

John D. Rockefeller IV
Governor



L. Clark Hansbarger, M.D.
Director

State of West Virginia

DEPARTMENT OF HEALTH

CHARLESTON 25305

NOTICE OF PUBLIC HEARING

Pursuant to Section five, Article three, Chapter twenty-nine-A of the Code of West Virginia, one thousand nine hundred thirty-one, as amended, the Regulatory Services Program of the West Virginia Department of Health shall convene a public hearing at 10:00 A.M. on Friday, January 8, 1982 in Conference Room D, Building 7, 1900 Washington Street, East, Charleston, West Virginia 25305, for the purpose of taking evidence pertaining to the filing of proposed Regulations for Certificate of Need, Chapter 16, Article 2D, Series I (1981).

Any citizen or other interested party may appear in person to present evidence. Any citizen or other interested party may submit written evidence to the West Virginia Department of Health, Regulatory Services Program, Room 416, 1800 Washington Street, East, Charleston, West Virginia 25305, not later than 5:00 P.M., Friday, January 8, 1982.

The issues to be heard shall be limited to the actual information contained in the proposed and above mentioned regulations. Copies of the proposed regulations may be obtained from the Regulatory Services Program, address heretofore appearing or by telephoning 304-348-2411.

FILED IN THE OFFICE OF
A. JAMES MANCHIN
SECRETARY OF STATE

THIS DATE 12-2-81
Administrative Law Division

L. Clark Hansbarger, M.D.
Director

Entered

December 2, 1981

FILED IN THE OFFICE OF
A. JAMES MANCHIN
SECRETARY OF STATE

THIS DATE 12-2-81
Administrative Law Division

West Virginia Administrative Regulations
Department of Health
Office of Health Planning and Evaluation
State Health Planning and Development Agency
Chapter 16-2D
Series I
(1981) amended

Subject: Certificate of Need

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WEST VIRGINIA ADMINISTRATIVE REGULATIONS
DEPARTMENT OF HEALTH
OFFICE OF HEALTH PLANNING AND EVALUATION
STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

CHAPTER 16 ARTICLE 2D
SERIES I
(1981) amended

~~Subject: Clarification of Provisions of the West Virginia Certificate of Need Law (the Code of West Virginia (1931) as Amended, Chapter 16, Article 2D, Sections 1-13.) and procedures for administration of the Certificate of Need. Law.~~

CON Reg. 1. GENERAL.

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

§1.02 AUTHORITY. These regulations are issued under the authority of Article 2D, Chapter 16 of the West Virginia Code of 1931, as amended.

§1.03. EFFECTIVE DATE. ~~November 6, 1980.~~ These regulations become effective on the day of , 1981.

§1.04. FILING DATE. These amended regulations are promulgated on the _____ day of _____, 1981, and were filed in the Office of the Secretary of State on ~~July 11, 1980~~, the _____ day of _____, 1981.

~~§1.05. FORWARD. The health care needs of West Virginians are extensive and demand the development of new health services in the State. This development will require the use of vast financial resources and manpower. Since these resources are limited, the State must take steps to insure that they are used effectively.~~

~~The Certificate of Need program can serve as a tool to help insure that health service development in the state takes place in a rational way and that the public in West Virginia has a voice in this development. The goal is the development of an effective and efficient health care system which is accessible to the residents of the State. This will mean, at times, that difficult and unpleasant decisions will have to be made when development proposed by individuals or institutions is not in accord with this goal. The Certificate of Need legislation provides the tools to make these decisions and brings into that decision making process all persons affected by such decisions. Because the process involves the public as well as State Government, it will require the commitment of both health care providers and the consumer public in making rational and necessary decisions.~~

CON Reg. 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.

~~§2.01. --The term "ambulatory health care facility" means a facility, which is free-standing and not physically attached to a health care facility, and which provides health care to noninstitutionalized and nonhomebound persons on an outpatient basis. --This definition does not include the legally authorized practice of medicine by any one or more persons in the private offices of any health care providers.~~

~~In determining that a health care provider is an ambulatory care facility and not a private office or private clinic of a physician, dentist or other practitioner of the healing arts, the State Agency shall consider the following:~~

