process to comply with requirements of Senate Bill 492.

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: CERTIFICATE OF NEED RULE

Type of Rule: X Legislative ____Interpretive ____Procedural

Agency WEST VIRGINIA HEALTH CARE AUTHORITY

Address 100 DEE DRIVE, SUITE 201

CHARLESTON, WV 25311-1600

1. Effect of Proposed Rule

	ANNUAL		FISCAL YEAR		
	INCREASE	DECREASE	CURRENT	NEXT	THEREAFTER
ESTIMATED TOTAL COST	$ 0	$ 0	$ 0	$ 0	$ 0
PERSONAL SERVICES	0	0	0	0	0
CURRENT EXPENSE	0	0	0	0	0
REPAIRS & ALTERNATIONS	0	0	0	0	0
EQUIPMENT	0	0	0	0	0
OTHER	0	0	0	0	0

2. Explanation of above estimates:

3. Objectives of these rules:

TO ENFORCE SIGNIFICANT CHANGES MADE TO THE CERTIFICATE OF NEED LAW DURING THE 1999 REGULAR SESSION IN S.B. 492. TO UPDATE THE RULE TO COMPLY WITH DIRECTIVES CONTAINED IN LEGISLATION.

Rule Title: CERTIFICATE OF NEED RULE

4. **Explanation of Overall Economic Impact of Proposed Rule.**

A. **Economic Impact on State Government.**

N/A

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

REDUCES ITEMS FOR WHICH A CERTIFICATE OF NEED IS REQUIRED FOR HOSPITALS AND OTHER HEALTH CARE FACILITIES. SHOULD LOWER ADMINISTRATIVE COSTS FOR THESE ENTITIES.

C. **Economic Impact on Citizens/Public at Large.**

RAISES THRESHOLDS FOR CERTIFICATE OF NEED REVIEW AND LIMITS SERVICES REVIEWED BY THE HEALTH CARE AUTHORITY. COULD RAISE HEALTH CARE COSTS TO PUBLIC.

Date: JUNE 30, 1999

Signature of Agency Head or Authorized Reprensentative

D. Clark Holding

RESPONSE TO COMMENTS RECEIVED TO "CERTIFICATE OF NEED RULE" TITLE 65, SERIES 7

The West Virginia Health Care Authority ("HCA") received several comments to the proposed legislative rule, "The Certificate of Need Rule", 65 CSR 7. The comments received were from hospitals or their related organizations and were general in nature. However, the West Virginia Hospital Association ("WVHA") filed specific comments on July 30, 1999 which correspond to individual sections of the proposed rule. The specific comments filed by the WVHA incorporate all the general comments received by the HCA from the individual hospitals; therefore, the HCA's response corresponds to the specific sections referenced by the WVHA.

Many of the arguments made by the WVHA are more appropriately made to the Secretary of State as they relate to emergency rule making authority. Because the WVHA has duplicated many of the arguments before the Secretary of State in its comments to the HCA, the HCA has attached a copy of its response to the Secretary of State for the Legislative Rule Making Review Committee's review.

Following are the HCA's specific responses to the WVHA's comments filed with the HCA on July 30, 1999:

An argument made by the opponents to Series 7 throughout their commentary is that the changes made to Series 7 are not contemplated by Senate Bill 492. This is not accurate. Senate Bill 492 specifically authorized the HCA to amend the existing Certificate of Need Rule pursuant to the authority granted by W. Va. Code §16-2D-8. In addition, Senate Bill 492 specifically

granted the HCA emergency rule making authority under W. Va. Code §16-2D-8(c). This Code section states as follows:

> Subsequent amendments and modifications to any rule promulgated pursuant to this article may be implemented by emergency rule.

This is new language. Previously, the HCA did not have the authority to amend certificate of need rules by emergency rule. The purpose of inserting this provision in Senate Bill 492 was specifically to allow the HCA to update and clarify HCA policy and to implement changes which have occurred in the Certificate of Need ("CON") laws since 1991, the last time Series 7 was amended. This language and its intended purpose was agreed upon by the co-chairs of the Certificate of Need Task Force. Therefore, the argument by the opponents that the changes to Series 7 are not within the scope of Senate Bill 492 is without merit.

The specific provisions of the Certificate of Need Rule upon which comments were received are as follows:

65 CSR §7-2.1. – The HCA's proposed amendment of the definition of "Acquire a Health Care Facility" simply reflects the agency's practice and policy for the last seven years. This definition is widely known and accepted by all entities regulated by HCA. The HCA has issued approximately nineteen (19) decisions in the last seven years which have consistently held that a stock acquisition which causes a change in the control or ownership of a health care facility is a reviewable activity under the Certificate of Need law. None of these decisions have ever been challenged or appealed upon the basis that a stock acquisition does not constitute a change in control or ownership of a health care facility. Furthermore, as admitted by the WVHA, the language contained in W. Va. Code §16-2D-11(a) clearly authorizes this practice.

The WVHA cites W. Va. Code §16-2D-3(b)(3) as a basis for its argument. However, this Code section relates to capital expenditures subject to certificate of need review and is not applicable to the current situation. The controlling statute is W. Va. Code §16-2D-3(b)(1) which requires the following activities be subject to CON review:

> The construction, development, acquisition or other establishment of a new health care facility or health maintenance organization;

This section requires that the "acquisition" of a health care facility be subject to certificate of need review, whether that acquisition is by asset acquisition or stock acquisition. Further, W. Va. Code §16-2D-11(a) clearly contemplates stock transfers as a type of acquisition.

In addition, the WVHA complains that the rule does not specify what type of stock acquisition constitutes the acquisition of a health care facility. This is not true. The rule specifically states that to obtain a majority of stock is considered an "acquisition" of a health care facility. Proposed 65 CSR §7-2.1 states:

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

In summary, the WVHA's comments are misguided as the rule simply clarifies existing law and policy. Further, the WVHA is mistaken regarding the amount of stock required, as the rule clearly requires a majority.

65 CSR §7-2.8. – The HCA was required to specify the health services subject to CON review as recommended by the CON Study conducted pursuant

to W. Va. Code §16-29B-19a. The term "Diagnostic Services" defined under 65 CSR §7-2.8 of the proposed rule was one of the reviewable services under the CON Study. In addition, the CON Study specifically states that "[t]he Subcommittee recommends that the [HCA] develop definitions, where needed, to clarify what is included in these services." (CON Study, p. 14). Thus, the HCA was given a specific directive by the CON Study to develop definitions for any of the listed services. This mandate grew out of the emergency rule language contained in W. Va. Code §16-2D-3(b)(5) and therefore the HCA is not violating Senate Bill 492.

The HCA used the definition of "Diagnostic Center" in 65 CSR §17-2.1 as the basis to develop the definition of "Diagnostic Services" in 65 CSR §7-2.8. The HCA has attempted to establish a single definition applicable to both situations. The definition proposed by the WVHA requires CON review of diagnostic services for new providers only. Existing providers of these services are not subject to review. This proposed definition by the WVHA discriminates between new and existing providers. There is no basis for this differentiation in the legislation or the CON study. In the absence of a legislative directive to differentiate among providers, the HCA elected to treat all providers equally.

65 CSR §7-2.14. – The HCA's definition of "Private office practice", similarly to "Acquire a Health Care Facility" simply reflects current and past practice and policy as enforced by the agency since 1996. The WVHA argues that health care facilities operated by physicians which are funded or controlled by hospitals or their related organizations should be considered a private office practice and exempt from certificate of need review. This is misguided. West Virginia Code §16-2D-4(a)(1) clearly does not contemplate that facilities which are controlled by hospitals should be exempt from certificate of need review. The WVHA's definition clearly exceeds the intent of the Certificate of Need law. Furthermore, the WVHA's interpretation is strongly opposed by primary care centers and other health care facilities which are subject to CON review and

which cannot compete with clinics and facilities funded by hospitals if they are exempt from review.

The WVHA refers to In re: Community Medical Associates, CON File #95-6-5379-PV ("CMA") as pertinent to this issue. This is inaccurate for several reasons. First, the arguments advanced in that case are not relevant to the current discussion regarding the HCA's rule making authority. Second, it is important to note that this case has been pending since 1996; has not been prosecuted by the appellant; and is subject to dismissal. Third, the WVHA was not a party and did not appeal this case. Finally, the HCA has issued numerous decisions since the case in question which are consistent with the policy enunciated therein; and none of these were appealed. In short, the WVHA's objections to this policy are inappropriate in this forum.

65 CSR §7-5.7. – 10.4. – The HCA, pursuant to Senate Bill 492 has developed a fast track review process for non-health related services. The statute requires that the process not exceed forty-five (45) days. Accordingly, the agency has created a new review process which shortens the normal expedited review from sixty-five (65) days to forty-five (45) days specifically for these types of services. The application for this type of project will be short and limited primarily to the financial impact of the project as suggested by the WVHA.

The WVHA argues that the HCA should establish a process by which non-health related projects are reviewed as "exemptions" under 65 CSR §7-16, rather than expedited CON applications under 65 CSR §7-5. However, Senate Bill 492 did not place the fast track review process for non-health related services in W. Va. Code §16-2D-4, "Exemptions from certificate of need review." West Virginia Code §16-2D-4 provides certain exemptions from CON review and the procedures for obtaining exemptions. Instead, Senate Bill 492 added the fast track review process for non-health related services under W. Va. Code §16-2D-7(u), "Procedures for Certificate of Need Review". If the Legislature had wanted

the review of non-health related projects to be fast tracked under the "exemption" procedure – the Legislature would have placed the fast track language introduced in Senate Bill 492 under the "Exemption from certificate of need" section of the Code. Instead, the language was included under W. Va. Code §16-2D-7, "Procedures for certificate of need reviews".

In addition, it should be noted that the contents of a certificate of need application have never been contained in a legislative rule as this is a document which requires some administrative flexibility as changes are needed on a regular basis and the application forms need to be updated. Therefore, the contents of the application have not been included in this rule in accordance with past practice; however, it is the HCA's position that the application form will be short with limited review criteria as requested by the WVHA.

65 CSR §7-8.1., 11.4. – These sections were amended to clarify existing statutory language and to implement the recommendations of the CON task force to shorten the CON decision time. The HCA receives numerous applications which are inaccurate and incomplete which lengthens the review process. The amendments require that an application must be accurate and complete as filed. The process permits the HCA to request more information if it is needed; however, the applicant will not be allowed to file an incomplete application and then continue to add to it throughout the certificate of need process, thus lengthening the review time needed. This process is consistent with the practice in the majority of states which have certificate of need laws and the language is specifically modeled after the regulatory language in North Carolina.

The WVHA's concerns about due process are unfounded. If there is a hearing request and a hearing is conducted on the application in question, there are specific rules dealing with due process and hearing procedures which govern in those instances. It is not credible for the WVHA to argue that they will be

unable to submit evidence at a hearing on the application. That is obviously far outside the scope of this amendment.

65 CSR §7-10.4. (deleted) – This section has been deleted and replaced with new subsection 10.6. This subsection details how expedited applications will be batched and should address the concerns of the WVHA.

65 CSR §7-11.4.b. – The amendment to this subsection again was simply to clarify current practice. Compliance with rate review requirements has always been required by the Certificate of Need Rule. The current rule cites the rate review statute without describing it. The HCA's purpose in adding the words "rate review" was simply to clarify that the applicant must be in compliance with the cited statutes. Therefore, there is no change in procedure or practice as a result of this amendment.

