WEST VIRGINIA
SECRETARY OF STATE
NATALIE E. TENNANT
ADMINISTRATIVE LAW DIVISION

Form #3

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OFFICE WEST VIRGINIA
SECRETARY OF STATE

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

AGENCY: WV Health Care Authority TITLE NUMBER: 65

CITE AUTHORITY: 16-2D-8(c)

AMENDMENT TO AN EXISTING RULE: YES X NO ____

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 7

TITLE OF RULE BEING AMENDED: The Certificate of Need Rule

IF NO, SERIES NUMBER OF 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.

Authorized Signature

TITLE 65
LEGISLATIVE RULE
HEALTH CARE AUTHORITY

SERIES 7
CERTIFICATE OF NEED RULE

SUMMARY AND STATEMENT OF CIRCUMSTANCES

This amendment clarifies the definition of "private office practice" for purposes of administering the Certificate of Need program. Those entities meeting this criteria may be eligible for an exception from Certificate of Need review pursuant to West Virginia Code § 16-2D-4(a).

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, Charleston, West Virginia 25311

Phone Number: 304-558-7000 Email: mkapinos@hcawv.org

Fiscal Note Summary

Summarize in a clear and concise manner what impact this measure will have on costs and revenues of state government.

There will be no fiscal impact on the costs and revenues of state government.

Fiscal Note Detail

Show over-all effect in Item 1 and 2 and, in Item 3, give an explanation of Breakdown by fiscal year, including long-range effect.

FISCAL YEAR			
Effect of Proposal	Current Increase/Decrease (use "-")	Next Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost			
Personal Services			
Current Expenses			
Repairs & Alterations			
Assets			
Other			
2. Estimated Total Revenues	0.00	0.00	0.00

Rule Title: Certificate of Need Rule

Rule Title: Certificate of Need Rule

3. **Explanation of above estimates (including long-range effect):**
Please include any increase or decrease in fees in your estimated total revenues.

There will be no increase or decrease in fees as noted above.

MEMORANDUM

Please identify any areas of vagueness, technical defects, reasons the proposed rule **would not** have a fiscal impact, and/or any special issues **not** captured elsewhere on this form.

The proposed rule will not have a fiscal impact because it merely clarifies the definition of an existing service.

Date: July 28, 2010

Signature of Agency Head or Authorized Representative

Sonia P. Cromer, D

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: July 28, 2010

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM:(*Agency Name, Address & Phone No.*) West Virginia Health Care Authority
100 Dee Drive
Charleston, WV 25311

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(c)

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

   June 15, 2010

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

   Charleston Newspapers, HCA Website and HCA Newsletter

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

   July 16, 2010

   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)

July 28, 2010

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

304-558-7000
Fax: 304-558-4776
Email: mkapinos@hcawv.org

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)

N/A

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

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. -- ~~March 29, 2007~~.

1.4. Effective Date. -- ~~March 29, 2007~~.

§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 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, 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 laboratory or imaging services, including but not limited to, radiology, ultrasound, mammography, fluoroscopy, nuclear imaging, densitometry, or computerized tomography at its existing facility, and proposing to add at its existing health care facility laboratory or imaging services not otherwise enumerated under subsection 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.

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

2.10. "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 W. Va. Code §16-5D-2, state homes for qualified veterans as defined in W. Va. Code §9A-2-1, or any institution operated by or on behalf of the West Virginia Division of Corrections.

2.11. "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 ~~o~~Office ~~p~~Practice" means the independent practice of one or more health professionals ~~licensed, authorized, or organized pursuant to the provisions of Chapter 30 of the West Virginia Code which is not controlled directly or indirectly, in whole or in part, by any other person or entity.~~ that meets the following requirements:

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

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

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

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

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

2.14.b. Practice composition:

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

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

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

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

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

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

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

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

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

2.14.e. For purposes of this definition, a "private office practice" shall be deemed to exist only when the services offered to the public are within the scope of practice of at least one of the owners, partners, shareholders, or members of the practice structure outlined in this rule.

2.14.f. Notwithstanding anything in this subsection 2.14 to the contrary, any practice granted a determination of nonreviewability as a private office practice by the board on or before the first day of July, 2010 shall be and remain a private office practice under the Act; provided the facts and circumstances provided in the request for determination of reviewability do not change.

