

**WEST VIRGINIA
SECRETARY OF STATE
BETTY IRELAND
ADMINISTRATIVE LAW DIVISION**

Form #3

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2006 JUL 28 P 2:37

OFFICE WEST VIRGINIA
SECRETARY OF STATE

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

AGENCY: West Virginia Health Care Authority TITLE NUMBER: 65

CITE AUTHORITY: W.Va. Code § 16-2D-8(c)

AMENDMENT TO AN EXISTING RULE: YES NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 7

TITLE OF RULE BEING AMENDED: Certificate of Need Rule

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: N/A

TITLE OF RULE BEING PROPOSED: N/A

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

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, 2006

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: (Agency Name, Address & Phone No.) West Virginia Health Care Authority

100 Dee Drive, Charleston, West Virginia 25311

(304) 558-7000

LEGISLATIVE RULE TITLE: Certificate of Need Rule

1. Authorizing statute(s) citation W Va Code § 16-2D-8(c)

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:
June 16, 2006

b. What other notice, including advertising, did you give of the hearing?
Notice of Public Comment Period on agency website

c. Date of Public Hearing(s) *or* Public Comment Period ended:
July 13, 2006, 5:00 p.m.

d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.
Attached Comments (1) No comments received _____

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

July 28, 2006

- 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

100 Dee Drive, Charleston, West Virginia 25311

Phone: 558-7000 Fax: 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)

same

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

Summary of changes to Title 65 Series 7

Certificate of Need Rule

The purpose of this rule is to implement 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.

The sole change to this legislative rule includes Computed Tomography scanning as a health service subject to Certificate of Need review and regulation. This change is noted in section 28.1.x of the rule. The circumstances supporting the request for emergency rule making are included as Attachment A.

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Certificate of Need Rule

Type of Rule: 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: _____

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 makes the development, acquisition or other establishment of computed tomography (CT) services reviewable. Current staff will review these applications and no additional hiring or other expenditures to process applications will be necessary.

Date: 5/24/06

Signature of Agency Head or Authorized Representative

Sonal Chandra

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TITLE 65
LEGISLATIVE RULE
HEALTH CARE AUTHORITY

2006 JUL 28 P 2:37

SERIES 7
CERTIFICATE OF NEED RULE

OFFICE WEST VIRGINIA
SECRETARY OF STATE

§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. -- May 5, 2000.

1.4. Effective Date. -- July 1, 2000.

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

§65-7-2. Definitions.

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

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

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

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

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

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

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

2.7. "Consistent With The State Health Plan" means a determination made by the board 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 office 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.

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.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.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

finer 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; and

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.



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WV HEALTH CARE
AUTHORITY

July 13, 2006

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

Dear Ms. Kapinos,

On behalf of the West Virginia State Medical Association (WVSMA), I respectfully submit the following comments to the proposed changes to 65 C.S.R. § 7, Certificate of Need Rule and 65 C.S.R. § 17, Health Services Offered by Health Professionals.

First, I would like share the concern of the WVSMA regarding the process that the West Virginia Health Care Authority (Authority) underwent in filing and gaining approval of these Emergency Rules. On May 24 the Authority filed both rules with the Secretary of State seeking approval to implement them on an emergency basis. Secretary Ireland then approved them both on June 7. The public comment was not filed by your office until June 12, four days after the approval of both rules.

Though I recognize that the rules were posted in the State Register for 14 days before they were approved as Emergency Rules, this is the bare minimum required to meet the notice requirements of the law. Our organization was not in the habit of randomly perusing the weekly register in anticipation of discovering an unanticipated filing. We therefore missed the opportunity to comment to the Secretary of State in advance of her approval. At no time prior to the approval of the Emergency Rule by the Secretary of State on June 7, 2006, did the Authority's Board or staff contact me or my staff about the proposed changes to the rules. In fact, I was disappointed to realize when I checked the dates that the first time I was advised by Sonia Chambers of the planned rule changes was on June 8, 2006, one day after the Secretary of State approved the implementation of the rules as Emergency Rules.

I preface all of this with a reminder that the particular section of language in Series 17 which is being substantially modified (i.e. bringing CT Scanners under review and strengthening the review of diagnostic centers) was specifically negotiated between the Authority, the West Virginia Hospital Association and the WVSMA nearly seven years ago. The changes to the certificate of need rules significantly impact West Virginia physicians and other professional providers. I believe that the Authority is well aware that any modification to this section in particular would, at a minimum, raise the interest of the physician community and should have resulted in the courtesy of a notice before the filing and certainly before the approval of the rule.