The HCA has reviewed the comments concerning the use of the word "and" versus "or" and finds that there was a typographical error. Therefore "or" has been substituted for "and" which should remedy the WVHA's concerns.

65 CSR §7-11.21. – Once again, the language contained in this section simply codifies current practice before the agency; a practice which has continued for a number of years without objection from the WVHA or any other party. The WVHA expresses concern that it will be prejudiced if it wants to file certain information as evidence at a hearing. As previously stated, once a hearing request is received and a hearing is scheduled, the sections of the rule regarding the hearing process are applicable and parties are allowed to submit documents as evidence in the case.

Deleted 65 CSR §7-12.2. and 12.4. – It appears that the WVHA's concerns are that this language has been deleted from the proposed rule; however, this language remains in the Code and is still applicable to the

certificate of need process. This language was removed from the rule as it was not appropriate under the section heading "Review criteria" and furthermore, because it was not necessary to recite verbatim the exact language which was already contained in the Code and to which the HCA must adhere.

65 CSR §7-16.3. – See responses to 8.1. and 11.4.

65 CSR §7-16.7. – This subsection contains no changes from the current Certificate of Need Rule and the HCA does not understand the WVHA's objections.

BEFORE THE WEST VIRGINIA SECRETARY OF STATE

In Re: **Proposed Emergency Legislative Rule**
West Virginia Health Care Authority
Title 65, Series 7 (Filed June 30, 1999)

RESPONSE OF THE HEALTH CARE AUTHORITY IN SUPPORT OF PROPOSED EMERGENCY RULE, "THE CERTIFICATE OF NEED RULE," TITLE 65, SERIES 7

A. Introduction.

During the 1999 legislative session, the Legislature passed Senate Bill 492 which made significant changes in the Certificate of Need ("CON") law. The bill also authorized the Health Care Authority ("HCA") to promulgate emergency rules to implement changes in the law and to amend and modify current CON rules. The proposed legislative rule and the proposed emergency rule, which are identical, were filed with the Secretary of State and the Legislative Rule Making Review Committee on June 30, 1999. The proposed rule makes significant modifications to the current legislative rule, "The Certificate of Need Rule," 65 CSR 7. The changes were such that the proposed rule was filed as a replacement for current legislative rule, 65 CSR 7, as suggested by the Secretary of State's legislative rule, 153 CSR §6-7.

On July 22, 1999, the West Virginia Hospital Association ("WVHA") filed a Petition for Disapproval of Proposed Emergency Legislative Rule Amending Title 65, Series 7 ("Petition for Disapproval"). In addition, various comments were

submitted to the Secretary of State by member hospitals of the WVHA opposing the proposed emergency legislative rule.

The opponents of the proposed rule present two basic arguments against the approval of this rule as an emergency rule. First, they argue that the HCA has no authority to file this rule as an emergency rule pursuant to W. Va. Code §29A-3-15a(b)(2). Second, they argue that the HCA has exceeded the scope of Senate Bill 492 and thus violated W. Va. Code §29A-3-15a(b)(1). These arguments are addressed separately below.

B. The Proposed Emergency Rule Meets the Criteria of W. Va. Code §29A-3-15 and the Secretary of State Should Not Disapprove the Proposed Emergency Rule under W.Va. Code §29A-3-15a(b)(2).

The comments received by the Secretary of State in opposition to the proposed emergency rule, "The Certificate of Need Rule," 65 CSR 7, argue that an emergency does not exist because the proposed emergency rule does not meet the required statutory criteria contained in W.Va. Code §29A-3-15(f). Thus, the opponents state that the Secretary of State should disapprove the proposed emergency rule on the grounds that an emergency does not exist under W. Va. Code §29A-3-15a(b)(2). This argument is without merit for the following reasons:

1. The proposed emergency rule is authorized by W. Va. Code §16-2D-8(c).

One of the most significant changes in the CON law implemented by Senate Bill 492 is the change made to W. Va. Code §16-2D-8(c). This Code section states as follows:

> Subsequent amendments and modifications to any rule promulgated pursuant to this article may be implemented by emergency rule. [Emphasis added.]

This language is new and specifically grants the HCA the authority to amend or modify any CON rule by emergency rule. The language is clear and unambiguous making an examination of legislative intent unnecessary. However, it is interesting to note that this specific language was discussed and agreed upon by the co-chairs of the CON task force which reviewed and studied the existing CON law and submitted the CON Study which included the recommendations for the changes made by Senate Bill 492.[1] The purpose of this significant amendment was to grant the HCA authority to promptly amend the CON rules in order to update and clarify current HCA policy and to implement changes which have been made in the Code since 1991, the last time Series 7 was amended. Prior to the passage of Senate Bill 492, the HCA did not have specific authority to amend CON rules by emergency rule.

West Virginia Code §29A-3-15 specifies the process an agency must undergo to implement emergency rules and also defines the criteria by which the Secretary of State must abide in determining whether an emergency rule may be approved. Specifically, this Code section states:

> An emergency rule shall be effective for not more than fifteen months and shall expire earlier if any of the following occurs:
>
> (1) The secretary of state. . . disapproves the emergency rule because: (A) The emergency rule or an amendment to the emergency rule exceeds the scope of the law authorizing or directing the promulgation thereof; (B) an emergency does not exist justifying the promulgation of the emergency rule; or (C) the emergency rule was not promulgated in compliance with the provisions of this section. An emergency rule may not be disapproved pursuant to the authority granted by paragraphs (A) or (B) of this subdivision on the basis that the secretary of state or

[1] The CON Committee was formed in 1997 when the West Virginia Legislature directed the HCA to conduct a study of the CON Program. The HCA empanelled a primary task force comprised of a cross section of interests, including consumers, government, health care providers, private industry, and health care payors. The co-chairs of the CON Task Force were, Steven J. Summer, President of the WVHA and Dayle Stepp, Director of the CON Division.

> the attorney general disagrees with the underlying public policy established by the Legislature in enacting the supporting legislation. . . When the supporting statute specifically directs an agency to promulgate an emergency rule...the emergency rule may not be disapproved pursuant to the authority granted by paragraph (B) of this subdivision. . . An emergency rule may not be disapproved on the basis that the Legislature has not specifically directed an agency to promulgate the emergency rule, or has not found that an emergency exists and directed the promulgation of the emergency rule. [Emphasis added.]

The opponents of this proposed emergency rule cite W. Va. Code §29A-3-15(f) as the applicable Code section in this matter. This Code section defines an emergency for those agencies which do not have specific emergency rule making power. This Code section is not applicable in the present case since W. Va. Code §16-2D-8(c) specifically empowers the HCA to promulgate emergency rules.

It should be pointed out that the opponents of the rule do not specifically address W. Va. Code §16-2D-8(c) in the Petition for Disapproval. The reason they failed to address W. Va. Code §16-2D-8(c) is that it undermines the basic premise of their arguments. Why would the Legislature grant to an agency the authority to promulgate emergency rules and then impose the additional standards contained in W. Va. Code §29A-3-15(f)? Such an interpretation would render the recent passage of W. Va. Code §16-2D-8(c) meaningless and clearly that was not the intent of the legislation.

Furthermore, the HCA's filing of the proposed rule is consistent with its past practice and the rulings of the Secretary of State. The Secretary of State has routinely recognized agencies' statutory authorization to file emergency rules and has approved the rules as emergency rules without applying the additional criteria in W. Va. Code §29A-3-15(f). For example, the HCA filed an emergency

rule with the Secretary of State in 1998 to implement changes in the agency's rate review process, "The Benchmarking and Discount Contract Rule," 65 CSR 26. This rule was approved as an emergency rule by the Secretary of State on December 3, 1998.

The statutory authorization for filing the Benchmarking and Discount Contract Rule is very similar to the authorization granted by Senate Bill 492 to amend the CON rules. West Virginia Code §16-29B-20(a)(2), the provision authorizing the rate rule, states as follows:

> (B). . . the board may promulgate rules, in accordance with the provisions of section eight of this article, that establish the criteria for review of discount contracts, which shall include that: (i) No discount shall be approved by the board which constitutes an amount below the cost to the hospital; (ii) the cost of any discount contained in the contract will not be shifted to any other purchaser or third-party payor; (iii) the discount will not result in a decrease in the hospital's average number of medicare, medicaid or uncompensated care patients served during the previous three fiscal years; and (iv) the discount is based upon criteria which constitutes a quantifiable economic benefit to the hospital. The board may define by rule what constitutes "cost" in subparagraphs (i) and (ii) of this paragraph; "purchaser" in subparagraph (iii) of this paragraph; and "economic benefit" in subparagraph (iv) of this paragraph. Any rules promulgated pursuant to this subsection may be filed as emergency rules. [Emphasis added.]

The emergency rate rule was similarly filed as a proposed legislative rule and was approved by the Legislative Rule Making Review Committee and passed by the Legislature in 1999. The issue of the HCA's authority to promulgate the rate rule as an emergency rule was never raised or questioned by the opponents of the CON rules or the Secretary of State. In fact, the opponents supported implementation of the Benchmarking and Discount

Contract Rule. The opponents' true objections to 65 CSR 7 are related to content and not to whether 65 CSR 7 meets the criteria for an emergency rule.

In addition, counsel for United Hospital Center argues in its comments that W. Va. Code §16-2D-8(c) should be read prospectively. They argue that the use of the word "subsequent" in the phrase "subsequent amendments and modifications . . . " should be read prospectively, so as not to deprive interested persons an opportunity to offer written comments. The HCA believes that this interpretation is wrong and that the word should be read in context and given its simple and clear meaning that all future amendments to any rule promulgated pursuant to the W. Va. Code §16-2D-1 et seq. can be implemented by emergency rule. The intent of the newly enacted language in W. Va. Code §16-2D-8(c) was to allow the HCA to amend any existing rule by emergency rule.

2. An emergency exists as defined by W. Va. Code §29A-3-15(f).

Although proposed emergency rule, 65 CSR 7, is not required to comply with W. Va. Code §29A-3-15(f), the criteria contained within this Code section are met by this proposed emergency rule. This Code section supplements W. Va. Code §29A-3-15(a)(1), previously discussed, and defines what constitutes "an emergency", absent statutory language authorizing the filing of emergency rules. W. Va. Code §29A-3-15(f) states in pertinent part:

> . . .an emergency exists when the promulgation of an emergency rule is necessary (1) for the immediate preservation of the public peace, health, safety or welfare, (2) to comply with a time limitation established by this code or by a federal statute or regulation, or (3) to prevent substantial harm to the public interest.

Title 65, Series 7 is a CON rule filed pursuant to the CON Act, W. Va. Code §16-2D-1 et seq. West Virginia Code §16-2D-1 defines the public policy of the State in regard to the CON programs as follows:

> It is declared to be the public policy of this State:
>
> (1). . . to contain or reduce increases in the cost of delivering institutional health services.
>
> (2) That the general welfare and protection of the lives, health and property of the people of this State require that. . . new institutional health services within this State be subject to review and evaluation...in order that appropriate and needed institutional health services are made available for persons in the area to be served. [Emphasis added.]