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 operated as one 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 shall 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 the 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, when the 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 acquired, offered, or developed.

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

3.3. Any charge or bill for health services associated with a new institutional health service for which a certificate of need has not been issued by the board 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 that 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 shall submit the original and three (3) copies of the application to the board. The application shall have a verification signed by the Chief Executive Officer and the person or persons who prepared the application.

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

4.2.a. The identification of the applicant;

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

4.2.c. A description of the project;

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

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

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

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

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

4.2.i. 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 of the reports 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, a statement of changes in fund balance, a statement of cash flows, balance sheets, and a statement of the specific assumptions upon which the feasibility study was based;

4.2.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. The 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, rules 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; and

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 shall submit to the board a long-range plan, adopted by the governing body of the hospital or 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 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:

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 the 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 the application is without prejudice.

9.2. The applicant shall 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 shall 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. A health care facility shall not offer or develop in this state any new institutional health service, until the health care facility submits an application for a certificate of need and the certificate of need is approved by the board or the health care facility is exempt from certificate of need.

11.3. Any person proposing a new institutional health service shall 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:

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 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 to the Code.

11.5. The board shall 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 shall 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 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 shall 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 shall be in writing and shall be addressed to: General Counsel, West Virginia Health Care Authority, Certificate of Need Program, 100 Dee Drive, Suite 201, Charleston, West Virginia 25311.

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

11.10. If a public hearing is held on an application, and the board has determined other applications to be potentially unnecessarily duplicative, 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.

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 shall 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 shall exchange a list of all witnesses and copies of all documents to be presented or introduced at a public hearing with all other parties to the hearing. The witness lists and the copies of the documents shall be filed by the parties with the 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. Parties 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. The board or its designee may strike a written communication from the record if it does not comply with the requirements of this section.

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, 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 affected parties may engage in discovery as provided by the West Virginia Rules of Civil Procedure. The scope of discovery is limited to relevant and admissible evidence. Affected parties engaging in discovery are required to file a copy of the certificate of service attached to the discovery request or response with the board. Affected parties shall not file copies of the actual discovery and responses 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 the services in terms of cost, efficiency and appropriateness do not exist and the development of 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 the services has for the 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 the 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 the 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 shall 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 the services in terms of cost, efficiency and appropriateness do not exist and that the development of 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 the hazards or meet the 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, the 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 or radiation therapy by one or more health professionals and as further defined in the Health Care Authority's legislative rule, "Health Services Offered by Health Professionals," 65 CSR 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 the Health Care Authority's legislative rule, "Exemption for New Primary Care Services," 65 CSR 23; and

15.1.f. The creation of birthing centers 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 the Health Care Authority's legislative rule, "Exemption for Birthing Centers," 65 CSR 24.

15.2.

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 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.

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 subsection 15.3.a.2., 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 that 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 the Health Care Authority's legislative rule, "Exemption for Shared Services," 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 other times 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 shall 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 shall 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 the 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 shall 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. of this rule.

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 Rules of Civil Procedure. The affected 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. Affected parties shall file a copy of the certificate of service attached to the discovery request and a copy of the certificate of service attached to the response to the discovery with the board. Affected parties shall not file copies of the actual discovery or responses with the board.

16.8. Only an affected party may request a hearing and the affected party shall 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 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 any 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 shall address or deliver a request for review to: West Virginia Health Care Authority/Office of Judges, P.O. Box 3585, Charleston, West Virginia 25328. Affected persons shall also address or deliver a copy of the request to the 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. The stay shall 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 is 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 shall 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 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 shall be submitted at least forty-five (45) days prior to the expiration of the certificate of need or exemption, or at such other time as directed by the board. The report shall include, at a minimum, the following:

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 shall 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 shall 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 shall 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 the 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 shall prepare and submit documented final cost figures within the time designated by the board in its notice of substantial compliance. The board may withdraw a certificate of need if the applicant fails to submit the final cost figures within the time designated 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 under the Act.

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 shall 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 of this rule 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 the 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; and

28.1.x. CT (computed tomography) scanning.

