

John D. Rockefeller IV
Governor



L. Clark Hansbarger, M.D.
Director

State of West Virginia

DEPARTMENT OF HEALTH

CHARLESTON 25305

Notice

Legislative Rule: Certificate of Need

The above titled legislative rule was submitted to the Legislative Rule Making Review Committee on June 3, 1982.

A handwritten signature in cursive script, reading "L. Clark Hansbarger, M.D.", written over a horizontal line.

L. Clark Hansbarger, M. D.
Secretary
West Virginia Board of Health

June 3, 1982

Entered

FILED IN THE OFFICE OF
A. JAMES MANCHIN
SECRETARY OF HEALTH
THIS DATE 6/7/82

John D. Rockefeller IV
Governor



L. Clark Hansbarger, M.D.
Director

State of West Virginia

DEPARTMENT OF HEALTH

CHARLESTON 25305

Certification

Legislative Rule: Certificate of Need

The above titled legislative rule constitutes the official rule approved by the West Virginia Board of Health on February 19, 1982 and filed pursuant to law in the Office of the Secretary of State, State of West Virginia.

A handwritten signature in cursive script, appearing to read "L. Clark Hansbarger", written over a horizontal line.

L. Clark Hansbarger, M. D.
Secretary
West Virginia Board of Health

June 3, 1982

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SECRETARY OF STATE

THIS DATE 6/7/82

WEST VIRGINIA LEGISLATIVE RULES
BOARD OF HEALTH

Chapter 16-2D
Series I
(1982)

Subject: Certificate of Need

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WEST VIRGINIA LEGISLATIVE RULES
BOARD OF HEALTH

CHAPTER 16-2D
SERIES I
(1982)

Subject: Certificate of Need.

Section 1. General.

1.01. Scope. These legislative rules shall be used to administer the Certificate of Need program for the State of West Virginia. These legislative rules supplement Code §16-2D-1 et seq. and must be read in conjunction therewith.

1.02. Authority. These legislative rules are issued and relate to the authority of Article 2D, Chapter 16 of the West Virginia Code of 1931, as amended.

1.03. Filing Date. These amended legislative rules were promulgated on the 2nd day of December, 1981, and were filed in the Office of the Secretary of State on the 2nd day of December, 1981.

1.04. Effective Date. These legislative rules became effective on the 1st day of July, 1982.

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1.05. Supersession and Repeal of Former Regulations. These amended regulations supersede and repeal WV Adm. Reg. (Board of Health) 16-2D, Ser. I, Sec. 1 et seq. (1978, 1980) and WV Adm. Reg. (State Health Planning and Development Agency) 16-2D, Ser. II, Sec. 1 et seq. (1979).

1.06. Forward. The West Virginia Legislature has declared in Code §16-2D-1 the following to be the public policy of this State:

- (a) That the offering or development of all new institutional health services shall be accomplished in a manner which is orderly, economical and consistent with the effective development of necessary and adequate means of providing for the institutional health services of the people of this State and to avoid unnecessary duplication of institutional health services, and to contain or reduce increases in the cost of delivering institutional health services;
- (b) That the general welfare and protection of the lives, health and property of the people of this State require that the type, level and quality of care, the feasibility of providing such care and other criteria as provided for in this article or by the state health planning and development agency pursuant to provisions of this article, needed in new institutional health services within this State be subject to review and evaluation before any new institutional health services are offered or developed in order that appropriate and needed institutional health services are made available for persons in the area to be served.

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Section 2. Definitions.

As used in these regulations, all terms have the same meaning as provided in the definition section (Code §16-2D-2) of the statutes. Verbatim definitions, therefore, are not repeated here. Definitions set forth below amplify and clarify the statutory definitions or define terms not specifically set forth in the statute.

2.01. Acquire a health care facility means to obtain by purchase, donation, lease, or comparable arrangement a health care facility's assets used in the provision of health services, including the transfer of a health care facility from a subsidiary corporation to its parent, or vice versa.

2.02. Batching category means any one of the subparagraphs of CON Reg. §16.01(a)(1) through (8).

2.03. Certificate of Need means a document issued by the State Agency indicating that the proposed new institutional health service is in compliance with the intent, purposes and provisions of Code §16-2D-1 et seq. and that a need exists for the proposed new institutional health service.

2.04. Code means the Code of West Virginia (1931), as amended.

2.05. Conclusion of such hearing as used in Code §§16-2D-7(t) and 16-2D-10(c) means the date after which evidence and oral arguments have been presented when any proposed findings of fact and conclusions of law and any permitted briefs have been submitted in the time allotted.

2.06. Consistent with the state health plan, as used in Code §§16-2D-9(b)(2), 16-2D-9(g)(1), and CON Reg. §10.03(a)(1)(A)(ii), means a determination made by the State Agency, after considering and weighing

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all the evidence with regard to an application, that the preponderance of such evidence supports the achievement of the applicable objectives of the State Health Plan, except any provisions of the State Health Plan in conflict with the Code or these regulations shall not be considered in determining consistency with such Plan. In determining consistency with the State Health Plan, the State Agency shall utilize the data referenced in CON Reg. §10.02(g).

2.07. Date upon which all parties received notice of the state agency decision as used in Code §§16-2D-7(t)(2) and 16-2D-10(a) means the date upon which the applicant receives notice of the decision or the date upon which legal notice of the decision appears in the Saturday Charleston Gazette and Charleston Daily Mail, whichever is later.

2.08. Emergency circumstances that pose a threat to public health means those circumstances proclaimed as such by the Director of the West Virginia Department of Health or those circumstances upon which the Governor or the Legislature base a decision to proclaim a state of emergency under Code §15-5-6.

2.09. Expenditure minimum, as adjusted under the authority of Code §16-2D-2(j) to reflect the impact of inflation from October 1, 1979 to October 1, 1981 in the U.S. Department of Commerce Composite Construction Cost Index, means \$181,000.00.

2.10. Expenditure minimum for annual operating costs, as adjusted under the authority of Code §16-2D-4(e) to reflect the impact of inflation from October 1, 1979 to October 1, 1981 in the U.S. Department of Commerce Composite Construction Cost Index, means \$90,000.00.