The statutory language contained in the CON Act meets the criteria of both Code §29A-3-15(f)(1) and (3). Title 65, Series 7, promulgated pursuant to the CON Act, promotes the public policy of containment or reduction of health care costs and the general protection of the lives, health and property of West Virginians. Obviously this legislatively declared public policy is in accord with (1) the immediate preservation of the public health, safety and welfare; and, also (3) the prevention of substantial harm to the public interest. Specifically, the rule allows competition among health care providers as it relates to certain services - increased competition can result in better access to health care and lower costs to the health care consumer. Furthermore, the basic premise behind the CON laws is the protection of the health and welfare of the public and the prevention of harm to the public. For these reasons, Series 7 meets the criteria of W. Va. Code §29A-3-15(f).

C. **The Proposed Emergency Rule Does Not Exceed the Scope of Senate Bill 492 Which Authorized the Amendments to 65 CSR 7 and the Secretary of State Should Not Disapprove the Proposed Emergency Rule under W.Va. Code § 29A-3-15a(b)(1).**

The major changes in 65 CSR 7 have been listed and discussed in the Petition for Disapproval filed in opposition to this rule by the WVHA. Although the HCA disagrees with most of the characterizations and descriptions contained within the discussion of 65 CSR 7 by the WVHA, none of that is relevant as it relates to this issue.

Essentially, the WVHA argues that the proposed rule is not valid because it is outside the scope of Senate Bill 492. The WVHA then proceeds to make a "wish list" of the items it finds acceptable, the items it finds somewhat acceptable and the items it finds unacceptable according to its interpretation of Senate Bill 492. The bottom line is it doesn't matter whether the WVHA finds the amendments to 65 CSR 7 acceptable. The issue is whether the rule complies with the requirements of W. Va. Code §29A-3-15a(b)(1). This Code section states as follows:

> (b) The secretary of state shall disapprove an emergency rule or an amendment to an emergency rule if he determines:
>
> (1) That the emergency rule or an amendment to the emergency rule exceeds the scope of the law authorizing or directing the promulgation thereof. . . [Emphasis added.]

The law authorizing the promulgation of this rule is W. Va. Code §16-2D-8(c) (also W. Va. Code §§16-2D-3(b)(5) and 7(u), as previously discussed). W. Va. Code §16-2D-8(c) states:

> Subsequent amendments and modifications to any rule promulgated pursuant to this article may be implemented by emergency rule. [Emphasis added.]

Thus, the scope of the authority to promulgate emergency rules extends to the entire CON Act, Chapter 16, Article 2D of the W. Va. Code. Contrary to the arguments of the opponents to this proposed emergency rule, the scope of 65 CSR 7 need not be limited to the specific items in Senate Bill 492. Indeed, one of the primary purposes of amending W. Va. Code §16-2D-8 of the Certificate of Need Act granting the HCA emergency rule making authority, was to allow the HCA to update 65 CSR 7 which had not been amended since 1991.

The overwhelming majority of items within 65 CSR 7 are a direct result of the passage of Senate Bill 492, as admitted by the WVHA. However W. Va. Code §29A-3-15a(b)(1) simply requires that the amendments be within the scope of the Certificate of Need Act. It is undisputed that the changes comply with this requirement.

In summary, Senate Bill 492 includes language under W. Va. Code §16-2D-8(c) allowing the HCA to make amendments and modifications to any existing rule by emergency rule. The HCA has made the modifications that it believes are necessary and they are not beyond the scope of the CON Act. For these reasons, the Secretary of State should not disapprove the proposed emergency rule under W. Va. Code §29A-3-15a(b)(1).

D. Conclusion.

The proposed emergency rule, "The Certificate of Need Rule," 65 CSR 7, is a valid emergency rule and meets all of the necessary requirements of W. Va. Code §29A-3-1 et seq.

Respectfully submitted,
West Virginia Health Care Authority
By Counsel

Marianne K. Stonestreet, General Counsel
West Virginia Health Care Authority
100 Dee Drive, Suite 201
Charleston, WV 25311-1600
State Bar ID #1781

WEST VIRGINIA
HOSPITAL ASSOCIATION

100 Association Drive
Charleston, WV 25311-1571
(304) 344-9744
FAX: (304) 344-9745
Web Page: www.wvha.com

July 26, 1999

JUL 30 1999

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

Dear Ms. Stonestreet:

On behalf of the West Virginia Hospital Association and its 69 member hospitals and health systems, we submit to the Health Care Authority our comments on the proposed Title 65 Series 7 and Title 65 Series 17 emergency and legislative Certificate of Need rules.

Previously, WVHA filed petitions with the Secretary of State and the Health Care Authority objecting to the promulgation of the Series 7 and Series 17 as emergency rules. In accordance with the notice for public comment, WVHA now presents its concerns regarding the important policy issues which will implemented by the proposed Series 7 and Series 17 rules, as enclosed.

WVHA believes that the proposed Series 17 rules will create an unlevel playing field, by substantially deregulating health professionals who develop diagnostic centers, while maintaining strict control over the development of freestanding diagnostic services by hospitals and other non-professional providers.

The proposed policy changes are obviously not in the best interests of the health care consumers in West Virginia. The new policies are also not consistent with legislative intent to contain health care costs by avoiding duplication of services and will increase per-unit costs to payors, including the State's Medicaid and PEIA programs. Finally, these provisions pose a serious threat to the financial viability of our state's hospitals and community-based primary clinics, particularly the more vulnerable ones within the rural areas which could experience a substantial loss of patient revenue.

We are also concerned with the numerous changes to the Series 7 rule which were not mandated by SB 492, which are enumerated in the enclosed comments, including the definition of an "acquisition," and the definition of "diagnostic services."

WVHA believes that the promulgation of these rules through emergency rule making rather than the standard legislative rule making process is inappropriate for such significant policy changes. The proposed rules will likely result in a proliferation of outpatient diagnostic services throughout the state, in direct competition with existing health care facilities. The proposed rules will have a serious detrimental impact on already financially vulnerable rural hospitals and clinics, by unnecessarily duplicating existing services in rural communities.

Sincerely,

Steven J. Summer
President

SJS/jm

Enclosures:
1. Comments to Proposed Rule-Making Title 65, Series 7
2. Comments to Proposed Rule-Making Title 65, Series 17

cc. D. Parker Haddix
Garry D. Black
Louie A. Paterno, Jr.

WEST VIRGINIA
HOSPITAL ASSOCIATION

100 Association Drive
Charleston, WV 25311-1571
(304) 344-9744
FAX: (304) 344-9745
Web Page: www.wvha.com

COMMENTS TO PROPOSED RULE-MAKING
TITLE 65, SERIES 7

The West Virginia Hospital Association ("Association") offers the following comments to the proposed emergency legislative rule and the proposed legislative rule promulgated by the West Virginia Health Care Authority ("Authority") seeking to amend Title 65, Series 7.

Section 2.1. The Authority's proposed amendment of the definition of "acquire a health care facility" under current Title 65, Series 7, is not required, mandated, or contemplated in any away by Senate Bill 492 recently passed by the West Virginia Legislature. Rather, it constitutes a discretionary policy choice by the Authority which impermissibly broadens its jurisdiction beyond the scope originally intended by the Legislature and originally enforced by the agency itself. This amended definition is also being inappropriately proposed on an emergency rule-making basis. A more complete discussion of this procedural issue is contained in the Association's "Petition for Disapproval of Proposed Emergency Legislative Rule Amending Title 65, Series 7" ("WVHA's Petition") previously filed with the Secretary of State and with the Authority.

The substantive change to the definition of "acquire a health care facility" consists of adding stock transactions to the scope of reviewable acquisitions. As stated above, stock acquisitions were originally deemed to be non-reviewable by this agency. See, e.g. Morgantown Health Care Center, Inc. d/b/a MonPointe Continuing Care Center, CON File No. 91-6-3595-X (April 2, 1991). In fact, as early as October 6, 1981, the

West Virginia Attorney General had issued an opinion concluding that a CON was not required for the stock acquisition of a health care facility. Subsequently, the Authority reversed its position on stock acquisitions, and began deeming them reviewable despite the fact that no statutory change had been enacted to justify such a change. See, e.g. In re: ReLife Acquisition Corporation, CON File No. 92-2-3881-X (July 31, 1992). To the Association's knowledge, the issue of whether such an interpretation of the statute is justified has never been decided by any appellate body.

The Association disagrees with the expanded scope of Section 2.1 for several reasons. First, the Legislature never intended stock acquisitions to be reviewable. This is evident in W.Va. Code § 16-2D-3(b)(3)(A), which defines when the obligation for a capital expenditure is considered to be incurred for acquisition (and other) purposes. It occurs when a contract, enforceable under state law, is entered into for the acquisition of a capital asset. Stock is not a capital asset under any generally accepted accounting principle or understanding of the term. As such, asset acquisitions, and not stock acquisitions, are the only type of acquisitions contemplated to be reviewable by the CON law.

The only exception to this general rule is set forth at W.Va. Code § 16-2D-11(a). In situations where a Certificate of Need ("CON") exists, and has not expired due to substantial compliance review or has otherwise not been withdrawn, the statute does prohibit its transfer as part of a stock transaction. Other than this limited circumstance, however, stock transactions are not made subject to review under the CON law.

There are other, more practical, reasons why stock transfers should not be reviewed. In these situations, the entity licensed to provide health care services is actually not being changed. While the entity's shareholders may change, this should not be viewed any differently than a change in the identity of members of the governing body of a non-stock entity over time. The definition itself is silent as to how much stock must change hands in order to trigger CON review. It likewise provides no guidance as to how to deal with publicly-traded entities, or with wholly-owned entities whose parent organization may be selling some or all of its stock.

In summary, the amendment of Section 2.1 of Title 65, Series 7 represents an impermissible expansion of the Authority's jurisdiction without any corresponding legislative change in Senate Bill 492 or elsewhere. The definition proposed is overly broad and vague, and no CON standards exist to guide the agency in its review of such transactions.

Section 2.8. The Authority's proposed definition of "diagnostic services" in Section 2.8 of Title 65, Series 7 is wholly inconsistent with both the intent and the literal language of proposed Section 28. It also represents a policy choice that, if permitted to go forward, will have drastic consequences for the health care system in West Virginia.

This proposed definition is a direct outgrowth of Senate Bill 492, and the language now contained at W.Va. Code § 16-2D-3(b)(5). Senate Bill 492 contemplated the promulgation of an emergency rule by July 1, 1999, to specify which health services

would be reviewable if added by or on behalf of a health care facility or health maintenance organization. In promulgating such an emergency rule, the Authority was required to specify the health services as recommended by the CON Study conducted pursuant to W.Va. Code § 16-29B-19a. "Diagnostic services" were included in the CON Study's list of reviewable services.

The Authority has historically applied W.Va. Code § 16-2D-3(b)(5) to require the review of an additional health service regardless of the amount of capital expenditure associated with such service. This is recognized on page 13 of the CON Study:

> Current CON regulations require a review of any new service, regardless of capital expenditure needed to develop the service. (Emphasis added.)

Senate Bill 492 was not intended to change this concept, but only to add specificity as to what services would be reviewable. In fact, proposed Section 28.2 to Title 65, Series 7, echos this interpretation of W.Va. Code § 16-2D-3(b)(5). It states:

> The services listed in subsection 28.1 are subject to certificate of need review regardless of the expenditure associated with the proposal.

Accordingly, it is improper and wholly inconsistent with proposed Section 28 of Title 65, Series 7, to define "diagnostic services" in such a way as to require a threshold expenditure of $2 million. This threshold expenditure level is in no way required by any other part of Senate Bill 492; if it were, then each listed health service

would be subject to this requirement. That was clearly not the intention of either the CON Study or the Legislature. Rather, the expenditure threshold for "diagnostic services" represents an unwise and illegal policy choice on the part of the Authority.