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

WEST VIRGINIA HOSPITAL ASSOCIATION

100 Association Drive
Charleston, WV 25311-1571
(304) 344-9744
FAX: (304) 344-9745
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July 16, 2010

Marianne Kapinos, General Counsel
West Virginia Health Care Authority
100 Dee Drive, Suite 200
Charleston, WV 25311

Dear Ms. Kapinos:

On behalf of the West Virginia Hospital Association (WVHA) and its 73 hospitals and health systems, I submit this comment letter on the proposed modifications to the Certificate of Need Legislative Rule Title 65 Series 7, clarifying the definition of "private office practice".

WVHA supports the proposed modifications proposed and offers the following recommendations:

In order to make the regulatory language consistent, we suggest these changes to 2.14 (b):

2.14.b. Practice ~~Entity~~ composition:

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

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

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

We also recommend that clarification be added regarding "grandfathering" of existing practices that have been granted a ruling of non-reviewability:

2.14.e. Notwithstanding anything in this subsection 2.14 to the contrary, any practice granted a ruling of non-reviewability as a private office practice by the board on or before the first day of July, 2010, shall be and remain a private office practice under the Act for any past, present, or future

office locations owned and operated by that practice.

Thank you for consideration of these recommendations and for your continued efforts to clarify this complicated Certificate of Need rule.

Sincerely,

Jill McDaniel
Vice-President

HOLZER CLINIC

Medical Excellence. Local Caring.

July 16, 2010

VIA HAND DELIVERY

Timothy E. Adkins, Director
Certificate of Need
West Virginia Health Care Authority
100 Dee Drive, Suite 201
Charleston, WV 25311

Dear Mr. Adkins:

This letter provides Holzer Clinic Inc.'s comments on one of the provisions of the Health Care Authority's recently proposed amendments to W.Va. CSR § 65-7. Holzer Clinic is a physician owned and managed practice group with 140 physicians and nine office locations across Ohio and West Virginia. Specifically, we have two office locations in West Virginia.

Our comments specifically address the changes related to the definition of "private office practice" contained in the various sections under W.Va. CSR § 65-7-2.14. The definitions contain requirements that all owners of a private practice group must be a health professional, licensed to practice in the State of West Virginia. Our practice has no issue with the requirement that all owners and those in position to control the practice should be licensed health care professionals. However, the requirement that all such individuals be licensed in the State of West Virginia is unduly restrictive, especially given the fact that much of the population of the state is in border areas.

The overwhelming majority of our physicians are licensed in both Ohio and West Virginia. However, given some of the peculiarities of West Virginia's licensing rules and other issues, a few of the physicians in the ownership and management (Board) of the practice are only licensed to practice in Ohio and execute a voting trust giving proxy to a licensed West Virginia physician. Obviously, the only physicians who practice in our West Virginia locations are those who are licensed there, but a strict reading of the definition contained in the Proposed Rule would cause our practice to lose its designation as a private practice in West Virginia.

As a result, we would request that the proposed Rule be amended to maintain the requirement that all owners be licensed physicians, but to allow for some of those owners to be licensed only in other venues as long as those practicing in the State of West Virginia are licensed by the State of West Virginia.

Holzer Clinic has been providing medical care to the citizens of West Virginia for many years though its various practice locations. We do not believe it is the intent of the Authority to legislate away our status. We appreciate the opportunity to comment on the proposed Rule and hope our concerns are adequately addressed in the final Rule.

If you have any questions or should you need any further information, please do not hesitate to contact me at 740-441-2136.

Very truly yours,

Ellen J. Garling
Chief Legal Counsel

cc: John Cunningham

PRESTON
MEMORIAL HOSPITAL

July 16, 2010

HAND DELIVERY

Marianne Kapinos
General Counsel
West Virginia Health Care Authority
100 Dee Drive
Charleston, WV 25311-1600

Re: Comments on CON Proposed Rule modifying definition of "private office practices", 65 CSR 7-2.14

Dear Ms. Kapinos:

Preston Memorial Hospital respectfully submits the following comments for your consideration in regards to the certificate of need ("CON") proposed rule modifying the definition of "private office practice" under65 CSR 7-2.14.