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2.11. Health care facility as defined in Code §16-2D-2(1), does not include personal care homes as defined in Code §16-5C-2(d), community mental health and mental retardation facilities, State homes for qualified veterans as defined in Code §9A-2-1, The West Virginia Children's Home described in Code §26-1-1, or institutions operated by or on behalf of the Department of Corrections. For purposes of this definition, "community mental health and mental retardation facility" means a public or private facility which provides such comprehensive services and continuity of care as emergency, outpatient, partial hospitalization, inpatient and consultation and education for individuals with mental illness, mental retardation or drug or alcohol addiction.

2.12. Medically underserved population as designated by the State Agency under the authority of Code §16-2D-2(x) means any of the populations of areas of the State designated as Medically Underserved Areas by the Federal Secretary of Health, Education, and Welfare in 41 Federal Register 45717-75 (October 15, 1976) based upon the methodology contained therein and upon the criteria of the ratio of primary care physicians to population, the infant mortality rate, the percentage of the population which is age sixty-five (65) or over, and the percentage of the population with family income below the poverty level, as contained in Title 42 Code of Federal Regulations §51c.102(e) and developed under the authority of the Public Health Service Act §330(b)(3), as amended, Title 42 United States Code §254c(b)(3). [Medically Underserved Areas designated by the Federal Government are not necessarily the same as the Health Manpower Shortage Areas also so designated. See 46 Federal Register 23816-7 (April 28, 1981)].

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2.13. Organizations representing health care providers as used in the definition of "affected person" in Code §16-2D-2(a) includes, but is not limited to, the following organizations:

- (a) Association of Community Mental Health/Mental Retardation Programs of West Virginia;
- (b) Health Care Association;
- (c) Marshall University Medical School;
- (d) Professional Nursing Home Association of West Virginia;
- (e) Public Health Officers' Association;
- (f) West Virginia Commission on Aging;
- (g) West Virginia Council of Home Health Agencies;
- (h) West Virginia Dental Association, Inc.;
- (i) West Virginia Department of Health;
- (j) West Virginia Department of Welfare;
- (k) West Virginia Division of Vocational Rehabilitation;
- (l) West Virginia Hospital Association;
- (m) West Virginia League for Nursing;
- (n) West Virginia Nurses Association;
- (o) West Virginia Primary Care Study Group;
- (p) West Virginia Public Health Association;
- (q) West Virginia School of Osteopathic Medicine;
- (r) West Virginia Society of Osteopathic Medicine;
- (s) West Virginia State Medical Association; and
- (t) West Virginia University Medical School.

2.14. Parties as used in Code §§16-2D-7(t)(2) and 16-2D-10(a) means the applicant, and if a hearing is held on an application, the

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person requesting the hearing and all persons designated as parties to the hearing.

2.15. Potentially unnecessarily duplicative, used as a term to describe applications, means applications in the same review cycle which propose new institutional health services to serve the same or similar health needs of the same, or partially the same, population.

2.16. Project means a proposed new institutional health service as defined in Code §16-2D-3.

2.17. Proposal means a proposed new institutional health service as defined in Code §16-2D-3.

2.18. Proposed State Health Plan means the document prepared and adopted by the Statewide Health Coordinating Council pursuant to section 1524(c)(2) of the Public Health Service Act, as amended, Title 42 United States Code section 300m-3(c)(2), before such document is approved by the Governor as the State Health Plan.

2.19. Redistributes beds among various categories as used in Code §16-2D-2(kk), includes a change in the status of beds from one classification to another (e.g., acute care, long term care, obstetrical, pediatric, etc.).

2.20. Undertaken, when used to describe an activity for which a Certificate of Need was issued or for which an exemption was granted, means the first use of the new institutional health service for its intended purpose.

Section 3. Scope of Certificate of Need Coverage.

3.01. Exempted Major Medical Equipment to Serve Inpatients. This subsection supplements Code §16-2D-3. If any major medical equipment

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not located in a health care facility is acquired without a Certificate of Need pursuant to Code §16-2D-3(i) and at any time it is proposed to use that equipment to serve inpatients of a hospital, a certificate of need shall be required before such equipment is so used, unless the use is one described in Code §16-2D-3(i)(5) or CON Reg. §4.04.

3.02. State Agency Plan of Action. This subsection supplements Code §16-2D-5(e). For the purpose of advancing health service quality assurance, cost effectiveness, access, and other purposes consistent with the public policy of the State, as stated in Code §16-2D-1 et seq., and consistent with the national health planning policy embodied in Title XV of the Public Health Service Act, as amended, Title 42 United States Code §300k et seq., where the State Agency identifies unnecessary duplication or excess supply of certain institutional health services or facilities for which competition will not appropriately allocate supply consistent with the State Health Plan, due to the prevailing methods of paying for health services by public and private health insurers or due to other reasons, the State Agency may develop, with cooperating health care facilities, a State Agency Plan of action for the merger, or sharing of resources of such health care facilities, and may, after considering the anticompetitive impact in consultation with the Attorney General, permit implementation of such Plan through the approval of Certificate of Need applications.

Section 4. Exemptions.

This regulation supplements Code §§16-2D-3 and 4.

4.01. Private Offices. Except as provided in Code §16-2D-3(i), private offices of physicians, private clinics of physicians, dentists

or other practitioners of the healing arts are, by Code §16-2D-4(a)(1), exempt from Certificate of Need review. A private office or private clinic of a physician, dentist, or other practitioner of the healing arts means any facility which:

- (a) Is organized as a sole practitioner, partnership or has a certificate of authorization issued to a medical corporation or a dental corporation by the appropriate licensing board of West Virginia pursuant to Chapter 30 of the Code; and
- (b) Is not licensed or required to be licensed as an ambulatory health care facility or other facility under the provisions of Chapters 16 and 27 of the West Virginia Code; and
- (c) Has not received or applied for accreditation as an ambulatory health care facility from the Joint Commission on Accreditation of Hospitals, Group Health Association of America, or other recognized accrediting body; and
- (d) Has not received grants or loans within the past twenty years from the federal or state government or from nonprofit corporations or foundations, within, or without the State, other than grants solely for the purpose of research or for clinical experience for physicians completing residency programs.

4.02. Health Maintenance Organizations. Pursuant to Code §16-2D-4(b)(5), the State Agency shall approve or deny an application for exemption filed with respect to a health maintenance organization under Code §16-2D-4(b)(1) within thirty (30) days of the receipt of the application, or if any additional information is then requested by the State Agency, within fifteen (15) days, approve or deny within thirty

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(30) days of receipt of the additional information. The method of payment for services (that is, prepaid or fee-for-service) is not relevant in determining whether an activity is exempt from review under Code §16-2D-4(b)(1).