- ~~1) --The facility is organized as a not-for-profit corporation rather than as a professional corporation under Chapter 30 of the code.~~
- ~~2) --Whether the provision of care is financed and operated or administered by or on behalf of a public entity, governmental entity or hospital. --The term "financed" shall not include acceptance of payment of patients' accounts by Medicare, Medicaid, or other state or federal agencies.~~
- ~~3) --Whether the facility is accredited or has applied for accreditation with the Joint Commission on Accreditation of Hospitals, Group Health Association of America or other recognized accrediting body as an ambulatory health care facility.~~

~~4)---Whether the facility is licensed or required to be licensed as an ambulatory health care facility by the State of West Virginia.~~

~~§2.02.---The term "applicant" means the owner/operator or legally constituted governing body responsible for the operation of an existing or proposed health care facility or health maintenance organization.---In the case of a proposed health care facility or health maintenance organization, incorporators or promoters who will not be the actual owner/operator or legally constituted governing body of the facility or organization once it is operational shall not be the applicant.~~

~~§2.03.---The term "capital expenditure" means an expenditure in excess of \$150,000 including a force account expenditure, which under generally accepted accounting principles consistently applied is a capital expenditure.---It includes but it is not limited to site acquisitions, transfers or ownership, purchase of equipment, modernization, renovation and new construction.---Any acquisitions by or on behalf of a health care facility or health maintenance organization under lease or comparable arrangement, or through donation, which would have required review had the acquisition been by purchase are also included.~~

§2.04. §2.02. The term "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 Chapter 16, Article 2D of the Code §16-2D-1 et seq. of West Virginia (1931), as amended, and that a need exists for the proposed new institutional health service.

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

§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(n)
and (t) and 16-2D-10(c) means the date when evidence and oral arguments have
presented and all 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 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).

~~§2.05. The term "Construction" means the erection, building, replacement, alteration, modernization, improvement, renovation, or modification of a health care facility or health maintenance organization.~~

~~§2.06. The term "institutional health services," except as used in CON Reg. §3 means health services provided in or through health care facilities or health maintenance organizations and, except as otherwise specified in these regulations, the term shall include the entities in or through which such services are provided.~~

~~§2.07. The term "total bed capacity" means the total number of beds within the facility, whether licensed or unlicensed.~~

~~§2.08. The term "existing bed complement" means the number of adult and pediatric beds permanently maintained for lodging in patients in a health care facility. For purposes of this definition "permanently maintained" means that the beds must be immediately available for use by patients and housed in patient rooms or wards (i.e., not in corridors or as temporary bed) and is not limited to the licensed beds of the health care facility.~~

§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, 1980 in the U.S. Department of Commerce Composite Construction Cost Index, means \$164,400.00.

§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, 1980 in the U.S. Department of Commerce Composite Construction Cost Index, means \$82,200.00.

§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(a). "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).

(b) 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).

§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 Mental Health/Mental Retardation Facilities of West Virginia;
- (b) Professional Nursing Home Association of West Virginia;
- (c) West Virginia Commission on Aging;
- (d) West Virginia Council of Home Health Agencies;
- (e) West Virginia Dental Association;
- (f) West Virginia Department of Health;
- (g) West Virginia Department of Welfare;
- (h) West Virginia Division of Vocational Rehabilitation;
- (i) West Virginia Health Care Association;
- (j) West Virginia Hospital Association;
- (k) West Virginia Nurses Association;
- (l) West Virginia Pharmacy Association;
- (m) West Virginia Primary Care Study Group;
- (n) West Virginia Society of Osteopathic Medicine;
- (o) West Virginia State Medical Association.

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

§2.15. "Potentially unnecessarily duplicative" applications means applications that are in the same review cycle and such applications 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.

~~§2.09.~~ §2.19. The term ~~"conversion of beds"~~ "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.), ~~including changes from nursing beds licensed for patients requiring skilled nursing care to nursing beds licensed for patients requiring intermediate nursing care and vice versa.~~

~~§2.10.~~ The term ~~"transfer of ownership"~~ means an acquisition of assets of a corporation, partnership or individually owned health care facility by a newly formed or an existing corporation, partnership or by an individual sufficient to effect control.

~~§2.11.~~ The term ~~"Health Systems Agency"~~ means the nonprofit private organization organized and operated as required by the National Health Planning and Resources Development Act of 1974, as amended.

~~§2.12.~~ The term ~~"State Agency"~~ means the State Health Planning and Development Agency designated by the governor to administer an Administrative program and carry out health planning and development functions prescribed by the National Health Planning and Development Act of 1974, as amended.