1. The modified proposed rule does not address whether any existing private office practices would be grandfathered and not subject to these rules and regulations. The proposed modifications to the definition of "private office practice" appear to narrow the definition of those physician practices and other licensed professional under Chapter 30 who will be considered exempt from certificate of need review. As such, the proposed rule does not address the question of whether existing physician practices and other licensed professional under Chapter 30 who believe they are currently exempt from certificate of need review will now be subject to review as a result of the modified rule.
2. These rules do not make it clear if there is to be any exception for the academic medical school practice plans in West Virginia. Based on our review of the proposed rule we do not see any language that suggests that the academic medical practice plans will be treated differently than other hospital affiliated physician practices under the modified definition. Preston Memorial supports equal and level regulation of all hospitals in West Virginia. We believe that academic medical school practice plans should not be treated differently than all other West Virginia hospitals.
3. The meaning of Section 2.14.d is unclear. It appears to be reaffirming that a third party is not a health professional who owns and operates a practice and is an employed provider of

professional health services to the practice. We suggest that this provision be removed from the proposed rule or revised and its purpose clarified.

4. We understand the entity composition and the third party control definitions are described in further detail in Sections 2.14.b through 2.14.d but would suggest in Section 2.14 adding the following underlined language:

> "Private Office Practice" means the independent practice of one or more health professionals and the entity be owned and the governing body be composed exclusively by health professionals licensed in West Virginia, the entity cannot be influenced, controlled or managed by any third party organization affiliated or unaffiliated with the entity, and the entity must directly employ the health professionals licensed in West Virginia.

Preston Memorial Hospital is pleased to see the Health Care Authority recognize the need for clarification to the CON rule for what constitutes a private office practice. We strongly believe hospital affiliated practices, such as the academic medical school practices, should not be given a "blanket" exemption to expand their services unless all hospitals are treated equally. The proposed rules strengthening the definition of a "private office practice" to include academic medical practice plans are essential to protect patients and the rural hospitals that provide essential primary care services to them.

Here in Preston County we have been the target of these so called private practices which have been allowed to be developed in Preston County without first obtaining certificate of need approval. West Virginia University Medical Corporation dba University Health Associates established two practices in our county in the past two years without CON review under the premise they qualify as a private office practice exempt from CON review as a "private office practice under Chapter 30." We have protested this exemption to the Authority in two separate penalty violations noted below:

WVU Healthcare – Preston County Pediatric and Internal Medicine
CON File # 08-6-8874-PV
Initial letter requesting investigation submitted on October 29, 2008

WVU Healthcare – Kingwood
Development of Cardiac Services
CON File # 08-6-8865-PV
Initial letter requesting investigation submitted on October 10, 2008

Though we are unsure why the Authority has not followed up on a full and complete investigation of these requested investigations and reached a final opinion on whether or not there has been a violation of the CON law by developing projects without first obtaining the required certificate of need approval, we are pleased to see the proposed rules help clarify the requirements for such cases in the future.

We would point out that we believe the provisions under 65 CSR 7-2.14.b regarding "entity composition" and 65 CSR 7-2.14-c. regarding analysis of the "control directly or indirectly" by a third party will remain difficult for the Authority to properly examine and assess in each particular case. If

possible, a bright line rule on CON review should try to be established rather than one that turns on unique questions related to governance and corporate control. It is this same type of complex analysis of corporate structuring and contracting that has made it difficult for the Authority to fully understand the pending investigative matters submitted by Preston Memorial related to WVU – Healthcare. For a full understanding of the complex issues that can arise in these matters one only needs to go back and read the various inquiry letters and responses by WVU – Healthcare and Preston Memorial in the above referenced penalty investigations (CON File # 08-6-8874-PV and CON File # 08-6-8865-PV). Thank you for the opportunity to submit these comments on behalf of Preston Memorial Hospital. If you have any questions, please contact me at (304) 329-4704.