Specifically, the proposed expenditure threshold for "diagnostic services" of $2 million will result in a proliferation and unnecessary duplication of laboratory and imaging services throughout the state. This, in turn, will decrease the utilization of these services already available at local community hospitals and other providers. A reduction in utilization will reduce revenues, and will make it more difficult for such facilities to support other necessary, but less profitable, services at these institutions. It is well known that the financial health of West Virginia hospitals is on the decline because of reimbursement cuts engendered by the federal Balanced Budget Act, as well as by other third-party payors. Those who will be hurt the most by such a dilution in utilization are the financially vulnerable rural hospitals in West Virginia. In general, however, all hospitals will have to increase rates to public and private payors, and their patients, in order to compensate for lost revenues on diagnostic services.

The second reason that the proposed definition of diagnostic services represents bad public policy is that it will add to health care costs in general, and specifically to the costs of the state's Medicaid and PEIA programs. The cost per unit of service at existing facilities will increase as these services proliferate. Meanwhile, new providers of these services will have invested millions of additional dollars that will ultimately have to be repaid by consumers and their third-party payors.

As an alternative to the Authority's proposed Section 2.8, the Association recommends the development of a definition of "diagnostic services" that does not utilize a threshold expenditure level for new providers of such services, consistent with the true intent of W.Va. Code § 16-2D-3(b)(5). This definition should also be flexible enough not to prevent those existing providers of diagnostic services from upgrading or diversifying those services (except for other services identified in Rule 28 and except for items of major medical equipment). Such a definition would read as follows:

> "Diagnostic services" means, as referenced in subdivision 28.1.b of this rule, the offering or development of laboratory or imaging services at a new or existing health care facility or health maintenance organization; provided however, that a health care facility or health maintenance organization already offering one or more imaging services, including but not limited to, radiology, ultrasound, fluoroscopy, or computerized tomography at its existing facility, and that wishes to add at its existing facility imaging services not otherwise enumerated under subdivision 28.1 and not constituting major medical equipment under subdivision 2.16.j, shall not be deemed to be engaged in the addition of health care services under subdivision 2.16.e of this rule.

The Association believes that the above definition is more consistent with the intent of Senate Bill 492 and the CON Study, and should be substituted for the one proposed by the Authority in its proposed Section 2.8 to Title 65, Series 7.

Section 2.14. The Authority's proposed definition of "private office practice" in Section 2.14 of Title 65, Series 7 is not required, mandated, or contemplated

in any way by Senate Bill 492. It is likewise an inappropriate subject for emergency rule-making. See, WVHA's Petition.

Beyond this objection, the Association believes that it is inappropriate for the Authority to "legislate" its recent decision in In re: Community Medical Associates, CON File No. 95-6-5379-PV (August 15, 1996), while this matter remains pending on appeal to the Office of Judges. This appeal, Docket No. 97-HC-13, is scheduled for oral argument on October 21, 1999, at 10:00 a.m. The true scope of what constitutes a "private office practice," should be decided as a result of that appeal, especially since no statutory changes have been enacted dealing with this subject in recent memory.

As was the case with stock transactions, the Authority has changed its course in recent years on physician practices that are affiliated with other health care facilities. For example, at one time the Authority held that the establishment of a physician's office by an appropriately structured medical corporation, which was related to a hospital or its parent, was not subject to CON review. See, e.g., In re: Davis Memorial Hospital, CON File No. 95-7-5083-X (April 25, 1995). However, in In re: Community Medical Associates, supra, the Authority adopted new standards for private office practices in which the direct or indirect control over such practices by a hospital was deemed sufficient to trigger CON review. This change runs contrary to many important policy considerations surrounding the issue.

For example, more and more providers are seeking to network and integrate into delivery systems. Managed care organizations are seeking out panels of providers

who can provide a continuum of services to its insureds, and at the same time, accept financial discounts or incentives for the most efficient provision of such care. The traditional, stand-alone private office practice does not readily lend itself to such organizations.

On the other hand, an integrated delivery system (such as a hospital and its affiliated medical corporation) can offer third party payors administrative convenience and economies of scale. Significantly, this can occur without sacrificing the exercise of independent medical judgment by licensed physicians on behalf of their patients. It is this independent professional judgment, not the legal structure of an office, which is the essence of the private practice of medicine anyway. The CON Study conducted pursuant to W. Va. Code § 16-29B-19a specifically recommended the following:

> The Subcommittee recognizes that the CON statute includes several provisions to foster integration of services among providers. The Subcommittee endorses efforts to promote integration, and recommends the need and benefits of integration be addressed explicitly in the SHP, and that specific standards giving preference to health service integration projects be developed.

CON Study at pp. 4-5.

Given this charge, the Authority should be looking for ways to promote and encourage the growth of integrated delivery systems which align the incentives of hospitals and physicians. The Authority's decision in In re: Community Medical Associates, supra, was an unfortunate retrenchment on this issue. However, given the pendency of the appeal in this contested matter, the Authority should maintain the status

quo, and refrain from "legislating" its most recent decision in the form of the amendment contained in Section 2.14 to Title 65, Series 7.

Section 5.7 and Section 10.4. The proposed amendments to Section 5.7 and Section 10.4 of Title 65, Series 7 establish an expedited review process for non-health related projects to be batched on a monthly basis. This procedure is an outgrowth of Senate Bill 492, and its requirement under W. Va. Code § 16-2D-7(u) that the Authority promulgate an emergency rule by July 1, 1999, to establish a review process (not to exceed 45 days) for non-health related projects. The CON Study underlying Senate Bill 492 also recommended the development of a "fast track" process to review such projects.

The Association believes the intent of the statutory changes and the underlying CON Study was to establish a process by which non-health projects could be reviewed as exemptions under Section 16 of Title 65, Series 7, rather than as full-blown expedited CON applications. This would be more appropriate because no CON standards exist for such projects in the fist place, and a CON application therefore appears unnecessarily burdensome upon the health care provider in question.

As stated above, the CON Study specifically called for a "fast track" process. It also stated the following:

The review process would largely entail an analysis of financial data. CON Study at p. 18. These descriptors are more in line with the review process for an exemption application under Section 16 rather than a full-blown, expedited CON application. Use of the exemption review process would also allow such projects to be

more readily considered than would monthly batching, and would be entirely consistent with the 45 day review period mentioned in Senate Bill 492.

It should be noted that nothing in Senate Bill 492 prohibits the review of non-health projects on an exempt basis. The Bill speaks only in terms of a "review process." Certainly, such a process is already provided for in Section 16, and should form the basis for review under W. Va. Code § 16-2D-7(u).

Section 8.1 and Section 11.4. The Authority's proposed amendments to Section 8.1 and Section 11.4 of Title 65, Series 7 are discretionary policy choices that are not required, mandated, or contemplated in any way by Senate Bill 492. They are likewise inappropriate subjects for emergency rule-making. See, WVHA's Petition.

These amendments prohibit a CON applicant from submitting additional information, except when requested by the Authority, after its CON application has been filed. Such a drastic and unjustified change places process ahead of substance. It also violates the due process rights of applicants, makes the meaningful conduct of a public hearing impossible, and otherwise violates W. Va. Code § 16-2D-7.

First and foremost, the CON statute itself contemplates that applicants may submit additional information after filing an application in at least three different subsections: (1) W. Va. Code § 16-2D-7(m) provides for a file closing date after which additional factual information may not be considered when no public hearing is requested; (2) W. Va. Code § 16-2D-7(n) regulates how and when such additional

information from an applicant may subject an application to a new CON review cycle; and (3) W. Va. Code § 16-2D-7(1) establishes a procedure for receiving additional evidence from the applicant and other persons in the case of a public hearing. The Authority's proposed amendments to Sections 8.1 and 11.4 are totally inconsistent with each of these statutory provisions.

In fact, applicants frequently have a need to supplement their CON applications after they have been filed. New data may become available after filing that requires analysis. Mistakes may be made in the application. Letters of support may be received after the fact. The Authority's rules should encourage the filing of these additional items rather than discouraging them. Otherwise, what need is there for a file closing date under W. Va. Code § 16-2D-7(m), or a rule allowing applicants to be re-batched pursuant to W. Va. Code § 16-2D-7(n)? The inflexibility of the Authority's proposed rule will only hinder, rather than foster, a full and fair review process for the CON applicant.

Most importantly, the proposed amendments create serious due process problems for CON applicants. The prohibition upon additional filings applies only to applicants, and not to other persons. Applicants therefore are not guaranteed any ability to respond to information placed in their files by others. Similarly, the prohibition appears to be one of an indeterminate term which would extend up to and through the time of a public hearing. No meaningful public hearing can be held when the applicant,

and not the other parties, faces a limitation upon its ability to present additional evidence under proposed Sections 8.1 and 11.4.

The Association recommends that the status quo be maintained allowing applicants a broad degree of discretion in submitting additional and relevant information. No significant problems have been identified to support such a drastic change in the Authority's procedures. Accordingly, the amendments to proposed Sections 8.1 and 11.4 should be abandoned.

Deleted Section 10.4. The Authority's proposed deletion of Section 10.4 of current Title 65, Series 7 is not required, mandated, or contemplated in any way by Senate Bill 492. It is likewise an inappropriate subject for emergency rule-making. See, WVHA's Petition.

Current Section 10.4 establishes monthly batching and a 65 day review cycle for any CON application falling under the batching category outlined in Section 10.1.h (other proposed new institutional health services). The deletion of Section 10.4 from Title 65, Series 7 makes it unclear as to how Section 10.1.h applications are to be batched, as no substitute rule for these applications can be identified. The Association favors retention of current Section 10.4 because it is clearer and provides added flexibility to the Authority's batching system.

Section 11.4.b. The Authority's proposed amendment of Section 11.4.b of Title 65, Series 7 is not required, mandated, or contemplated in any way by Senate Bill

492. It is likewise an inappropriate subject for emergency rule-making. See, WVHA's Petition.

The effect of the proposed amendment is to add to the grounds under which the Authority may refuse to declare a CON application complete. Current Section 11.4.b requires an applicant to be current in its financial disclosure filings. The proposed amendment would add rate review filings as well. The Association has two objections to such a change.

First, the change as drafted would appear to indicate that Section 11.4.b applies only to hospitals. The Authority's use of the conjunctive "and" between financial disclosure and rate review suggests that only those facilities subject to both forms of regulation are covered by the requirements of amended Section 11.4.b. At a minimum, the word "or" should be substituted for "and" to clarify that hospitals are not the only facilities covered under this subsection.

More fundamentally, the addition of rate review to Section 11.4.b places greater burdens upon hospitals than other potential CON applicants. Frequently, rate review is a contested or adversarial type of proceeding, and the interpretation as to what reports, records, data, and other information must be filed with the Authority by hospitals is in dispute. Rate review is also a separate function of the Authority. The Authority has ample means under W. Va. Code §§ 16-29B-14, 15, and 27 to compel a hospital's compliance with the rate setting statute without "bootstrapping" it to the CON program as well. Accordingly, the proposed amendment to Section 11.4.b of Title 65, Series 7 not

only impacts hospitals more adversely than other providers, but it also represents administrative overkill.

Section 11.21. The Authority's proposed amendment of Section 11.21 of Title 65, Series 7 is not required, mandated, or contemplated in any way by Senate Bill 492. It is likewise an inappropriate subject for emergency rule-making. See. WVHA's Petition.