West Virginia State Medical Association

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The Authority cites as a reason for seeking the approval of the Emergency Rules that there is a health care crisis due to the "unregulated proliferation of diagnostic imaging centers" and that without regulation CT services by hospitals and physicians will lead to the duplication of services throughout West Virginia which will in turn result in increased health care costs. The WVSMA questions whether there is an actual emergency that justified the promulgation of the emergency rules and the ultimate approval by the Secretary of State. At the same time as the Authority filed the Emergency Rules the Authority issued an immediate moratorium on the development of new CT services, except for the replacement or expansion of existing CT services. This 180 day moratorium served the purpose of halting any proliferation of CT services as alleged by the Authority in its support for the emergency issuance of the rules. Thus, no emergency existed regarding the further development of CT services in West Virginia.

Additionally, the WVSMA disagrees with the Authority's argument that the increased availability of diagnostic imaging centers and CT related services leads to skyrocketing health care costs. The Authority gives this as a basis for the emergency nature and filing of the rule changes to Series 7 and 17. The availability and better access to diagnostic imaging services may ultimately lead to further competition among providers, including hospitals, physicians and other health care professionals. The increased competition to provide the service can have a positive impact and actually reduce the cost of the service to the patient or patient's insurer. Moreover, there are cost savings recognized by having the service provided in a more convenient, cost effective matter. Often it is more efficient and convenient for diagnostic imaging services to be performed by the patient's physician in an office setting rather than having to refer the patient to another provider, including a hospital, to perform the particular diagnostic service.

Further, the Authority may have overstepped its statutory authority by adding CT services as a service subject to certificate of need review and regulation under Series 7 and 17. West Virginia Code § 16-2D-3(b)(5) requires the Authority to define the health services subject to certificate of need review based upon the certificate of need study that was conducted pursuant to W.Va. Code § 16-29B-19a. This study conducted by the certificate of need task force was used as the basis for changes to the certificate of need laws that came about as a result of Senate Bill 492. The study conducted specifically excluded CT as a health service subject to review. Based on the language of the last sentence of W.Va. Code § 16-2D-3(b)(5), the Authority is required to utilize the recommendations of the study to define the scope of the health services that are reviewable when creating the list of health services under 65 C.S.R. 7-28 and 65 C.S.R. 17-3. Instead, in contradiction with the statutory mandated language the Authority has now added CT scanning as a reviewable health service.

Following are additional specific comments on each of the proposed rule changes:

65 C.S.R. § 7, Certificate of Need Rule:

The Certificate of Need Rule has been modified to include CT (computed tomography) scanning under 65 C.S.R. 7-28.1.x. as a health service subject to certificate of need review if the service was not offered on a regular basis within the twelve month period prior to the time the service. As discussed above, this change to the certificate of need standards is outside the scope and

authority of the Authority based on the provisions of W.Va. Code § 16-2D-3(b)(5) which requires the Authority to use the study conducted by the certificate of need task force which specifically excluded CT services as a reviewable health service as the basis for the Addition of Health Services provisions under 65 C.S.R. § 7-28.

The WVSMA takes the position that this change to the certificate of need law has little direct impact on its members since Chapter 30 licensed professionals are generally exempt from the certificate of need law requirements under W.Va. Code § 16-2D-4(a)(1). However, the WVSMA objects to this modification to the rule to the extent that the Authority interprets the addition of this provision as meaning that Chapter 30 licensed professionals in West Virginia who desire to add, acquire or replace CT scanning equipment will now be subject to certificate of need review.

This rule change has little or no impact on the hospital community and other CT providers in West Virginia other than to protect the monopoly power on the provision of CT services within the state since the provisions only apply to the addition of CT services and does not impact the replacement of CT services by existing providers.

65 C.S.R. § 17, Health Services Offered by Health Professionals:

The WVSMA finds the rule changes to Series 17 much more problematic because these changes directly impact the ability of Chapter 30 licensed health professionals, including physicians, to acquire, develop or offer laboratory and diagnostic services. The Authority has made major changes to the definition of a "diagnostic center" under 65 C.S.R. § 17-2.1 and severely limited the ability of a Chapter 30 health care professional to offer laboratory or imaging services without first undergoing certificate of need review. In particular, the changes impede the ability of cardiologists and radiologists to offer diagnostic services to their patients.