Very truly yours,

Melissa K. Lockwood

Melissa K. Lockwood

President and CEO

ValleyHealth
East Mountain
Health Advantage

July 15, 2010

VIA FEDERAL EXPRESS
Attention: Marianne Kapinos, General Counsel
West Virginia Health Care Authority, Legal Division
100 Dee Drive
Charleston, West Virginia 25311-1600

Re: Comments regarding Certificate of Need Rule § 65 CSR 7

Dear Ms. Kapinos:

East Mountain Health Advantage, Inc. submits the enclosed comments regarding the recently released Proposed Amendments to Certificate of Need Rule § 65 CSR 7 ("Proposed Rule"). We operate two hospitals and a wellness center in West Virginia and respectfully request your consideration of the concerns and suggestions mentioned below. Comments 1 and 2 recommend expanding the definition of "private office practice" rather than restricting the definition. In the alternative, Comments 3 and 4 propose modifications to the Proposed Rule.

Comment 1: The Linchpin of Healthcare Reform is Integration

The proposed definition of "private office practice" that limits private office practices to those entities that are wholly owned and controlled by licensed healthcare professionals will result in a Certificate of Need (CON) program that is overly burdensome in the face of healthcare reform. This expanded definition appears to be more restrictive than the CON precedent and will require a CON application for any healthcare entity attempting to meet the challenge of healthcare reform through clinical integration. Rather than creating a more restrictive environment by regulating healthcare entities that fail to meet the small exception provided for private office practices, the definition of private office practice should be expanded to facilitate the implementation of healthcare reform initiatives.

On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act (PPACA), the most significant health reform bill passed since the Social Security Act of 1965 created the Medicare program. A week later on March 30, 2010, the President signed the Health Care and Education Reconciliation Act of 2010. These two laws, known as healthcare reform, are the driving force to achieving higher quality healthcare at a lower cost. Central to the success of healthcare reform and achieving higher quality healthcare at a lower cost is clinical integration.

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Specifically, healthcare reform introduces new reimbursement methodologies that shift from fee-for-service payments to value-based payments in order to control costs and promote paying for quality. This shift in reimbursement methodology favors hospital-physician alignment over the private-practice model that has traditionally dominated the healthcare industry. In particular, PPACA provides for Accountable Care Organizations (ACOs), bundled payments, medical homes, reduced readmissions, quality and performance based reimbursement, and demonstration project models. Each of these initiatives will require hospitals and physicians to align in order to coordinate care and receive optimal payment.

For example, under PPACA, hospitals and physicians may establish ACOs to increase their Medicare reimbursement. Providers that participate in an ACO will continue to receive their typical Medicare payments, but will be eligible for bonus payments if the ACO meets certain standards for quality and cost savings. Given the requirements for an ACO, the most viable ACO model is a joint venture between hospitals and physicians (often formed as physician hospital organizations). Also, PPACA provides for bundled payment demonstration programs. A bundled payment system makes a single payment for all services related to a treatment or condition, possibly spanning multiple providers in multiple settings. These systems are designed to decrease readmissions and decrease incentives to overbill for a course of treatment. In order for such a system to be viable, there must be some level of integration between healthcare facilities and physicians. Finally, under the medical home scenario, practices are paid a per member, per month fee for intensive primary care including working with the patient's other doctors and physicians and managing hospital transitions. Coordinated and integrated care is a core principal of the medical home.[1]

Each of these initiatives, as well as many more in healthcare reform, require some level of clinical integration between healthcare facilities and physicians. The level of integration will likely vary, but probable models for integration include hospitals directly employing physicians, hospitals or health systems forming physician organizations to employ or contract with physicians, and contractual arrangements with physician organizations. Regardless of the form, clinical integration will facilitate the success of healthcare reform by using or promoting:

1. The interdependence and cooperation of providers to encourage coordinated care for enhanced quality and efficiencies;
2. Evidence-based practice standards and clinical protocols, and provider benchmarking;
3. Programs and mechanisms to monitor and control quality and utilization of healthcare services;
4. Information management systems, including electronic health records; and

[1] While many of these initiatives are currently demonstration projects, CMS will likely implement the initiatives as requirements for providers participating in Medicare.

5. Credentialing aimed at selecting and maintaining a cost-conscious, high-quality provider panel.

Clinical integration is the future of health care because it is necessary to achieve the goals of healthcare reform. As a result, the traditional private practice model of healthcare delivery will become less and less prominent. As with any change, the move towards integration will be costly in terms of both time and resources. However, because it is utterly critical to the success of healthcare reform, it will be a required change, rather than an optional change. Accordingly, the definition of "private office practice" under the CON regulations should not be narrowed to require a CON application for many actions, thereby increasing the costs of integration.