The proposed amendment to Section 11.21 prohibits a party engaged in discovery prior to a public hearing on a CON application from filing discovery responses with the Authority. The Association does not object to such a rule as long as it is without prejudice to a party who later decides that such discovery should be filed as evidence in the public hearing itself. In other words, proposed Section 11.21 of Title 65, Series 7 should not be relied upon by the Authority to discourage the later filing of any information that a party deems necessary to its case.

Deleted Sections 12.2 and 12.4. The Authority's proposed deletion of Sections 12.2 and 12.4 of current Title 65, Series 7 is not required, mandated, or contemplated in any way by Senate Bill 492. It is likewise an inappropriate subject for emergency rule-making. See, WVHA's Petition.

The current Sections 12.2 and 12.4 provide as follows:

> 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), (d), (e), (f), (g), (i), (m), (s), (t) and (w) of subsection 12.1 of this rule that tends

to compensate for the absence of market controls in a noncompetitive market.

* * * *

12.4. The board shall, in its consideration of an application, give significant consideration to criteria (q) and (r) of subsection 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.

Each of these provisions require the Authority to grant special preferences to CON applications that have the result of strengthening the effect of competition upon the supply of health services. The Authority is effectively required to give such preferences under current law by virtue of W. Va. Code § 16-2D-5(d). Nothing in Senate Bill 492 changed this statutory requirement.

Accordingly, the Association opposes the elimination of Sections 12.2 and 12.4 from Title 65, Series 7. W. Va. Code § 16-2D-5(d) was enacted for a purpose, and Sections 12.2 and 12.4 serve to provide the Authority with further guidance as to how to implement the statute in situations where the effect of competition is strengthened by a

project. The Authority should not and cannot ignore W. Va. Code § 16-2D-5(d) through the deletion of these regulatory provisions.

Section 16.3. See comments to proposed Sections 8.1 and 11.4.

Section 16.7. See comments to proposed Section 11.21.

JACKSON & KELLY PLLC

ATTORNEYS AT LAW

1600 LAIDLEY TOWER
P O BOX 553
CHARLESTON, WEST VIRGINIA 25322

TELEPHONE 304-340-1000 TELECOPIER 304-340-1130

http://www.jacksonkelly.com

300 FOXCROFT AVENUE
MARTINSBURG, WEST VIRGINIA 25401
TELEPHONE 304-263-8800

256 RUSSELL AVENUE
NEW MARTINSVILLE, WEST VIRGINIA 26155
TELEPHONE 304-455-1751

5000 HAMPTON CENTER
MORGANTOWN, WEST VIRGINIA 26505
TELEPHONE 304-599-3000

412 MARKET STREET
PARKERSBURG, WEST VIRGINIA 26101
TELEPHONE 304-424-3490

1000 TECHNOLOGY DRIVE
FAIRMONT, WEST VIRGINIA 26554
TELEPHONE 304-368-2000

1144 MARKET STREET
WHEELING, WEST VIRGINIA 26003
TELEPHONE 304 233-4000

1660 LINCOLN STREET
DENVER, COLORADO 80264
TELEPHONE 303-390-0003

175 EAST MAIN STREET
LEXINGTON, KENTUCKY 40507
TELEPHONE 606-255-9500

2401 PENNSYLVANIA AVENUE N W
WASHINGTON, D C 20037
TELEPHONE 202-973-0200

MEMBER OF LEX MUNDI
THE WORLD'S LEADING ASSOCIATION
OF INDEPENDENT LAW FIRMS

Direct Dial No. 340-1319
e-mail: jthomas@jacksonkelly.com

July 22, 1999

Via Hand Delivery

Ms. Judy Cooper
West Virginia Secretary of State
State Capitol Complex
Charleston, WV 25305

RE: Proposed Emergency Legislative Rule - Title 65, Series 7
Proposed Emergency Legislative Rule - Title 65, Series 17

Dear Ms. Cooper:

Enclosed you will find two (2) Petitions filed on behalf of the West Virginia Hospital Association seeking disapproval of certain proposed emergency legislative rules recently filed with the Secretary of State on June 30, 1999, by the West Virginia Health Care Authority. The rules in question seek to amend Title 65, Series 7, as well as Title 65, Series 17.

Thank you for your review and consideration of these Petitions. If we can provide further information, please do not hesitate to give us a call.

Very truly yours,

JAMES W. THOMAS

JWT/rs
Enclosure
cc: Marianne K. Stonestreet, Esq. (w/enc.)

CO301818

BEFORE THE WEST VIRGINIA SECRETARY OF STATE

In Re: Proposed Emergency Legislative Rule
West Virginia Health Care Authority
Title 65, Series 7 (Filed June 30, 1999)

PETITION FOR DISAPPROVAL OF
PROPOSED EMERGENCY LEGISLATIVE
RULE AMENDING TITLE 65, SERIES 7

A. Background Information.

On June 30, 1999, the West Virginia Health Care Authority ("HCA") filed a proposed emergency legislative rule with the Secretary of State's office seeking to amend an existing legislative rule codified at Title 65, Series 7 entitled "Certificate of Need Rule." In associated materials filed by the HCA with its proposed emergency legislative rule, the HCA stated that the facts and circumstances which required the rule to be filed on an emergency basis were twofold: (1) to comply with the time limits set forth in Senate Bill 492 at W. Va Code § 16-2D-3(b)(5), § 16-2D-7(u), and § 16-2D-8(c); and (2) to update the Certificate of Need ("CON") process to comply with the requirements of Senate Bill 492 passed by the 1999 West Virginia Legislature. For the reasons set forth below, the HCA's attempt to amend Title 65, Series 7 by emergency rule must be disapproved by the Secretary of State as contrary to law under W. Va. Code § 29A-3-15a.

B. The HCA's Emergency Rule To Amend Title 65, Series 7 Violates W. Va. Code § 29A-3-15a.

The West Virginia CON law at W. Va. Code § 16-2D-1 et seq. establishes an administrative process which requires the review and approval of specified new health services and expenditures. The state agency designated to administer the CON law in West Virginia is the HCA. W. Va. Code § 16-2D-1 directs the HCA to avoid unnecessary duplication and to reduce increases in costs when evaluating and approving proposed new health care services and expenditures.

The enactment this year of Senate Bill 492 amended in CON law in certain respects. Most notably:

a) it increased the capital expenditure threshold level from $1 million to $2 million;

b) it increased the major medical equipment threshold level from $750,000 to $2 million;

c) it required the HCA to promulgate an emergency rule by July 1, 1999, specifying which new services offered by health care facilities or health maintenance organizations will require CON review consistent with the findings of a recent CON study task force;

d) it deleted certain CON exemptions for health maintenance organizations;

e) it deleted certain CON exemptions for new services having annual operating costs less than $300,000;

f) it called for a review and modification of the State Health Plan within three (3) years;

g) it called for a study of the existing moratorium on nursing home beds in West Virginia;

h) it expanded the HCA's powers to order a moratorium upon new health services;

i) it required the HCA to promulgate an emergency rule by July 1, 1999, specifying a new review process for nonhealth-related projects of not more than 45 days; and

j) it clarified the CON appeal process.

The HCA's proposed emergency legislative rule to amend Title 65, Article 7 can be broken down into three (3) different components. The first component relates to provisions of the rule intended to comply with the July 1, 1999, time limitations set forth in Senate Bill 492 at W. Va. Code § 16-2D-3(b)(5) and § 16-2D-7(a). These are covered in §§ 2.8, 2.11, 2.16.e, 5.7, 10.4, 28.1.a-w, and 28.2. The petitioner recognizes that compliance with statutory time limitations does constitute an emergency under W. Va. Code § 29A-3-15(f)(2). Hence, although it may disagree with some of the policy choices made by the HCA in these provisions, it agrees that they may be validly promulgated as an emergency rule with the Secretary of State. The changes included in this first component therefore do not form the basis of the petitioner's objections.

A second component of the HCA's proposed emergency legislative rule relates to provisions in tended to comply with the changes in the law enacted by Senate Bill 492, as well as other legislative enactments and gubernatorial designations related to the CON appeal process. Examples of these provisions include, but are not limited to, §§ 2.16.f, 2.16.1, 12.4, 12.5, 15.1.f, 15.4, 18.1 through 18.9, and 19.1 through 19.3. While it is laudable that the HCA wishes to harmonize Title 65, Series 7 with the provisions of W. Va. Code § 16-2D-1 et seq.,

it is questionable whether such changes need to be made via an emergency rule. This is because the CON law contains the following provision at W. Va. Code § 16-2D-15:

> All rules previously promulgated to implement this article shall continue in force following the amendments to this article; except that, where such previous rules differ from the requirements of the amendments to this article, then such part of those rules are hereby abrogated and shall have no further legal effect. The state agency shall commence a review of such rules and shall promulgate revised rules.

Clearly, the above statute abrogates any provision of an existing rule that may differ from the statute without the need for an emergency rule amendment. The petitioner believes that he more appropriate procedure would be for the HCA to harmonize its rule with changes in the statute by the filing of a proposed legislative rule with the legislative rule-making review committee. The filing of an emergency rule appears unnecessary given the language of W. Va. Code § 16-2D-15. However, the provisions which make up this second component of the HCA's proposed emergency legislative rule to amend Title 65, Series 7 are not the focus of this petition.

The primary focus of this petition relates to the third component of HCA's proposed emergency legislative rules. This third component does not relate to any provisions of the rule that have time limitations set forth in Senate Bill 492, nor does it relate to provisions intended to comply with changes in the laws enacted by Senate Bill 492 or other previous legislative enactments or gubernatorial designations. Rather, the third component consists solely of specific policy changes that are discretionary in nature and that the HCA chose to include in its proposed emergency legislative rule. The amended provisions in this third component to which the petitioner specifically objects are found at §§ 2.1, 2.14, 8.1,

11.4, 11.4.b, 11.13, 11.21, 16.3, and 16.7. The petitioner also objects to the elimination of current §§ 10.4, 12.2, and 12.4.

The various amended provisions enumerated above which compose the third component of the HCA's proposed emergency legislative rule consist of a potpourri of issues. They may be summarized as follows:

a) the expansion of the definition of "acquire a health care facility" to include stock transactions;

b) the creation of a restrictive definition of "private office practice" despite a pending appeal seeking guidance on this issue from the courts;

c) the placement of strict limits upon the ability of applicants to submit additional evidence to the HCA in support of their CON applications or exemption requests;

d) the expansion of the grounds by which the HCA may declare a CON application incomplete due to a lack of all appropriate rate review filings;

e) a modification of the time frame in which prehearing motions can be filed with the HCA;

f) a modification of procedures which prohibits the filing of discovery materials with the HCA;

g) the elimination of a monthly batching alternative for certain CON applicants; and

h) the elimination of provisions which require the HCA to grant preference to CON applications that strengthen the effect of competition in the health care market.

Importantly, none of the third component changes have any relationship to the changes contained in Senate Bill 492, and cannot be justified by the HCA as emergency

updates to comply with that bill's requirements. Likewise, none of the time limitations in Senate Bill 492 are ever remotely related to any of these changes. Finally, and most significantly, the HCA has not set forth or even alleged any underlying emergency facts or circumstances justifying the changes included in this third component.