4.03. Health Services Not Associated with a Capital Expenditure with Projected Annual Operating Costs of Less than the Expenditure Minimum. The addition of certain health services not associated with a capital expenditure may be exempted from review by the State Agency under the authority of Code §16-2D-4(e). The applicant seeking such an exemption shall complete an expedited application form for a Certificate of Need. After an application for the proposed health service is determined to be complete by the State Agency, the State Agency shall consider if the proposed health service to be delivered is likely to be substantially expanded within the next five years without being subject to Certificate of Need review, and if such expansion is likely, whether such expansion would appear to be consistent with the State Health Plan.

The State Agency may exempt the application from review after the State Agency makes the following written findings:

- (a) The addition of the proposed health service is not associated with any capital expenditure and is projected to entail annual operating costs of less than the expenditure minimum for annual operating costs; and
- (b) The application for the addition of the health service has no obvious inconsistency with the State Health Plan or the findings in CON Reg. §10.03(a) required for the issuance of a Certificate of Need.

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4.04. Major Medical Equipment. The State Agency may consider the following criteria in addition to those provided in Code §16-2D-3(i)(5) under which acquisitions of major medical equipment which will not be owned by or located in a health care facility will not be reviewed if the proposed use of the major medical equipment is to provide services to inpatients of a hospital only on a temporary basis, but only if such following criteria are acceptable to the Federal Secretary of Health and Human Services:

- (a) In the event of temporary emergency circumstances that pose a threat to public health; or
- (b) In those circumstances when inpatients are in imminent danger of death or permanent injury and the proposed major medical equipment could on a temporary basis aid in reducing the danger; or
- (c) In those circumstances where a hospital that has inpatients who will be served on a temporary basis by the proposed major medical equipment has been denied a Certificate of Need for the same or similar major medical equipment as that proposed, and to transport the hospital's inpatients to another location with major medical equipment similar to that proposed would present a greater risk to patients than the risk of providing service by the use of the proposed major medical equipment.

4.05. Acquisitions of Health Care Facilities. Subject to the notice and change in facility provisions of Code §16-2D-4(d), the State Agency may under that subsection exempt from review the obligation of a capital expenditure to acquire, either by purchase or under lease or

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comparable arrangement, an existing health care facility appraised at a fair market value of less than one million dollars (\$1,000,000).

4.06. Progress Reports and Withdrawal of Exemptions. Any health care facility which has received an exemption shall report the progress toward completion of the exempt project to the State Agency not less than forty-five (45) days prior to the anniversary date of the exemption. Failure to report progress or a substantial change in the scope of the project as exempted will be cause for the State Agency to withdraw the exemption or to determine that the change is subject to review.

Any person whose exemption is withdrawn and who wishes to proceed with that project must obtain a Certificate of Need.

Section 5. Access to Information and Facilities.

This regulation supplements Code §16-2D-7(e). The owners, governing boards, operators and staffs of health care facilities and health maintenance organizations covered by these regulations shall provide access to information, records, meetings, sites and facilities pertinent to an application currently under review by the State Agency, to the State Agency upon proper notice and as is reasonable and necessary in the performance of the State Agency's responsibilities in administering the Certificate of Need program.

Section 6. Annual Hospital Rates Form.

This regulation supplements Code §16-2D-8(a)(2). The State Agency shall provide consultation to health system agencies serving health service areas within the state in the development of a form for the annual collection from hospitals of the rates charged for each of the twenty-five (25) most frequently used hospital services in the state, including the average semi-private and private room rates.

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If the health systems agencies collect the completed forms from the hospitals, the hospitals shall send a copy to the State Agency. Enforcement is provided for in CON Reg. §10.01(d) under the authority of Code §16-2D-8(a)(2).

Section 7. Application Required for Certificate of Need.

This regulation supplements Code §§16-2D-5(a), 16-2D-7(d) and (e), and 16-2D-8(a)(1). An Application for a Certificate of Need shall be prepared on the form published by the State Agency and shall be submitted to the State Agency in as many copies as requested. Additional copies may be required by the applicable health systems agency.

7.01. Information Required. The information required on the application form may include:

- (a) Identification of the applicant;
- (b) Copy of the governing body's approval of the proposal and its written authorization empowering specified individual(s) to sign the application and to act on its behalf;
- (c) Description of the project;
- (d) Timetable for implementation of the project, including the projected date(s) for incurring the obligation for any capital expenditure.
- (e) Documented analysis of the need of the population to be served, including the medically underserved, by the project and the extent to which the proposed service will be accessible to that population;
- (f) Policies for patient admission and provision of fully or partially uncompensated care;

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- (g) Documented analysis of alternatives to the proposal considered by the applicant;
- (h) Documented analysis of the proposal's relationship to the existing health care system, to include 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 such training programs;
- (i) Analysis of the relationship of the proposal to the applicant's long range plan on file with the State Agency;
- (j) Documented analysis of the proposal's relationship to the State Health Plan, Proposed State Health Plan, and applicable health systems plan and annual implementation plan;
- (k) Analysis of the extent to which competition allocates services of the type being proposed and promotes quality assurance, cost effectiveness and accessibility;
- (l) 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, and copies of such survey reports, or portions thereof, may be required;
- (m) Documentation of the availability of resources including health care providers, management personnel, and funds for capital and operating needs;

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- (n) Copies of existing or proposed policies with respect to employment of facility staff and, where applicable, admission to medical staff membership;
- (o) Preliminary financial feasibility study including an analysis of historical and projected utilization, charges, source(s) of revenue, statements of revenues and expenses, statement of changes in fund balance, balance sheets, and a statement of the specific assumptions upon which the feasibility study was based;
- (p) Documentation of existing or proposed mechanism(s) for soliciting consumer input into the applicant's decision-making process;
- (q) In the case of construction projects, a documented analysis of the cost and methods of the proposed construction, including provisions for energy conservation, and the probable impact of the proposed construction on the applicant's cost of providing health services;
- (r) If applicable, documented analysis of the needs and circumstances of entities such as health professional schools, multidisciplinary clinics and specialty centers which provide a substantial portion of their services to individuals not residing in the health service area in which they are located or in adjacent health service areas;
- (s) If applicable, documented analysis of the needs and circumstances of health maintenance organizations; and

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- (t) If applicable, documented analysis of the need and circumstances of research projects.