Because clinical integration is necessary to achieve the goals and implement policies and procedures of healthcare reform, the definition of private office practice should be broadened to expand the exemption from CON regulation with respect to private office practices. Failure to expand the definition will require hospitals, health systems, and physicians to obtain CON approval prior to integrating in order to meet the demands of healthcare reform. Requiring CON approval prior to integration will add an additional unnecessary strain on healthcare providers attempting to adapt to healthcare reform. It will undoubtedly increase the costs associated with adapting to healthcare reform and increase the time to comply with new laws or to participate in new reimbursement methodologies.

As a result, the definition of private office practice should be broadened to include any physician office practice so long as it is licensed, organized, or authorized under the provisions of Chapter 30 of the West Virginia Code. Accordingly, we propose the following definition of "private office practice":

> *"Private office practice" means the practice of one or more health professionals licensed, authorized, or organized pursuant to the provisions of Chapter 30 of the West Virginia Code.*

Maintaining the requirement that the health professionals be "licensed, authorized, or organized pursuant to the provisions of Chapter 30 of the West Virginia Code" ensures that the practice does not violate the corporate practice of medicine and that participating physicians maintain their independent medical judgment.

Utilizing such a definition will help to facilitate the success of healthcare reform in West Virginia by allowing hospitals, health systems, and physicians to integrate without having to obtain a CON. By expanding the definition of private office practice, West Virginia's Certificate of Need laws will be more in line with those of other CON states, permitting physicians to be employed by hospitals or physician groups, regardless of ownership, so long as the physicians maintain their independent medical judgment. If

such a move is made, the West Virginia Health Care Authority will have taken affirmative steps to facilitate the successful transition of healthcare in West Virginia to meet the new challenge of healthcare reform.

Comment II. The West Virginia Health Care Authority should expand the definition of private office practice.

While West Virginia currently exempts "private office practices" from CON regulation, the narrow definition of private office practice often results in a great deal of regulation of physician offices. The definition of private office practice as currently written has been interpreted narrowly such that many physician offices have been deemed ambulatory healthcare facilities, subject to CON review. The proposed definition is arguably more restrictive than the CON precedent, and will result in more physician offices being deemed ambulatory healthcare facilities subject to CON review. West Virginia should adopt a broad definition of private office practice to ensure that CON review is limited, as it is in many other CON states, to (1) adding or expanding regulated health care services, (2) exceeding the capital expenditure thresholds, (3) obtaining major medical equipment, or (4) developing or acquiring new health care facilities, excluding new physician offices.

The proposed definition limits the definition of a "private office practice" to for-profit entities that are physician owned, controlled and governed and to non-profit entities whose members are physicians, and that are controlled and governed by physicians. This definition prohibits the use of health system or hospital owned or controlled physician groups unless CON approval is obtained for most of the groups' actions, including employing physicians or opening new physician offices. In many other states, actions by physician groups, regardless of ownership or control, are exempt from CON review so long as the physicians maintain their independent medical judgment and so long as the practice is not adding or acquiring a regulated piece of medical equipment or offering a regulated medical service. Similarly, in West Virginia, the exemption for private office practices only applies unless the office is acquiring, offering or developing major medical equipment or the office seeks to provide a regulated service. However, because of the narrow definition of private office practice, many physician practices are more heavily regulated as ambulatory healthcare facilities.

We propose expanding the definition of "private office practice" to include all physician offices and groups, regardless of ownership and control, in order to reduce the number of entities classified as ambulatory healthcare facilities and to permit physicians to organize in contemporary models. Expanding the definition will reduce the regulation of private office practices unless the practice is acquiring, offering or developing major medical equipment or the office seeks to provide a new regulated service. Accordingly, an alternative proposed definition to that set forth in Comment I is as follows:

> *"Private office practice" means the practice of one or more health professionals licensed, authorized, or organized pursuant to the provisions of Chapter 30 of the West Virginia Code, regardless of ownership and control, so long as the health professionals maintain the sole authority to make clinical decisions.*

Expanding the definition of private office practice to all physician groups, regardless of ownership and control, permits physicians to practice through modern mechanisms, including employment and contracting with hospitals and health systems through physician groups without having to obtain CON approval.