The law is clear as to what constitutes an emergency. W. Va. Code § 29A-3-15(f) requires a need to immediately preserve the public peace, health, safety, and welfare; to comply with statutory time limitations; or to prevent substantial harm to the public interest. While the HCA's amendments constituting the first component of its proposed emergency legislative rule meet the second qualification for an emergency under W. Va. Code § 29A-3-15(f), none of the rest of the amended provisions, especially those comprising the third component, are of an emergency nature. As a result, the HCA's proposed emergency legislative rule to amend Title 65, Series 7, is so tainted by its non-emergency, discretionary policy choices that it cannot withstand scrutiny under W. Va. Code § 29A-3-15a(b)(2). Moreover, the HCA exceeded the scope of Senate Bill 492's limited authorization of emergency rule-making in violation of W. Va. Code § 29A-3-15a(b)(1).

The Secretary of State cannot be reasonably expected to pick and choose specific provisions for approval and disapproval under W. Va. Code § 29A-3-15a. The better course would be for the HCA to withdraw its proposed emergency legislative rule in its current form, but simultaneously refile a substituted emergency legislative rule containing only those provisions meeting the requirements of W. Va. Code § 29A-3-15 and W. Va. Code § 29A-3-15a. If this is done, the HCA cannot be deemed to have failed to met its time limits established in Senate Bill 492 since those will have been fulfilled by one or the other of its filings with the Secretary of State.

C. Conclusion.

In conclusion, significant portions of the HCA's proposed emergency legislative rule to amend Title 65, Series 7 cannot be justified as emergency rule-making. Not only do many of the provisions bear no relation to the time limits imposed by Senate Bill 492, but many also are not required to comply with the provisions of either that bill or previous bills enacted by the Legislature. Not a single threat to the public peace, health, safety, welfare, or interest has been identified by the HCA in its filing with the Secretary of State to justify the promulgation of many of the revisions to Title 65, Series 7. Accordingly, the proposed emergency legislative rule, when read in its entirety, must be disapproved by the Secretary of State pursuant to W. Va. Code § 29A-3-15(b)(2) because an emergency does not exist, as well as pursuant to W. Va. Code § 29A-3-15a(b)(1) because the HCA exceeded the scope of Senate Bill 492's limited authorization of emergency rule-making.

Respectfully submitted,

WEST VIRGINIA HOSPITAL ASSOCIATION

By Counsel

James W. Thomas
Jackson & Kelly PLLC
1600 Laidley Tower
P.O. Box 553
Charleston, WV 25322
(304) 340-1319

CO301623

UNITED HOSPITAL CENTER
Post Office Box 1680 ■ Clarksburg, West Virginia 26302-1680 ■ Telephone 304 / 624-2121

July 30, 1999

Via Facsimile (304) 558-7001 and Mail

Marianne Stonestreet, Esq
West Virgina Healthcare Authority
100 Dee Drive
Charleston, WV 25311

COMMENTS TO PROPOSED RULEMAKING

TITLE 65, Series 7
Certificate of Need Rule

TITLE 65, SERIES 17
Health Services Offered by Health Professionals

United Hospital Center ("UHC") offers the following comments to the proposed legislative rules promulgated by the West Virginia Health Care Authority to amend Title 65, Code of State Regulations, Series 7, Certificate of Need Rule, and to amend Title 65, Series 17, Health Services Offered by Health Professionals.

UHC is a not-for-profit community hospital located in Clarksburg, West Virginia, with 373 licensed beds, and is a part of the West Virginia United Health System. It is a major provider of basic health care to the citizens of north central West Virginia, and offers essential services, including services to many who are unable to pay. Its continued viability is essential for citizens in the area to have access to quality health care services.

UHC previously, at the July 22, 1999 meeting of the Authority submitted comments on these same rules as promulgated on an emergency basis. On July 7, 1999, it filed a letter with the Secretary of State, asking him to disapprove the rules on an emergency basis, and on July 29, 1999 appeared before the Authority, asking that the emergency rule be withdrawn. In that request, we made it clear that the rules as promulgated do not constitute an "emergency" as that term is defined in Chapter 29A of the West Virginia Code.

UHC also has several policy concerns with these rules in their formulation as proposed legislative rules, because of the profound impact they will have on the ability to provide our citizens with access to health care. UHC has reviewed and endorses the comments on these rules submitted by the West Virginia Hospital Association, but also wants to offer the perspective of what implementation of the rules would mean to our facility and the people we serve.

Both rules were promulgated on June 30, 1999, ostensibly to comply with Senate Bill 492, enacted by the Legislature during the 1999 regular session. That legislation, in turn, was based

largely on the recommendations of a Certificate of Need Study conducted by the Authority pursuant to a previous legislative mandate. The Study's recommendations were carefully developed by a Task Force consisting of health care providers of various kinds, and representatives of government, business and consumers, and were issued in September 1998. Nonetheless, both proposed rules go far beyond the letter and intent of Senate Bill 492 and the underlying Study.

The most significant impact of the proposed rules that UHC wishes to address is that the effect of the proposed rules is to create an uneven playing field by which diagnostic services could be offered by physicians and others without CON review, but identical services offered by hospitals and related organizations would be subject to review. This phenomenon was not required, or even anticipated by either S.B. 492 or the CON Study, and results from the inter-relationship of following provisions of the proposed rules:

- 65-7-2.8: Definition of "diagnostic services"

- 65-7-2.14: Definition of "private office practice"

- 65-7-15.1.a: Exemption from CON review of a "private office practice"

- 65-7-28.1 and 28.1.b: Addition of certain health services offered by a health care facility, including diagnostic services

- 65-17-2.1: Increasing the threshold from $300,000 to $2 million for a diagnostic center

- 65-17-3.2 and 3.39: Establishing that the cost associated with a diagnostic center is an element in determining its reviewability

- 65-17-3.3.1: Eliminating computerized tomography (CT) as a reviewable item when offered, developed or acquired by health professionals

The net effect of these provisions is that without revision, the proposed rules will have a dramatic adverse effect on hospital revenues, will increase health care costs and will cause duplication of services. They will adversely affect the ability of community hospitals to survive long term and to continue to provide adequate care for the citizens of their respective communities, by forcing rate increases and a diminished capacity to provide indigent and uncompensated care.

One of the principal missions of the HCA is to prevent unnecessary duplication of services in order to curtail the increased cost of health care services. The proposed legislative rules will have the opposite effect.

While, with the exception of diagnostic centers, Magnetic Resonance Imaging ("MRI") remains subject to review under the proposed rules, Ohio's history with MRIs since their deregulation

in March 1996 for urban areas and May, 1997 for rural areas is instructive, with increases of 39 and 15 MRIs - a total of 54 - since those respective deregulation dates. To assume that similar duplication of other diagnostic services that are now effectively exempted from review when offered in a physician's office will not now occur in West Virginia is naive and unrealistic. It is self-evident that an increased supply in diagnostic services will result in a smaller demand for those services to each current provider, leaving the management of the current providers such as UHC no option but to try and replace the revenue lost as a result of the decreased demand, by raising its chargeable rates or reducing costs, which will lead to reductions in the quality of care provided, or both.

The proposed rules will allow entrepreneurial partnerships between doctors and venture capitalists to arise and establish lucrative diagnostic centers offering diagnostic services for private payors, without competition from hospitals or services for public employees or the indigent.

Under the rules as drafted, one can expect "diagnostic centers" to spring up with MRI, ultrasound, C/T scanners and nuclear cameras - all available for well under $2 million - and provide such services from 8 to 5, Monday through Friday, with a primary focus on lucrative insurance payors. Experience shows that such "cherry picking" operations are likely not to accept government pay patients, or provide indigent care, leaving the already strapped hospitals to continue to provide care to those groups. Under the proposed rules, all this would be accomplished without review by the state or consideration of the necessity for such services in the service area.

The proposed rules promulgated by HCA in 65 C.S.R. 17 do not incorporate the exemptions detailed in the recommendations from the CON Study, which were mandated to be incorporated into the proposed rules promulgated by the agency pursuant to S. B. 492. Rather, contrary to recommendations of the CON Study, HCA's proposed rules have inexplicably exempted from those services subject to review for physician practices only, CT scanners - a diagnostic service - despite the Study's specific recommendations that diagnostic services be subject to review regardless of cost and despite the fact that recommendations to exempt those services from review were expressly rejected by the subcommittee when it formulated its report. (See Recommended List of Reviewable Services at page 14 of the Study.)

Further contrary to the Study's recommendations to make diagnostic services reviewable regardless of cost (page 14), HCA has promulgated rules under Section 17 that would exempt diagnostic centers from review under the physician practices provisions unless the total cost of the diagnostic equipment and services offered are in excess of two million dollars, despite the subcommittee's express inclusion of diagnostic services on its Recommended List of Reviewable Services.

The clear effect of the agency's rules as promulgated in 65 C.S.R. 17 is to create a situation whereby physicians' practices and groups of physicians could provide diagnostic services and establish diagnostic centers offering new services or services already available in an area without CON review or rate review, thereby defeating the very purpose of the statute, which is to contain health care costs and to provide access to health care for West Virginia citizens regardless of ability to pay. In addition to creating an unfair competitive advantage for physicians and diagnostic centers by largely exempting

them from review while still subjecting hospitals to review of any services they might attempt to offer to compete for the market share that the new players in the diagnostics field will inevitably draw, the proposed rules will allow those new players to reduce the likelihood that hospitals will even be able to secure CONs for services they need and want to offer, but will not be able to show need because of entrepreneurial offerings that are secured without review.

The effect of the proposed rules will be to create duplication, remove revenue from hospitals, and increase cost to patients in West Virginia.

It is not an understatement to say that the revenue derived from diagnostic services at UHC is in large part the lifeblood of the hospital. In fact, the contribution margin of diagnostic services at UHC represents UHC's entire operating margin.

Assuming that a loss of 50% of the volume of UHC diagnostic services results from the anticipated proliferation of diagnostic services available through physician offices and diagnostic centers, the estimated effect on UHC alone would be to remove $4,308,055 annually of net contribution margin revenue that is currently being generated through the provision of diagnostic services. That figure is well in excess of half of UHC's total operating margin. A reduction of that size would require a 24.43% overall rate increase for the hospital to make up for that lost contribution margin. Should the anticipated revenue loss differ from the estimated 50% figure, a rate increase of approximately 5% would be required to recover a 10% increment of lost contribution margin. In light of the minimal rate increases that have been granted in the past, such an expectation is unrealistic.

The foregoing effect is brought into sharp focus when one considers that UHC historically provides uncompensated and indigent care that is between 7 and 8 percent of the total care provided when care is measured by the value of the services provided. No hospital can continue to provide uncompensated care at anywhere near that level in the face of the foregoing anticipated revenue losses.

Further, when the effects of the federal Balanced Budget Act are taken into consideration, resulting in Federal reimbursement revenue at more than two and one half percent less than expenses after inflation, resulting in an annual shortfall of an estimated two to two and one half million dollars for Medicare services provided at UHC, the adverse effects of the proposed legislative rules on the long-term viability of the hospital and the services it provides to the community only compound the difficulty that community hospitals are likely to experience because of the federal Balanced Budget Act's negative impact on revenues. In order for hospitals like ours to survive, either rates for the services that remain will have to rise dramatically or the amount of uncompensated care provided to the community must be reduced, or both.

The proposed rules may diminish quality of care for the selected services.