7.02. Application Revisions. The application form may be revised and published periodically, as appropriate.

Section 8. Long Range Plans.

8.01. When Considered. Long range plans shall be considered in Certificate of Need reviews in accordance with Code §16-2D-7(a) and CON Reg. §10.01(c).

8.02. Contents. Each long range plan as defined in Code §16-2D-2(v) shall consist of the overall plan for the health care facility proposing a new institutional health service for at least the following five-year period and shall contain at a minimum:

- (a) A description of the organization, its purpose and structure;
- (b) A statement of the goals and objectives of the organization (e.g. construction, new service development, equipment purchase, sharing/merger arrangements, staff recruitment);
- (c) An analysis of the resources necessary to accomplish the goals and objectives (e.g. manpower, finances);
- (d) The assumptions and rationale which form the basis for the goals and objectives which have been developed (e.g. population, demographic data, health status, morbidity and mortality, area health resources, utilization);
- (e) Documents which support and supplement the long range plan;
- (f) Supplements required by CON Reg. §8.03.

8.03. Supplements. As supplements to the long range plan, each health care facility may be requested by the State Agency to provide the

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following:

- (a) The annual capital expenditure budget, if any, for the health care facility;
- (b) The annual report of the health care facility or its parent corporation;
- (c) If the health care facility or its parent corporation is required to submit an annual Form 10-K with the Securities and Exchange Commission, a copy of such form.

Section 9. Letters of Intent and Pre-Application Conference.

Letters of intent, as provided for in Code §16-2D-7(b), shall contain sufficient information to inform the State Agency of the name and the approximate location, nature, scope, cost and timing of the project. Letters of intent shall be effective for one year. In response to a letter of intent, the State Agency shall forward either a standard or an expedited application form. In addition, the State Agency may arrange a preapplication conference.

Section 10. Review Process.

10.01. Review for Completeness. This subsection supplements Code §16-2D-7(f).

- (a) Declaration of an application as being complete means that sufficient information is in the application for the State Agency to make an informed decision, not that the information in the application warrants an approval of the application.
- (b) An application under review for completeness but with no response from the applicant for a period of one year after the State Agency has asked additional questions shall be consi-

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dered withdrawn, and a new letter of intent and application must be filed if the applicant desires to pursue the project.

- (c) The State Agency shall not, except in emergency circumstances that pose a threat to public health, accept to review for completeness a standard Certificate of Need application unless a long range plan, as defined in Code §16-2D-2(v), conforming to CON Reg. §8, and adopted by the applicant within the preceding four years is on file with the State Agency.
- (d) Under the authority of Code §16-2D-8(a)(2), the State Agency shall not, except in emergency circumstances that pose a threat to public health, accept to review for completeness a Certificate of Need application from a hospital until that hospital has submitted, if requested, to the applicable health systems agency and the State Agency a copy of the annual hospital rates form described in CON Reg. §6.
- (e) The State Agency shall not, except in emergency circumstances that pose a threat to public health, accept to review for completeness a Certificate of Need application from a health care facility subject to the financial disclosure provisions of Code §16-5F-1 et seq. until such facility has filed all reports required therein.

10.02. Review of a Complete Application. This subsection supplements Code §§16-2D-7(c)(1), 16-2D-7(g), (m), (n), (o), and (u).

- (a) Notification of the beginning of the review as provided for in Code §16-2D-7(g) shall be published as a legal notice in the Saturday Charleston Gazette and Charleston Daily Mail, and the

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State Agency's notice of the beginning of the review shall include whether the application is potentially unnecessarily duplicative of other applications.

- (b) To be effective, a request for a public hearing during the review of an application must be in writing and received within thirty (30) days of the date of notification of the beginning of the review as provided in Code §16-2D-7(g). The request shall be addressed to:

Director, Certificate of Need Program
West Virginia Department of Health
1800 Washington Street, East
Charleston, West Virginia 25305

- (c) If a public hearing is held on an application and there are other applications undergoing the same review cycle as such application and one or more of those other applications have been determined under CON Reg. §16.01(e) to be potentially unnecessarily duplicative of such application, then any public hearing held on such application shall also be held as a hearing on such potentially unnecessarily duplicative applications.
- (d) The State Agency may continue a hearing or hold a rehearing on an application.
- (e) If a public hearing is not conducted during the review of an application, the State Agency shall, under the authority of Code §16-2D-7(o), close the review file on the application on the seventy-fifth (75th) day of the review, except in the case

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of an expedited application where the applicable health systems agency has submitted its recommendation to the State Agency in accordance with CON Reg. §11.05, the State Agency shall close the review file five (5) days after receiving the recommendation. If the applicable health systems agency has submitted in writing to the State Agency an indication that it does not intend to submit a recommendation with regard to an application, and a public hearing is not conducted during the review of an application, then the State Agency may close the review file on the application at any time after the thirtieth (30th) day of the review, but no later than as provided above. The State Agency may extend the file closing date in accordance with CON Reg. §14.03. When a review file is closed, the ex parte contact prohibition of Code §16-2D-7(m)(4) attaches.

(f) The schedule set forth in accordance with Code §§16-2D-7(c)(1) and 16-2D-7(m) is that in order for the applicable health systems agency's recommendation with regard to an application to be considered in the State Agency review of the application, such health systems agency shall deliver its recommendation to the State Agency on or before the seventieth (70th) day of a review.

(g) The State Agency may, after publishing legal notice in the Saturday Charleston Gazette and Charleston Daily Mail, and after allowing thirty (30) days for public comment, adopt population projections. Such projections shall be used in Certificate of Need decisions as soon as adopted. In evalu-

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ating health needs and resources for the purpose of a project review, the State Agency shall utilize, where available, data projections for the year five years after the calendar year in which the Certificate of Need decision is made.

10.03. Decision.

(a) Required Written Findings for Approval. This subdivision restates and supplements Code §§16-2D-6(e) and 16-2D-9.