Under the current West Virginia CON laws and regulations, the Healthcare Authority will maintain the ability to regulate such groups if the groups seek to acquire major medical equipment subject to review or if the groups seek to add a new regulated service. By maintaining this ability, the Healthcare Authority can ensure that equipment that encourages overuse is limited and that new regulated services are added to West Virginia on an as-needed basis. On the other hand, physicians will be permitted to practice through modern models of alignment without having to obtain CON approval for most actions.

Comment III: Other Authorized Physician Groups

The West Virginia Board of Medicine has issued a Public Policy Statement stating that corporations not owned and operated by licensed physicians and podiatrists are not per se violative of the corporate practice of medicine doctrine.[2] The West Virginia Board of Medicine has stated that it will evaluate such entities on a case by case basis under factors set forth in the Public Policy Statement to ensure that the physicians maintain their independent medical judgment. Accordingly, it is possible that a corporation not owned and operated exclusively by licensed physicians and podiatrist may be authorized to employ physicians in West Virginia. However, the Proposed Rule limits the definition of "private office practice" to sole proprietorships, general partnerships, professional corporations, and professional limited liability companies, each of which must be owned or controlled exclusively by health professionals.

As a result, it is possible to have a corporation authorized by the Board of Medicine to employ physicians, but that does not qualify as a "private office practice" exempt from CON regulation. Such corporation would be required to obtain CON approval for many actions, including employing physicians. Due to the cost and time associated with the CON approval process and the different directions of the Board of

[2] Statement of Public Policy West Virginia Board of Medicine; Re: Corporate Practice of Medicine: Is the Employment of a Physician by a Corporation Other Than a Medical Corporation PER SE Violative of the West Virginia Medical Practice Act?; Wade, John A., President; May 8, 1995; Amended May 10, 2010.

Medicine policy and the Healthcare Authority rules, we suggest adding a provision as § 65-7-2.14.a.5 that provides:

> *As a medical corporation duly registered with or certified by the appropriate health professional licensure board.*

To permit such a medical corporation that may not be owned or controlled exclusively by licensed physicians to qualify as a "private office practice," §§ 65-7-2.14.b and 65-7-2.14.c must also be revised. We suggest revising § 65-7-2.14.b.2 and b.3 to read:

> *2.14.b.2. If the entity is a non-profit entity and has a membership, all of the members of the entity must be health professionals, all of whom are duly licensed to Practice in the State of West Virginia, or non-profit entities authorized to conduct business in the State of West Virginia.*
>
> *2.14.b.3. If the entity is a non-profit entity and does not have a membership, the governing body of the entity must be composed of a majority of health professionals, all of whom are licensed in the State of West Virginia.*

We suggest revising § 65-7-2.14.c as follows:

> *The independent medical judgment of health professionals may not be controlled, directly or indirectly, by any third person or entity. If the "private office practice" is not owned or controlled by health professionals, contractual provisions must guarantee that health professionals maintain sole discretion with respect to clinical decisions.*

We recommend deleting §§ 65-7-2.14.c.1-4 because the suggested revision to § 65-7-2.14-c adequately ensures that health professionals will maintain the sole discretion for clinical decisions. Also, in light of the suggested revisions §§ 65-2.14.d and 65-7-2.14.e are no longer necessary and should also be deleted.

Comment IV: Management Services Agreements

The Healthcare Authority precedent shows that a medical corporation owned and controlled entirely by licensed physicians, even if managed by a Management Services Organization (MSO), is a "private office practice" exempt from CON regulation.[3] Most times MSO manage office practices through a management services agreement. Management services agreements are widely used in the healthcare industry and in

[3] See In re: MedExpress Urgent Care, PLLC- Wheeling, CON File # 08-10-8679-PV.

West Virginia to provide physician practices with management services and expertise so that the physicians may focus on providing high quality care rather than running a practice. A critical component of these agreements is the MSO's ability to support the practice financially, either by providing capital, paying expenses and indebtedness or by reducing liabilities.