Again, the WVSMA asserts that the addition of CT services as a reviewable health service is outside the scope and authority of the agency under W.Va. Code § 16-2D-3(b)(5). Further, proposed changes to the definition of "diagnostic center" under 65 C.S.R. § 17-2.1 result in many activities that would have been otherwise determined not reviewable under the private office practice exemption to now be reviewable and require certificate of need approval.

First, although the dollar threshold of \$2,000,000 was not changed under 65 C.S.R. § 17-2.1.a., the Authority has added the costs of the facility and any related construction of the facility to the calculation of whether or not the project exceeded the expenditure threshold. Prior to this change the cost of the equipment was the only cost used to calculate whether or not a particular diagnostic center project met the definition of a "diagnostic center" and was therefore required to undergo certificate of need review.

Second, under 65 C.S.R. § 17-2.1.b. the proposed changes do not define the term "primary purpose." This term seems extremely vague and subject to interpretation by the Authority. Also the nature of the service offered by a professional might change over time. At first the primary purpose of the facility might not be to offer lab or imaging services but after time the purpose may change. Will this mean that the owner of the facility has to constantly reexamine whether the services are subject to certificate of need review. Moreover, the prior language under this

section which was negotiated between the WVSMA and the West Virginia Hospital Association was meant to reflect the idea that professional services offered outside the scope of the general practice or specialty of that professional should be subject to certificate of need review. The changes now focus on the services to be offered rather than the relationship of the services to the type of provider or specialist offering such service.

Third, under 65 C.S.R. § 17-2.1.c. the proposed changes significantly impact providers whose practice is largely a referral based practice. For example, radiologists rely exclusively on referrals. This change restricts any radiologist from providing diagnostic services since such services are typically referred by other licensed health care providers.

Fourth, the Authority under 65 C.S.R. § 17-2.1.d. and § 17-2.1.e. adds two new triggers for meeting the "diagnostic center" definition. Subsection 2.1.d. appears to restrict the ability of a health care professional to form a legal entity, not otherwise formed as an approved medical corporation or professional limited liability company to offer laboratory or imaging services. The WVSMA is not clear why this provision was added since any physician who forms another legal entity to provide health care services is required to first obtain approval for such entity through the West Virginia Board of Medicine. Subsection 2.1.e. again increases the ability of the Authority to find a basis on which to determine an otherwise nonreviewable project as reviewable under the "diagnostic center" definition. The professional owners or operators of a lab or imaging services must provide at least 75% of the services through the facility. The language appears to apply to all owners if there are multiple owners, so that if any one of them fall under the 75% threshold then the service becomes reviewable. Further, the Authority has built in multiple measurements (time spent, services billed or patient encounters) for calculating the 75% threshold all of which must be met to qualify as an exempt lab or imaging project.

The WVSMA would have liked to have had the opportunity to discuss our concerns addressed above prior to the implementation of the Emergency Rule and the filing of the comment period for the Proposed Rule; however, we were never given the opportunity. We request that in the future to the extent possible the Authority advise us of any rule changes that will likely impact the West Virginia physician community. Further, we request that the Authority involve the WVSMA in any future discussions involving the pending changes being made to Series 7 and 17 as they move through the legislative rule making review process.

Very truly yours,



Eyan H. Jenkins
Executive Director

cc: Sonia Chambers, Chair

The West Virginia Health Care Authority (HCA) received comments from the West Virginia State Medical Association (WVSMA) on July 14, 2006 regarding HCA's proposed changes to 65 C.S.R. § 7, Certificate of Need Rules and 65 C.S.R. § 17, Health Services Offered by Health Professionals. This was the only comment received with respect to the above referenced rules.

Based upon a review of WVSMA's comments, HCA has the following response:

- WVSMA takes issue that it was not provided with advance copies or notice of intent to change the above referenced rules. Such advance notice is not required by law. HCA complied with all applicable statutory provisions in filing and noticing the proposed emergency rules.
- WVSMA argues that HCA lacks authority to add computed tomography (CT), a reviewable service, since a study conducted approximately eight years ago recommended that CT services not be subject to Certificate of Need review. The health care field is dynamic and ever changing, HCA has the ability to respond to such market dynamics.
- WVSMA contends that the proposed definition of a diagnostic center results in many activities that would have been otherwise determined not subject to Certificate of Need review now to be reviewable. HCA's intent in making such changes was to clarify the definition of a diagnostic center and to clearly delineate what services are subject to Certificate of Need review.

Based upon WVSMA's comments, HCA does not have any changes to the proposed rules.