(1) Except as provided in CON Reg. §§10.03(a)(2) and (3), a Certificate of Need may only be issued if:

(A) The State Agency makes written findings that the proposed new institutional health service is:

(i) Found to be needed; and

(ii) Except in emergency circumstances that pose a threat to public health, consistent with the State Health Plan; however, the State Agency may not disapprove an application solely because the proposed new institutional health service is not discussed in the State Health Plan, Proposed State Health Plan, or applicable health systems plan or annual implementation plan.

(B) After consideration of the appropriateness of the use of existing facilities providing services similar to those being proposed, the State Agency makes each of the following findings in writing:

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- (i) That superior alternatives to such services in terms of cost, efficiency and appropriateness do not exist and the development of such alternatives is not practicable;
 - (ii) That existing facilities providing services similar to those proposed are being used in an appropriate and efficient manner;
 - (iii) That 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 practicable;
 - (iv) That patients will experience serious problems in obtaining care of the type proposed in the absence of the proposed new service; and
 - (v) That 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.
- (C) The State Agency makes a written finding, which shall take into account the current accessibility of the facility as a whole, on the extent to which the new institutional health service will meet the

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criteria in Code §§16-2D-6(a)(4), (14), and (25) regarding the needs of medically underserved population, except where the new institutional health service is a proposed capital expenditure not directly related to the provision of health services or to beds or major medical equipment.

- (2) Notwithstanding review criteria in Code §16-2D-6(a)(12) and required findings for approval in CON Reg. §10.03(a)(1), if a health care facility which is controlled, directly or indirectly, by a health maintenance organization applies for a Certificate of Need, such application shall be approved by the State Agency if the State Agency finds that:

(A) Approval of such application is required to meet the needs of the members of the health maintenance organization and of the new members which such organization can reasonably be expected to enroll; and

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

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health professionals associated with it.

- (3) (A) Notwithstanding review criteria in Code §16-2D-6 and required findings for approval in CON Reg. §10.03(a)(1), an application for a Certificate of Need shall be approved, if the State Agency finds that the facility or service with respect to which a capital expenditure is proposed to be made is needed and that the obligation of such capital expenditure is consistent with the State Health Plan, for a capital expenditure which is required:

- (i) To eliminate or prevent imminent safety hazards as defined by federal, state or local fire, building or life safety codes or regulations;
- or
- (ii) To comply with state licensure standards; or
- (iii) To comply with accreditation or certification standards, compliance with which is required to receive reimbursements under Title XVIII of the Social Security Act or payments under the state plan for medical assistance approved under Title XIX of such act.

- (B) An application for a Certificate of Need approved under this subsection shall be approved only to the extent that the capital expenditure is required to eliminate or prevent the hazards described in CON Reg. §10.03(a)(3)(A)(i), or to comply with the stan-

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dards described in either CON Reg.

§§10.03(a)(3)(A)(ii) or (iii).

- (b) Written Finding if the Application Is Disapproved. This subdivision restates Code §16-2D-9(e)(2). If the State Agency disapproves a proposed new institutional health service for failure to meet the needs of medically underserved populations, it shall so state in a written finding.
- (c) Decision Distribution and Notice. This subdivision supplements Code §§16-2D-9(h)(1) and 16-2D-9(k).

The decision and findings shall be sent by certified mail to the applicant and to parties to any hearing held on the application and shall be sent or delivered to the applicable health systems agency and shall be available to other persons upon request (at a cost set out in the fee schedule referred to in CON Reg. §17.).

Notice of the decision shall be published as a legal notice by the State Agency in the Charleston Gazette and the Charleston Daily Mail.

The State Agency shall provide to the applicant any statement provided to the applicable health systems agency under Code §16-2D-9(k) with regard to a State Agency decision which is inconsistent with such health systems agency's recommendation or health systems plan or annual implementation plan.

Section 11. Expedited Application Form.

This regulation supplements Code §16-2D-7(v). The purpose of the

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expedited application form shall be to permit appropriate consideration and response for those projects which would create minimal impact on the scope, quality or costs of health services to be provided by a health care facility. Such projects may include but are not limited to:

- (a) Changes required of a facility or organization in order to comply with applicable building and fire codes and other laws and regulations and standards designed to preserve life and safety; or
- (b) Capital expenditures which do not involve the renovation, replacement or substantial change to the bed capacity or a substantial change to the health services of the facility; or
- (c) The replacement of equipment; or
- (d) Acquisition of health care facilities; or
- (e) Substantial changes (as defined in CON Reg. §21) in an approved new institutional health service for which a Certificate of Need is in effect; or
- (f) New institutional health services proposed to eliminate or alleviate emergency circumstances that pose a threat to public health; or
- (g) Applications from ambulatory health care facilities, home health agencies, ambulatory surgical facilities, and health maintenance organizations;
- (h) Applications from health care facilities for projects that could be undertaken without a Certificate of Need by persons that are not health care facilities; for example, projects for parking buildings and medical office buildings proposed by

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hospitals or the provision of personal care services by intermediate care facilities; or

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

11.01. Request for Expedited Application Form. An applicant may request an expedited application form in the letter of intent. The State Agency will forward an expedited project application form, as appropriate, in response to a letter of intent.

11.02. Determination of Eligibility of an Expedited Application Form for a Project. Meeting any or all of the categories in CON Reg. §11 does not automatically render a project eligible for an expedited application form. This determination is made by the State Agency after consultation with the applicable health systems agency.

If, in the judgment of the State Agency, after an expedited project application form is submitted, the project will require a standard application form, the applicant will be required to complete a standard application form.

Any affected person may present reasons to the State Agency as to why the applicant should be given a standard application form. The reasons shall be submitted in writing to the State Agency within ten (10) days of the date of initiation of the review. If in the opinion of the State Agency there is cause to use the standard application form the review shall be stopped, and, after the standard application form is declared complete, the application shall be included in the next appropriate review cycle.

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11.03. (Deleted)

11.04. Review of an Expedited Application Form. Except as otherwise provided, standard review procedures shall be followed in the review of an expedited application.

11.05. Decision on an Expedited Application. After the period for the request of a public hearing has passed, the State Agency shall issue its decision and findings in writing within ten (10) days after receiving the applicable health systems agency's recommendation; but, if no recommendation is received from the health systems agency within sixty days after the initiation of the review, the State Agency shall, unless CON Reg. §14 is invoked, issue its decision on or before the sixty fifth (65th) day after the initiation of such review. If the applicable health systems agency has submitted in writing to the State Agency an indication that it does not intend to submit a recommendation with regard to an expedited application, then the State Agency may issue its decision on the application after the thirtieth (30th) day of the review, but no later than the sixty-fifth (65th) day of the review, unless CON Reg. §14 is exercised.