Proposed § 65-7-2.14.c.4 states that control is manifested if a third party or entity, through an agreement, may "guarantee, pay, or otherwise discharge any indebtedness, liability, or other financial obligation of the practice." This section threatens to jeopardize those practices managed by an MSO from qualification as a "private office practice" despite Healthcare Authority precedent condoning MSO arrangements. Accordingly, if the Healthcare Authority insists on narrowing the definition of "private office practice," the Healthcare Authority should remove § 65-7-2.14.c.4 from the final rule and explicitly condone the use of management services agreements. The Healthcare Authority may explicitly condone the use of management services agreements by including a provision stating:

> *The provision of management services to a "private office practice" shall not constitute control, either direct or indirect, of the health professional.*

In closing, due to the need for clinical integration required for the success of healthcare reform and because of modern models of alignment and delivering healthcare, we urge the Healthcare Authority to expand the definition of private office practice rather than narrow the definition. Expanding the definition will help to facilitate West Virginia's move towards providing the highest quality care at lower costs. In the alternative, the Proposed Rule should be modified to align the directions of the Board of Medicine and Healthcare Authority with respect to physician groups and to ensure that management services arrangements are protected.

Should you have any questions or wish to receive further input on the Proposed Rule, please feel free to contact me at 540-536-4706.

Sincerely,

M. Todd Way

M. Todd Way
President
East Mountain Health Advantage, Inc.

Camden-Clark Memorial Hospital
For Your Lifetime

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P.O. Box 718
Parkersburg, WV 26102
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July 13, 2010

Timothy E. Adkins, Director
Certificate of Need
West Virginia Health Care Authority
100 Dee Drive
Charleston, WV 25311-1600

RE: CON Standards 65 CSR7 2.14
Private Office Practices

Dear Mr. Adkins:

On June 30, 2010, Camden-Clark Memorial Hospital received a copy of the proposed new standards for "Private Office Practices" from the West Virginia Hospital Association. The new standards were written to more clearly define the development and ownership of a private office practice. These new standards would also better define the difference between a private office practice and an ambulatory care center.

My staff and I have reviewed the standards and find them to be very concise and complete and do indeed remove the ambiguity from past definitions. I am fully supportive of the new standards and wish to thank the West Virginia Health Care Authority for their diligent work and research to complete the new standards.

Sincerely,

Michael A. King
President and Chief Executive Officer

MK:mm

cc: Sonia Chambers, WV HCA
Allen Butcher
Todd Kruger
Dave McClure

Camden-Clark Memorial Hospital
For Your Lifetime

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FAX

Date: July 20, 2010

Number of pages including cover sheet _____

TO: Timothy E. Adkins

FROM: Michael A. King

Telephone: _____

Fax Number: 304-558-4776

Telephone: 304-424-2204

Fax Number: 304-424-2906

COMMENTS:

RESPONSE TO COMMENTS

The Health Care Authority received five sets of comments on the proposed amendment to 65 CSR 7. The following persons or entities filed comments:

(1) West Virginia Hospital Association
(2) Preston Memorial Hospital
(3) Holzer Clinic
(4) ValleyHealth – East Mountain Health Advantage
(5) Camden-Clark Memorial Hospital

The clarifications requested in regard to hybrid organizations and "general" versus "limited" partnerships were made by the agency.

In addition the request for a "grandfather" clause by Preston Memorial Hospital and the Hospital Association was also added to the rule.

Holzer Clinic requested that the definition be expanded to permit physicians who are not licensed in West Virginia to have ownership and/or management responsibilities related to the practice. This is contrary to what is permitted by the Board of Medicine and the agency determined it does not want to have conflicting requirements for physicians. Therefore this request was not included in the amendment to the rule.

Valley Health requested the agency to delay the amendment until it is better known what health care reform will look like. The agency decided this was too long to wait and the amendment is needed now, not in the future. Valley also suggested that the agency put an exception into the rule for MSO's. However, it was decided that there are various types of MSO's, not all of which may be exempt. Therefore, the agency determined not to include this language in the proposed amendment.

Finally, the agency received comments in support of the amendment from Camden-Clark Memorial Hospital.