~~§2.13.~~ The term ~~"Hospital"~~ means an institution which is primarily engaged in providing to inpatients, by or under the supervision of physicians, diagnostic and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons excluding services provided in psychiatric and tuberculosis hospitals.

§2.14.---The term "tuberculosis hospital" means an institution which is primarily engaged in providing to inpatients, by or under the supervision of a physician, medical services for the diagnosis and treatment of tuberculosis.

§2.15.---The term "psychiatric hospital" means an institution which is primarily engaged in providing to inpatients, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of mentally ill persons.

§2.16.---The term "health care facility" includes hospitals, psychiatric hospitals, tuberculosis hospitals, skilled nursing facilities, kidney disease treatment centers, including freestanding hemodialysis units, intermediate care facilities, ambulatory health care facilities, ambulatory surgical facilities, home health agencies and community mental health and mental retardation facilities; whether under public or private ownership, or as a profit or nonprofit organization and whether or not licensed or required to be licensed in whole or in part by the state.

§2.17.---The term "affected person" includes the person whose proposal is being reviewed, the health systems agency for the health service area in which the proposed new institutional health service is to be offered or developed, contiguous health systems agencies in adjacent states, health care facilities and health maintenance organizations located in the health service area which provide institutional health services, any agency which establishes rates for health care facilities or health maintenance organizations in the state, those members of the public who are to be served by the proposed new institutional health services, and all hospital service corporations and medical service

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~~corporations-as-defined-in-article-twenty-four,-chapter-thirty-three-of
the-West-Virginia-Code-~~

~~§2-18.--The-term-"person-directly-affected-by-the-review"-includes,
the-person-whose-proposal-is-being-reviewed,-members-of-the-public-who
are-to-be-served-by-the-proposed-new-institutional-health-services;
health-care-facilities-and-health-maintenance-organizations-located-in
the-health-service-area-in-which-the-service-is-proposed-to-be-offered
or-developed-which-provide-services-similar-to-the-proposed-services
under-review;-any-agency-which-establishes-rates-for-health-care-facil-
ities-or-health-maintenance-organizations-in-the-state;-and-health-care
facilities-and-health-maintenance-organizations-which,-prior-to-receipt
by-the-state-agency-of-the-proposal-being-reviewed,-have-formally-indi-
cated-an-intention-to-provide-such-similar-services-in-the-future,
either-through-the-filing-of-a-letter-of-intent-or-by-adoption-of-a
plan-~~

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§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.

CON Reg. 3. SCOPE OF CERTIFICATE OF NEED COVERAGE. ~~These regulations cover the offering or development of any new institutional health service within this state. For purposes of this section, "New institutional health service" shall include:~~

- ~~1) The construction, development, or other establishment of a new health care facility or health maintenance organization;~~
- ~~2) The partial or total closure or relocation of a health care facility or health maintenance organization;~~
- ~~3) Any expenditure by or on behalf of a health care facility, health care provider except as exempted in CON Reg. §4 or health maintenance organization, in excess of one hundred fifty thousand dollars (\$150,000) which, under generally accepted accounting principles consistently applied, is a capital expenditure; where a person makes an acquisition by or on behalf of a health care facility, health care provider except as exempted in CON Reg. §4 or health maintenance organization under lease or comparable arrangement, or through donation, which would have required review if the acquisition had been by purchase such acquisition shall be deemed an expenditure subject to review. A series of capital expenditures, each less than one hundred fifty thousand dollars, which when taken together are in excess of one hundred fifty thousand dollars, may be determined by the State Agency to be a single capital expenditure subject~~

~~to review. In making its determination under this~~

~~Section, the State Agency shall consider:~~

~~a) if the expenditures are for components of a system~~

~~which is required to accomplish a single purpose;~~

~~b) if 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;~~

~~c) if the expenditures are to be made within a two~~

~~year period within a single department such that~~

~~they will constitute a significant modernization of~~

~~the department;~~

~~4) A change in the existing bed complement of a health care~~

~~facility or health maintenance organization within a~~

~~two-year period through:~~

~~a) the addition or conversion of ten (10) or more beds~~

~~or more than ten percent (10%) of the total bed~~

~~capacity of such facility or organization, which~~

~~ever is less; or~~

~~b) the relocation of ten (10) or more beds or more~~

~~than ten percent (10%) of the total bed capacity of~~

~~such facility or organization, whichever is less;~~

~~from one physical facility or site to another.~~

~~A series of additions, conversions or relocations of~~

~~beds, each less than ten (10) beds or ten percent (10%)~~

~~of the total bed capacity of such facility or organiza-~~

~~tion, but which when taken together comprise ten (10) or~~

~~more beds or more than ten percent (10%) of the total bed capacity of such facility or organization, whichever is less, may be determined by the State Agency to be a single change subject to review;~~