Section 12. Additional Information and Amendments to Applications.

(a) If after a review of an application has begun, the applicant submits a substantial amendment to its application, or if the State Agency requests additional information from an applicant under the authority of Code §16-2D-7(i) and the applicant does not provide the information in accordance with that Code section, the State Agency may:

(1) Exercise the review extension provision of CON Reg. §14,

or

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- (2) Put a hold upon the running of the review of an expedited application or upon a standard application in the batching category of CON Reg. §16.01(a)(8), or
 - (3) Withdraw the application from review.
- (b) The extent of the additional information received from an applicant with respect to the impact on the project originally accepted for review may be cause for the State Agency to determine the application to be a new proposal, subject to a new review cycle.

Section 13. Withdrawal of an Application.

Any applicant may withdraw an application at any time during the review process without prejudice. This notice of withdrawal must be made in writing to the State Agency.

Section 14. Holds and Extensions on Review Periods.

This regulation supplements Code §16-2D-7(k).

14.01. Holds. At any time during a review of an expedited application or of a standard application in the batching category of CON Reg. §16.01(a)(8), the State Agency may grant an applicant's request that a hold be put on the running of the review period on its application. The State Agency may not grant a hold on the running of the review period on a standard application in batching categories in CON Reg. §16.01(a)(1) through (7) without the agreement of all applicants with applications in those batching categories in the same review cycle as the application for which the hold is requested.

14.02. Extensions. The State Agency may find it would not be practicable to complete a review on an expedited application within the

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time provided in CON Reg. §11.05, or in the case of a standard application, within ninety (90) days. In such situations the State Agency may extend the review process for up to an additional thirty (30) days, but if the review process is extended for a standard application in the batching categories of CON Reg. §16.01(a)(1) through (7), all standard applications in the same batching category that are in the same review cycle shall be similarly extended. Such situations shall include those in which:

- (a) A project is of such a comprehensive nature that to review it in ninety (90) days would not do justice to the applicant or to the population which the proposed project would serve;
- (b) Additional information related to the review criteria is requested from the applicant in accordance with Code §16-2D-7(i), and it is not provided by the applicant in accordance with that Code section.
- (c) Weather conditions or other natural disasters have prevented the review process from taking place in a timely manner.

14.03. File Closing Date Extensions. If the State Agency puts a hold on the running of a review, or extends the review period on an application, it may extend the file closing date, and if the file closing date has passed when the review is extended or the hold is imposed, the State Agency may reopen the file and reestablish the file closing date.

If a public rehearing is scheduled, or if a file closing date is extended or reestablished, or if a hold or extension is put on a review, all affected persons shall be notified of the reasons.

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Section 15. (Deleted).

Section 16. State Agency to Batch Applications.

Under the authority of Code §16-2D-7(c)(3), all completed applications [except those covered by CON Reg. §16.02] pertaining to similar types of services, facilities, or equipment affecting the same health service area shall be considered in relation to each other.

16.01. Batching Categories.

(a) The State Agency shall consider applications in relation to each other according to the following batching categories:

- (1) Medical-surgical: beds, major medical equipment, or health services associated with a capital expenditure in excess of the expenditure minimum;
- (2) Psychiatric: beds, major medical equipment, or health services associated with a capital expenditure in excess of the expenditure minimum;
- (3) Obstetric: beds, major medical equipment, or health services associated with a capital expenditure in excess of the expenditure minimum;
- (4) Pediatric: beds, major medical equipment, or health services associated with a capital expenditure in excess of the expenditure minimum;
- (5) Skilled nursing: beds, major medical equipment, or health services associated with a capital expenditure in excess of the expenditure minimum;
- (6) Intermediate care: beds, major medical equipment, or health services associated with a capital expenditure in

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excess of the expenditure minimum;

- (7) Proposed new institutional health services that do not fall in batching categories (1) through (6) but which directly relate to: beds, major medical equipment, or health services associated with a capital expenditure in excess of the expenditure minimum.
 - (8) Other proposed new institutional health services.
- (b) If an application is broader in scope than one batching category, the components of the application shall be included in as many batching categories as are appropriate.
- (c) (1) Except for standard applications reviewed under CON Reg. §16.01(c)(2), standard applications shall be reviewed in cycles beginning every four months. On the last working days of the weeks containing the first days of the months of January, May, and September, the State Agency shall collect by the batching categories of CON Reg. §16.01(a) the standard applications determined to be complete since the previous collection. A ninety (90) day review cycle shall then begin on those eight (8) batches of standard applications in accordance with Code §16-2D-7(g) and CON Reg. §10.02.
- (2) Standard applications falling entirely into the batching category of CON Reg. §16.01(a)(8) shall be reviewed in cycles beginning each week. On the last working day of each week, the State Agency shall collect the standard applications determined to be complete during that week that fall entirely into the batching category of CON Reg.

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§16.01(a)(8). A ninety (90) day review cycle shall begin each week on such standard applications in accordance with Code §16-2D-7(g) and CON Reg. §10.02.

(d) Expedited applications shall be reviewed in cycles beginning each week. On the last working day of each week, the State Agency shall collect by the batching categories of CON Reg. §16.01(a) the expedited applications determined to be complete during that week. Reviews shall begin each week on those eight (8) batches of expedited applications in accordance with Code §16-2D-7(g) and CON Reg. §10.02.

(e) In considering applications in relation to each other, the State Agency shall consider the extent to which proposed new institutional health services within each batching category that are in the same review cycle are potentially unnecessarily duplicative of each other, and where the potential for such unnecessary duplication exists, the State Agency shall conduct its review of such applications so as to compare the potentially unnecessary duplicative portions of the applications, and if one or more of the applicants are granted a Certificate of Need, the comparative analysis shall be included in the decision or decisions. The determination that applications are potentially unnecessarily duplicative shall be made before the review cycle begins.

16.02. Applications Exempt from Batching. The State Agency shall review independently from other applications any application for a new institutional health service that is proposed solely to eliminate or

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prevent the imminent safety hazards described in Code §16-2D-9(g)(1)(A) or to comply with the licensure, accreditation or certification standards described in Code §§16-2D-9(g)(1)(B) and (C). Reviews on such completed applications shall begin weekly in accordance with Code §16-2D-7(g) and CON Reg. §10.02.