Another effect of the proposed rules in permitting certain freestanding diagnostic services to be developed is a potential diminution of the quality of care. It is questionable whether the quality of delivery of services can be maintained when services are delivered by doctors without the support

of specialists currently either employed by or contracted with West Virginia's hospitals. While we do not suggest that the physicians practicing in the various specialties are not capable of reading results of diagnostic tests, unless the physician offering a diagnostic service is a radiologist or has at his or her disposal the services of a radiologist, the level of service that can be provided to the patient will inevitably suffer.

Conclusion

Neither Senate Bill 492 nor the Certificate of Need Study was designed to create an uneven playing field by which certain services could be offered by freestanding operations without CON review, while the same services would be subject to such review if offered by hospitals.

Based on the intent of the Legislature and the Task Force which conducted the CON Study, the rules as proposed should be amended. In enacting Senate Bill 492, the Legislature did not change the language in West Virginia Code § 16-2D-4(a)(1), relating to the reviewability of services offered by a private office practice. Nor did the Task Force which conducted the CON Study for the Health Care Authority recommend a change in the playing field. In effect, the agency is attempting in the proposed rule to supersede the appeal in its recent decision in the Community Medical Associates matter, which is scheduled for oral argument on October 21, 1999.

Of greater consequence, however, is the drastic effect that implementation of the rules as proposed will have on community hospitals such as UHC, and we respectfully request that the proposed rules be amended to comport with Senate Bill 492, the recommendations of the CON Study, and the fundamental purpose of Articles 2D and 29B of Chapter 16 of the West Virginia Code, to ensure cost-effective high quality health care services to the people of our state.

Respectfully submitted,

Bruce C. Carter
President

BC/lc

Putnam General Hospital

1400 Hospital Drive
P.O. Box 900
Hurricane, West Virginia 25526
FAX (304) 757-1732/Phone (304) 757-1700

July 28, 1999

Ms. Marianne Stonestreet, General Counsel
West Virginia Health Care Authority
100 Dee Drive, Suite 201
Charleston, WV 25311

Dear Ms. Stonestreet:

I am writing in response to the two certificate of need rules, 65CSR7 and 65CSR17, recently filed by the Health Care Authority. As the CEO of a small hospital, a nurse, a wife and a mother, I too want to make sure that the best medical care is within easy access to everyone in the state. However, I do not believe that the proposed changes will improve the quality or availability of these services to our most under-served neighbors, the uninsured and underinsured people of our state.

As they stand, the changes that you are considering have the potential to greatly damage the ability of my hospital, Putnam General Hospital, to provide healthcare services to our community. A large percentage of the people that we serve are Medicare and Medicaid. It is my fear that if the proposed changes are made, private practitioners will chose not to serve these patients and limit their practice to the insured. Since our hospital depends heavily upon the revenue that outpatient services, such as diagnostic testing, generates to offset the losses that we continue to see due to changing reimbursement rates, this diversion of resources will threaten our ability to care for underinsured patients.

I believe that making slight revisions to the proposed rules can lessen much of the negative impact. In 65CSR7, Section 65-17-3.3.9 should be revised to read:

> " 'Diagnostic Services' means, as referenced in subdivision 28.1.b of this rule, laboratory or imaging services **which include the addition of computed tomography (CT) equipment or...**"

In 65CSR17, Section 65-17-3.3.9, "Diagnostic centers" should be changed to read "**Diagnostic services.**"

Thank you for your time and consideration. I appreciate your willingness to consider changes to these rules.

Sincerely,

Patsy Hardy, CEO

Greenbrier Valley Medical Center

202 Maplewood Avenue
P.O. Box 497
Ronceverte, WV 24970
(304) 647-4411

1999 JUL 19 P 12:59

July 15, 1999

Marianne K. Stonestreet, General Counsel
West Virginia Health Care Authority
100 Dee Drive, Suite 201
Charleston, WV 25311-1600

Dear Ms. Stonestreet:

I am writing to make you aware of our opposition to two sets of emergency rules filed on June 30, 1999 by the Health Care Authority (HCA). The emergency rule will amend Title 65 Series 7 and Series 17 revising the CON Rule and the rule governing the private office practice of health professionals. The revisions include changes to the certificate of need law which we do not believe were mandated by passage of Senate Bill 492.

These revisions constitute major policy changes which will result in a proliferation of diagnostic centers in West Virginia. Having actively lobbied for passage of SB 492 during the 1999 legislative session, I can assure you that legislators did not intend for this bill to increase the number of diagnostic centers, nor to increase the cost of health care in our state.

We do not believe that these rules constitute an emergency, nor do we believe that HCA is correctly interpreting the legislation to give them the authority to change the Series 7 and Series 17 rules. We ask that you reject the proposed amendments to Title 65 Series 7 and Series 17 as not constituting an emergency.

Sincerely,

Donald D. Sandoval, FACHE
Chief Executive Officer

DDS/sbf

CC: Steve Summer, President of West Virginia Hospital Association
Patricia McGill, Vice-President Legislative Policy at WVHA
Steve Barthelmess, Health Care Consultant

WHEELING HOSPITAL
1 MEDICAL PARK
WHEELING, WV 26003-6300

Donald H. Hofreuter, M.D.
Administrator / C.E.O.
304-243-3263 • Fax: 304-243-5045

July 28, 1999

Marianne Stonestreet
West Virginia Health Care Authority
100 Dee Drive
Charleston, WV 25311

Dear Ms Stonestreet:

The purpose of this letter is to ask that the changes to the current rules as *Emergency Rule 65, CSR 7 and 17* not be accepted as emergency rules as they have serious potential ramifications for the cost of health care in the State of West Virginia. Further, the changes do not represent an emergency and, therefore, should be subjected to the standard rule making process.

The primary area of concern is with the changes which would allow physicians to acquire expensive medical equipment without Certificate of Need (CON) approval. Currently, physician practices must obtain CON approval if the cost of the equipment exceeds $300,000. The proposed rules would exempt physician practices from CON review so long as the cost of the equipment did not exceed $2 million.

This would, in effect, allow physicians to purchase expensive pieces of medical equipment such as CT scanners, or develop complete ambulatory diagnostic centers without CON review. This has the potential to lead to the costly duplication of medical equipment and services without any corresponding increase in need or demand for the service.

Hospitals, on the other hand, would still be required to obtain CON approval for any diagnostic outpatient center off of its main campus, regardless of cost. This discrepancy provides an unfair business advantage to physician practices which would ultimately increase health care costs to everyone.

While the acquisition of equipment or development of an outpatient diagnostic center will increase a physician's practice revenue, it will result in a loss of that outpatient revenue from the local hospital. However, since the hospital must continue to offer these testing services to its inpatient population, it cannot reduce its staffing costs or eliminate the equipment costs associated with this service. Consequently, the hospital has no alternative but to increase its rates to the remaining payors and patients to cover these expenses and the lost revenue, resulting in higher health care costs overall.

As indicated above, most of a hospital's staffing and equipment costs are "fixed" because they are either required by regulatory agencies or are needed to care for the more seriously ill inpatient population. Therefore, it is important to fully utilize these units to the extent possible to spread these "fixed costs" over large volumes to keep the per test cost as low as possible. If a hospital loses its outpatient testing volume to a physician practice, it will not only duplicate equipment and staffing costs; but will also increase the per test cost to the hospital's remaining patients.

This is obviously not in the best interests of the health care consumers in the State. It s also not consistent with legislative intent to contain health care costs by avoiding duplication of services. Finally, this provision poses a serious threat to the financial viability of our State's hospitals, particularly the more vulnerable ones within the rural areas which could experience a loss of patient revenue.

We strongly urge that you disapprove these changes as emergency rules. If you would like to discuss this matter personally, please do not hesitate to call me at 304-243-3263.

Sincerely,

Donald H. Hofreuter, M.D.

Donald H. Hofreuter, M.D.
Administrator/CEO

DHH/ba

SAINT FRANCIS HOSPITAL
an affiliate of Columbia/HCA

333 Laidley Street
P.O. Box 471, Charleston, West Virginia 25322
Phone (304) 347-6500

July 30, 1999

Marianne Stonestreet, General Counsel
West Virginia Health Care Authority
100 Dee Drive
Suite 201
Charleston, WV 25311

Dear Mrs. Stonestreet,

As President and CEO of Saint Francis Hospital in Charleston, WV I am writing you regarding the two proposed CON rules (title 65, Series 7, and Series 17) recently filed by the Health Care Authority. As always, I appreciate the Health Care Authority's willingness to consider changes to proposed rules, and with that in mind I would like to make some comments and suggestions for your consideration.

The proposed rule changes provides the opportunity for the proliferation of expensive technical equipment such as CT scanners to be purchased by physician practices or other entities without regard for the potential harm that could be experienced by the hospital industry and the general public. Such proliferation of this technology without oversight or adherence to established quality health and safety standards could prove costly to consumers through repeat studies being performed due to poor quality or incomplete exams. Additionally, private practitioners or private entities accepting only paying patients for CT scanning services will drive charity or low income patients to hospital facilities already hit hard by Balance Budget Act changes. Finally, from a local perspective, does the Charleston Area really need additional CT services other than those provided for by the existing hospitals in the area?

Some suggestions that would correct and prevent the above issues from occurring would be to revise Series 7 Section 65-7-2.8 to define diagnostic services as laboratory services or imaging services **"which include the addition of computed tomography (CT) equipment "** or for which the total cost of all the equipment required to provide these services exceeds $2,000,000.

Additionally, Series 17 revisions to Section 65-17-3.3.9. should read **"Diagnostic Services"** rather than Diagnostic Centers. This change is needed so there is no confusion between the two rules.

If the Authority believes that these proposed changes have merit, I would ask that the authority revise the emergency rules prior to their being effective. I truly believe that the proposed policy changes I have outlined above have merit, and I ask the Health Care Authority to give serious consideration to these changes.

If you have any questions or comments please do not hesitate to call me at (304) 347- 6872. I appreciate your consideration in this matter.

Respectfully Submitted,

Daniel Lauffer, CEO

Faxed on July 30, 1999
Mailed on July 30, 1999

Raleigh General Hospital

1710 Harper Road
Beckley, WV 25801
Telephone (304) 256-4100

July 28, 1999

Marianne Stonestreet
General Counsel
WV Health Care Authority
100 Dee Drive, Suite 201
Charleston, WV 25311

Re: Proposed Certificate of Need Rules

Dear Ms. Stonestreet:

As you well know, the West Virginia Health Care Authority (the Authority) proposed rule changes to the CON statutes, specifically Title 65, Series 7 and Series 17. As I understand it, these proposed rules were also submitted as emergency rules and may become effective immediately upon acceptance by the Secretary of State.

There is one significant area of concern that I have regarding the proposed emergency rules. This concern is the impact that the current language of the proposed rules have regarding computed tomography (CT). As I understand it, the proposed rules would only require providers interested in establishing CT services to submit an application should the cost of the project exceed two (2) million dollars. Should this become effective, I anticipate that a number of physicians will attempt to establish CT services in their own offices. On the surface this may not appear to be a reason of concern; however, I do not feel that there is a problem with access to this service currently. In addition, and more importantly, I feel that if this occurs there will be a significant loss of control of the quality of this service provided to patients as there is currently no monitoring process for physicians who offer this service.

To remedy this situation, I suggest the following changes to Series 7 and Series 17. First, the definition of diagnostic services included in Series 7 should be revised to include computed tomography equipment. This definition may read as follows: "Diagnostic Services" means, as referenced in subdivision 28.1.B. of this rule, laboratory or imaging services **which include the addition of computed tomography (CT) equipment or** for which the total cost of all equipment required to provide these services exceeds two (2) million dollars." In determining whether medical equipment exceeds two (2) million dollars, the cost of studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the acquisition of equipment shall be included. If the

equipment is acquired for less than fair market value, the term "cost" includes fair market value.