Section 17. Public Access to Information.

The public shall have access to State Agency files in accordance with Code §16-2D-7(s) and the West Virginia Freedom of Information Act, Code §29B-1-1 et seq. The State Agency shall provide copies of materials at a cost of twenty-five cents (25¢) per page copied.

Section 18. Review Criteria.

This regulation supplements Code §§16-2D-5(d) and (e), and 16-2D-6.

18.01. Health Systems Plans and Annual Implementation Plans. In considering, under Code §16-2D-6(a)(2), the relationship of the health services being reviewed to the applicable health systems plan and annual implementation plan, the State Agency shall only consider such relationship to such plans, or portions thereof, that have been delivered to the State Agency by the applicable health systems agency with a written verification that such plans are a true and accurate copy of the plans as adopted by the applicable health systems agency. All application reviews that begin after the receipt of such verified health systems plan and annual implementation plan shall be reviewed in relation to such plans.

A Certificate of Need shall not be denied on the basis of a provision in the applicable health systems plan or annual implementation plan if such provision is in conflict with the Proposed State Health Plan,

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the State Health Plan, these regulations, or the Code.

18.02. Proposed State Health Plan. The State Agency shall, in making its determination as to whether Certificates of Need shall be issued, consider as review criteria supplementing those criteria in Code §16-2D-6(a), the applicable provisions of the Proposed State Health Plan, except any provisions of the Proposed State Health Plan in conflict with the State Health Plan, these regulations, or the Code shall not be considered in determining whether a Certificate of Need shall be issued. The State Agency shall consider the Proposed State Health Plan in the application reviews that begin after its adoption by the State-wide Health Coordinating Council.

18.03. State Health Plan. When the Governor approves a State Health Plan, the State Agency shall use that Plan in the application reviews that begin after such approval.

18.04. Relative Weight of Review Criteria in a Competitive Market. Where the State Agency determines that a substantially competitive market exists or may occur for a health service, the State Agency may, in its review of applications regarding such health service, give minimal consideration to the following review criteria that tend to compensate for the absence of market controls in a noncompetitive market; namely, the criteria in Code §§16-2D-6(a)(3), (5), (6), (7), (8), (10), (15), (21), (22), and (26).

18.05. Competitive Effects. The State Agency shall, as part of its consideration of whether the written findings in CON Reg. §10.03(a) should be made with respect to an application, give significant consideration to the review criteria regarding competition in Code

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§§16-2D-6(a)(19) and (20). As a part of such consideration, the State Agency may, particularly where supply of a health service is, or upon approval of the application would be, within an acceptable range of supply for that service, give significant consideration as to whether the applicant has suitably demonstrated that approval of the application will, through the implementation of improvements or innovations in financing, reimbursement, service delivery arrangements or through other means, strengthen the effect of competition on such service by creating incentives for the market to respond to quality of service delivered, prices charged, or by placing the applicant at greater financial risk. For example, depending upon the circumstances, such innovations might include pre-payment provider contracts with potential patients for the delivery of the service, arrangements for more reliance upon private payment for service where appropriate, or provider-insurer risk contracts with clear limits on prices or such contracts with effective utilization controls.

18.06. Use and Development of Standards. The State Agency may utilize and develop standards relating to the review criteria in the Code and these regulations. If a local or statewide standard is not available the State Agency may use nationally or commonly accepted standards, which the State Agency finds relevant and appropriate.

Section 19. Progress Reports and Extension of the Duration of a Certificate of Need.

This regulation supplements Code §16-2D-11(a).

(a) The State Agency shall require the person holding the Certificate to submit in writing to the State Agency, with a copy

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to the applicable health systems agency, a report on the progress being made toward completion of the project according to the timetable in the application. Such report shall be submitted not less than forty-five (45) days prior to the expiration of the Certificate of Need and shall include:

- (1) The current status of the project in relation to the timetable in the application;
 - (2) The projected date of completion;
 - (3) The causes of any delays encountered;
 - (4) Changes in the project, including any proposed changes for which a request is made for the State Agency to determine whether the proposed change is reviewable as a substantial change under CON Reg. §21.
 - (5) The projected total project cost; and
 - (6) Compliance with any conditions of certification.
- (b) The person holding the Certificate shall submit any relevant additional information whenever requested by the State Agency.
- (c) Creation of shelled in space shall not be considered completion unless explicitly provided for in the decision.
- (d) New conditions, unrelated to representations made by the applicant, may not be added to the project at the time of recertification.
- (e) In addition to reasons given in Code §16-2D-11(b), the Certificate may be withdrawn by the State Agency in accordance with Code §16-2D-11(b) for failure to submit a complete and timely progress report.

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- (f) The obligation for any capital expenditure associated with a project shall be incurred, as described in Code §16-2D-3(c), within twelve (12) months after the Certificate of Need is issued, except in the case of an application where the State Agency has approved a timetable submitted under Code §16-2D-7(d) for the obligation of a series of obligations for capital expenditures for discrete components to be incurred over a period longer than one year, the obligation for the first component shall be incurred within twelve (12) months after the Certificate of Need is issued. The twelve (12) month period for the incurring of an obligation required by this subsection may, pursuant to a showing of good cause by the applicant, be extended by the State Agency for up to an additional six (6) months, but if any obligation that is required to be incurred by this subsection has not been incurred within eighteen (18) months of issuance of the Certificate of Need, the Certificate of Need shall expire at the end of said eighteen (18) months.
- (g) If a renewal review is underway but is not complete at the end of a certification period, the old Certificate shall automatically be extended until the renewal review is complete.
- (h) Failure to request renewal of a Certificate of Need prior to its expiration without a showing of good cause will result in the automatic expiration of the Certificate.

Section 20. Notice of Substantial Compliance.

This regulation supplements Code §16-2D-11(a). All new institu-

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tional health services shall receive a substantial compliance review by the State Agency. No later than forty-five (45) days prior to licensure or undertaking of the activity for which the Certificate of Need was issued, the applicant shall request in writing a substantial compliance review by the State Agency. A copy of the request shall be sent to the applicable health systems agency.