Second, I suggest that the rules regarding Series 17 simply be revised to reflect the words diagnostic services as opposed to the current language which is diagnostic centers. I believe that this revision will clarify and avoid any confusion as a result of the difference in wording between these two series.

I appreciate the Authority's efforts in drafting rules which consistently and equitably apply to all providers. I do feel that the suggestions listed above, if accepted by the Authority, will reach the same goal.

I also appreciate the Authority's consideration for any revisions to these proposed rules. I also request that the Authority, if it agrees with these suggested revisions, strongly consider withdrawing the emergency rule and immediately refiling with the suggested revisions.

Your consideration in this matter is greatly appreciated. Should you have any questions, please feel free to contact me.

Sincerely,

David B. Darden

David B. Darden
President/CEO

DBD/sl

Camden-Clark Memorial Hospital
100 YEARS
For Your Lifetime

800 Garfield Avenue
P.O. Box 718
Parkersburg, WV 26102
(304) 424-2111

July 30, 1999

D. Parker Haddix Chairman
West Virginia Health Care Authority
100 Dee Drive, Suite 201
Charleston, WV 25311-1600

Re: Comments to Proposed Rule Making
Title 65, Series 7 and 17

Dear Chairman Haddix:

Camden-Clark Memorial Hospital (CCMH) wishes to provide the following comments with respect to the proposed emergency legislative rules and proposed legislative rules filed by the West Virginia Health Care Authority (Authority) to amend Title 65, Series 7 and Title 65, Series 17:

1. Title 65, Series 7 - The proposed rules to amend Title 65, Series 7 set forth a wide variety of issues and policy decisions. CCMH believes that Senate Bill 492 only contemplated emergency rules to define the list of health services which would be reviewable under W.Va. Code § 16-2D-3(b)(5), and to prescribe the procedure for the "fast track" review of non-health related projects pursuant to W. Va. Code § 16-2D-7(u). The remainder of the issues addressed by the Authority are not appropriate candidates for emergency rule making. Rather, many constitute discretionary policy-making by the Authority which should be considered by the Legislative Rule Making and Review Committee before becoming effective.

Included within the items which are unnecessary for emergency rule making are Section 2.1 (amended definition of "acquiring a health care facility"); Section 2.14 (proposed definition of a "private office practice"); Section 8.1 and 11.4 (drastically limiting the ability of a CON applicant to file additional information); Section 11.4.b (adding rate review non-compliance to the grounds under which the Authority may refuse to deem a CON application complete); and deleted Sections 12.2 and 12.4 (granting preference to CON applications which strengthen the effect of competition for health services). CCMH wishes to indicate its agreement with the West Virginia Hospital Association's (WVHA's) written comments opposing these amendments to Title 65, Series 7.

In addition, CCMH wishes to note its strong disagreement with the definition of "diagnostic services" proposed by the Authority in Section 2.8 of Title 65, Series 7. Proposed Section 2.8 defines "diagnostic services" as being reviewable only if an expenditure threshold of $2 million is exceeded. This is contrary to the intent of Senate Bill 492, and the CON Task Force Study completed earlier. Each of the listed services in proposed Section 28 to Title 65, Series 7 should be reviewable regardless of the level of capital expenditure associated therewith, including "diagnostic services." CCMH agrees with the proposed definition of "diagnostic services" included in the comments filed by the WVHA.

CCMH also believes that the review process for non-health related projects as set forth in proposed Sections 5.7 and 10.4 of Title 65, Series 7 are too restrictive. CCMH believes that applicants should not be required to file a full CON application for non-health related projects, but instead should be able to file an exemption application on such matters. CCMH believes that this was in fact the intention of the CON Task Force Study, which described the new process as a "fast track" one involving only the review of financial information.

2. Title 65, Series 17 - CCMH vehemently disagrees with the proposed amendment to the definition of a "diagnostic center" as set forth in proposed Section 2.1 of Title 65, Series 17. An increase in the capital expenditure minimum for a "diagnostic center" from $300,000 to $2 million will result in a proliferation of such facilities in our area. Specifically, CCMH believes that physicians in the Mid-Ohio Valley are likely to seek to develop free-standing mammography, ultrasound, radiology, fluoroscopy, CT, nuclear, and other imaging services to compete with those already provided by CCMH and other local hospitals. The proliferation of such centers will reduce utilization of such services at CCMH, and make it more difficult to provide other necessary, but less profitable, services. CCMH is also concerned about the built-in advantage for physicians under Title 65, Series 17 to develop such freestanding "diagnostic centers" without a CON, while hospitals would have to obtain CON approval to develop similar freestanding facilities.

Senate Bill 492 does not require any change to Title 65, Series 17. Accordingly, CCMH supports maintaining the status quo of that rule, including the current definition of a "diagnostic center" under Section 2.1. CCMH also supports retaining CT as a listed service under Title 65, Series 17.

Without a doubt, the Authority's proposed amendments to Title 65, Series 17 represent the single largest regulatory threat to hospitals in West Virginia in quite sometime. Since they are not required by law, they should not be made. Certainly, such drastic and potentially catastrophic changes should not be made on an emergency rule making basis by this agency. CCMH urges the Authority to reconsider its position, and to withdraw the proposed emergency rule amending Title 65, Series 17.

Thank you for your kind consideration of these comments. If we can provide further information, please do not hesitate to give us a call.

Sincerely,

Thomas J. Corder

Thomas J. Corder
President and Chief Executive Officer

TJC:mlm

St. Joseph's Hospital
In Affiliation with COLUMBIA/HCA®

1824 Murdoch Avenue P.O. Box 327
Parkersburg, West Virginia 26102-0327

General Information: **(304) 424-4111**
http://www.wvha.com/web/sjh

St. Joseph the Worker with the Child Jesus
- sculpture by William D. Hapen

July 29, 1999

Marianne Stonestreet, General Counsel
West Virginia Health Care Authority
100 Dee Drive, Suite 201
Charleston, WV 25311

Dear Marianne:

I am writing in reference to the proposed changes to certificate of need rules filed recently by the WV Health Care Authority, specifically Title 65, Series 7 (65CSR7) and Series 17 (65CSR17).

My primary concern relates to the definition of diagnostic services. In Series 7, I recommend the definition of diagnostic services be changed to include CT scanners. Proposed specific language to be included, bolded and underlined, reads:

> 65-7-2.8 "Diagnostic services" means, as referenced in subdivision 28.1.b of this rule, laboratory or imaging services **which include the addition of computed tomography (CT) equipment or** for which the total cost of all the equipment required to provide these services exceeds $2,000,000.00 ..."

In addition, I urge you to consider changing the language in Series 17 in Section 65-17-3.3.9 from "Diagnostic centers" to "**Diagnostic services**." I believe this would eliminate any confusion between the two rules.

By changing this language to include CT scanners, patients will be ensured of continued quality of scans while the cost of equipment, supplies and patient charges are kept within reason. Additionally, allowing private practitioners to acquire CT scans without regard to need for the additional CT services, could result in a proliferation of unneeded equipment and increase the potential for hospitals to bear further financial loss. As you may be aware, hospitals have already been financial impacted by recent changes in Medicare reimbursement. If physicians acquire CT scanners, they have the option, which hospitals do not, of seeing only patients with insurance or the ability to pay. This could leave hospitals with a higher percentage of low income, uninsured patients with little or no ability to pay for the services.

It takes trained people to perform CT scans and read the results. CT techs have a lot of expertise, and we provide 24 hour a day, seven day a week service. If private practitioners perform CT scans, quality could be impacted. The quality of the result is very dependent on the quality of the CT scan. The cost of the equipment, coupled with the expense of hiring experienced CT techs, will be quite a financial undertaking for private practitioners. If these physicians cannot provide experienced staff to interpret scan results, quality of the scans will be diluted.

If you agree to the changes described above, I ask that the Health Care Authority also revise the emergency rules prior to their becoming effective, even if the rules must be withdrawn and then re-filed. It is possible that a re-filed emergency rule could be approved by the Secretary of State immediately, since there will have been a thirty-day comment period.

Thank you in advance for any consideration given to my recommendations on these rules. As always, I appreciate the willingness of the Authority to listen to concerns voiced by those of us who may be impacted by any changes made to the certificate of need rules.

Respectfully,

Stephens Mundy
Chief Executive Officer

Davis Health System

July 29, 1999

Ms. Marianne Stonestreet
West Virginia Health Care Authority
100 Dee Drive
Charleston, WV 25311

Dear Ms. Stonestreet:

I would like to have the enclosed letter addressed to the Secretary of State included as my comments on the Health Care Authority emergency rules Title 65 Series 7 and Series 17. Further, I urge the careful consideration be given to the legal brief filed by the West Virginia Hospital Association.

Sincerely,

Robert L. Hammer, II
President & CEO

RLH/jnl

Enclosure

▲ P.O. Box 1697 ▲ Elkins, West Virginia 26241
▲ (304) 637-3767 ▲ FAX: (304) 637-3184

Davis Health System

July 19, 1999

The Honorable Ken Hechler
West Virginia Secretary of State
Administrative Law Division
Building 1, Suite 157K
1900 Kanawha Boulevard, East
Charleston, WV 25305-0770

Subject: Health Care Authority emergency Rules Title 65 Series 7 and Series 17

Dear Mr. Secretary:

The Health Care Authority (HCA) has sent you emergency rules Title 65 Series 7 and Series 17 to revise the Certificate of Need (CON) Rule as a result of legislation (Senate Bill 492) passed in the 1999 session.

The Authority was authorized to issue new emergency rules to implement certain sections of the legislation. In the process HCA has revised the old procedural rules (65 CST 7 "Series 7") for CON and included the two mandated provisions of the legislation. However, in revising the old rule, the Authority also made some existing provisions more stringent, going beyond the emergency rule making requested by the Legislature.

For example, the rule has a definition for "diagnostic services" which would allow any health care facility to acquire lab or imaging services as long as the cost does not exceed $2 million. Davis Health System believes the emergency rule making is inappropriate for implementing the additional provisions which were not specifically authorized by the Legislature.

Another existing rule (65 SCR 17 "Series 17"), pertaining to the private office practice of health professionals was revised with a proposed emergency rule. The revisions would allow physician practices to be exempt from review as long as the acquisition of major medical equipment does not exceed $2 million, with some restrictions. This policy change was not mandated by the legislation and was a discretionary changes made by the Authority.

The result of this proposed rule will now allow any health professional to develop CT, diagnostic imaging and lab services anywhere as long as the $2 million threshold is not

▲ *P.O. Box 1697* ▲ *Elkins, West Virginia 26241*
▲ *(304) 637-3767* ▲ *FAX: (304) 637-3184*

exceeded. However, existing healthcare facilities are prohibited from developing any new services "off campus". I can see "outside investors" opening "diagnostic centers" with healthcare dollars going to "stockholders" rather than re-invested in West Virginia to help take care of our people. In addition, we could have unnecessary duplication of existing services in rural communities.

My request is that you disapprove the emergency rules that reach beyond the legislative mandate and allow the normal legislative process to address these public policy issues.

Thank you for consideration of my views.

Sincerely,

Robert L. Hammer, II
President and Chief Executive Officer

RLH/bes