The State Agency shall issue findings as to substantial compliance within forty-five (45) days of the receipt of the request for a substantial compliance review. The State Agency shall consider the recommendation of the applicable health systems agency. If the State Agency finds that a project is not in substantial compliance with its Certificate of Need, the State Agency may withdraw the Certificate of Need under Code §16-2D-11(b) and may direct revocation or denial of a license to operate the facility or seek a fine or injunction against the use or operation of the facility under Code §§16-2D-12 or 13.

Where the State Agency finds that it would be impractical for the applicant to prepare final cost figures for the project prior to the time the project is ready for licensure or the undertaking of the activity for which the Certificate of Need was issued, the State Agency's notice of substantial compliance authorizing licensure or undertaking of the activity may be made conditional for up to one year within which time the applicant must provide documented final cost figures to the State Agency. The Certificate of Need shall remain in effect until such condition is removed, and upon failure of an applicant to provide such final cost figures within the period allowed, the State Agency may withdraw the Certificate of Need under Code §16-2D-11(b) and bring

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enforcement actions under Code §§16-2D-12 and 13.

Section 21. Project Changes While a Certificate of Need Is in Effect.

This regulation supplements Code §16-2D-11.

21.01. Prima Facie Evidence of a Substantial Change. In making its determination under Code §§16-2D-3(j), 16-2D-9(j), and 16-2D-11(b)(1)(C) whether changes proposed in an approved project for which a Certificate Need is in effect are substantial, the State Agency shall consider the following as prima facie evidence of a substantial change:

- (a) Change in location reducing accessibility of patients who otherwise have no alternative to such services reasonably available or a change in location to a county that was not significantly impacted by the proposal when it was originally approved;
- (b) Addition in number or change in type of beds;
- (c) Acquisition of major medical equipment not described in the application as part of the project;
- (d) Addition of health services;
- (e) Increase or decrease in square footage in excess of ten (10) percent, or one thousand (1,000) square feet, whichever is greater;
- (f) An unapproved capital expenditure, or an increase in the approved capital expenditure in excess of the expenditure minimum or in excess of twenty (20) percent, whichever is greater.

21.02. Consequences of a Substantial Change Without a Certificate

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of Need. Failure to inform the State Agency of a proposed substantial project change may result in withdrawal of the Certificate of Need by the State Agency in accordance with Code §16-2D-11(b).

No proposed substantial project change shall be initiated by an applicant until a determination of the need for review has been made by the State Agency. The State Agency shall issue a decision as to whether or not a new Certificate of Need review is required within fifteen (15) days of the receipt of the request or if any additional information is then requested by the State Agency, within fifteen (15) days of receipt of the additional information. Substantial changes made without a Certificate of Need therefor may be grounds for imposing the penalties referenced in CON Reg. §20 or may require the submission of a new application for the changes.

Section 22. Transferability.

This section supplements Code §16-2D-11(a). A finding by the State Agency that a transfer of a Certificate of Need has occurred will result in its withdrawal pursuant to Code §16-2D-11(b).

Section 23. (Deleted).

Section 24. Reconsideration of a Final Decision of the State Agency by the State Agency.

This regulation supplements Code §16-2D-7(t).

24.01. Request for Reconsideration Hearing. A request for a reconsideration hearing shall be addressed to:

Director, State Health Planning and Development Agency
West Virginia Department of Health
1800 Washington Street, East
Charleston, West Virginia 25305

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A request for a reconsideration hearing that does not show good cause within the meaning of Code §16-2D-7(t)(1) shall be denied.

Section 25. Review Hearing of Any Final Decision of the State Agency by the State Review Agency Designated by the Governor.

This regulation supplements Code §16-2D-10.

25.01. Request for Review Agency Hearing. A request for a Review Agency hearing shall be in writing and shall state the basis upon which the hearing is requested. The request shall be addressed or delivered to:

Chief Hearing Examiner
Office of Hearings and Appeals
West Virginia State Tax Department
1217 Quarrier Street
Post Office Box 2389
Charleston, West Virginia 25328

25.02. Stay of Review Agency Time Periods. The timely submission to the State Agency of a request for reconsideration under CON Reg. §24 shall stay the operation of all Review Agency time periods until the State Agency has denied the request or issued a reconsideration decision.

25.03 and 25.04. (Deleted).

25.05. Designation of Review Agency Hearing Officers. No person who has taken part in any State Agency or applicable health systems agency consideration or action upon the application may conduct a hearing pursuant to these regulations.

25.06. (Deleted).

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25.07. How Review Agency Hearings Conducted. Pending the decision of the Review Agency, the State Agency or the Hearing Officer may delay the effect of the State Agency Decision.

The person requesting the hearing, as part of the request, shall include an assignment of the errors of law or procedure.

Failure of the person requesting the hearing to appear at the date, time and place of hearing shall, without a showing of good cause, result in a dismissal of the proceeding.

The Review Agency may continue a hearing or hold a rehearing on an application. If no applicant appellant objects, the Review Agency may grant a request for a general continuance of an appeal, but if no applicant appellant seeks to pursue its appeal within one year of the grant of a continuance, the appeal shall be considered as withdrawn with prejudice.

25.08. (Deleted).

25.09. Form of Decision. Where the hearing officer remands the matter to the State Agency, the hearing officer may specify a date by which further action shall be completed by the State Agency. The decision shall state if any findings of the State Agency are reversed or revised.

25.10. Review Agency Regulations and Procedures. The Review Agency may adopt regulations and procedures for the conduct of reviews of State Agency decisions, except the Review Agency's regulations and procedures shall not be inconsistent with the Code, these regulations, or Title XV of the Public Health Service Act, as amended, Title 42 United States Code §300k et seq., and implementing regulations therefor,

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Title 42 Code of Federal Regulations Part 123.

Section 26. Applicability.

An application review begun prior to the effective date of these amended regulations shall not be subject to the provisions of these amended regulations that are not contained in Code §16-2D-1 et seq., except by request of the applicant.

Section 27. Severability.

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

Section 28. Construction.

Where Code §16-2D-1 et seq. or these regulations are silent or where they are ambiguous, but where they are not clearly inconsistent with other provisions of the Code, they should be construed so as to be consistent with Title XV of the Public Health Service Act, as amended, Title 42 United States Code §300k-1 et seq., and implementing regulations, Title 42 Code of Federal Regulations Part 123.

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