~~5) Health services which are offered in or through a health care facility or health maintenance organization and which were not offered on a regular basis in or through such health care facility or health maintenance organization within the twelve (12) month period prior to the time such services would be offered;~~

~~6) The deletion of one or more health services, previously offered on a regular basis by a health care facility or health maintenance organization or the relocation of one or more health services from one physical facility or site to another;~~

~~7) Expenditures in excess of one hundred fifty thousand dollars (\$150,000) in preparation for the offering or development of a new institutional health service and arrangement or commitment for financing the offering or development of the new institutional health services. Expenditures in preparation for the offering or development of a proposal for a new institutional health service shall include only expenditures for surveys, studies, designs, plans, working drawings, specifications, site acquisition, commitment, or development, access road development or improvement, and the financial participation in the planning or construction of utility or sewer~~

~~service lines to the site, but may not include expenditures for feasibility surveys for health maintenance organizations which are funded under section 1303 of the Public Health Service Act or expenditures for planning of health maintenance organizations which are funded under section 1304 of that Act.~~

~~8) Radiological diagnostic health services through, by or on behalf of a health care facility or health maintenance organization (including services offered in space leased or made available to any person by the health care facility or health maintenance organization), which are provided by fixed or mobile computed tomographic (CT) scanning equipment, except where these services are an addition to or replacement of the same service offered in, at, through, by, or on behalf of the health care facility or health maintenance organization and do not involve a capital expenditure in excess of one hundred fifty thousand dollars (\$150,000). For purposes of this subparagraph, a CT head scanner and a CT body scanner do not provide the same service, and a CT fixed scanner and a CT mobile scanner do not provide the same service.~~

§3.01. This subsection supplements Code §16-2D-3. If any major medical equipment 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 issued before such equipment is so used, unless the use is one described in Code §16-2D-3(i)(5) or CON Reg. §4.04.

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§3.02. 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 and may, after considering the anticompetitive impact in consultation with the Attorney General, permit implementation through the Certificate of Need process of a plan of action with cooperating health care facilities for the merger, or sharing of resources, of such health care facilities.

CON Reg. §4. EXEMPTIONS. ~~The following health care providers are exempt from coverage of the Certificate of Need program.~~ This regulation supplements Code §§16-2D-3 and 4.

§4.01. 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)~~ A private office or private clinic of a physician, dentist, or other practitioner of the healing arts means any facility which:

~~1)~~(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

~~2)~~(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; ~~or is not an ambulatory care facility as defined by the State Agency pursuant to these regulations;~~ and

~~3)~~(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

~~4)~~(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.

~~b)---A private office or private clinic does not include any space under lease or other arrangement from a health care facility or health maintenance organization for use by a physician, dentist, or other practitioner of the healing arts or group of same, where such space is within the confines of a health care facility or health maintenance organization for provision of services traditionally falling within the context of ancillary services offered by that health care facility or health maintenance organization.~~

~~§4.02.--Dispensaries-and-first-aid-stations-located-within-business-
or-industrial-establishments-maintained-solely-for-the-use-of-employees;
provided,-that-such-facility-does-not-contain-inpatient-or-resident-beds
for-patients-or-employees-who-generally-remain-in-the-facility-for-more
than-twenty-four-hours;~~

§4.02. 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 infor-
mation is then requested by the State Agency, within fifteen days (15),
approve or deny within thirty (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.---Establishments, such as motels, hotels and boarding houses which provide medical, nursing personnel and health-related services;~~

§4.03. 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.

~~§4.04.--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;~~

§4.04. The State Agency may consider the following circumstances 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; provided, that such additional circumstances are acceptable to the Federal Secretary of Health and Human Services:

- (1) In the event of temporary emergency circumstances that pose a threat to public health; or
- (2) 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
- (3) 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. Health care facilities or health maintenance organizations which on the effective date (July 8, 1977) of Article 2D, Chapter 16 of the West Virginia Code were committed to a formal plan of development or expansion of new institutional health services, where preliminary expenditures toward that formal plan of development or expansion of one hundred fifty thousand dollars or more were made during the three-year period preceding the effective date of the Article, or which prior to the effective date of Article 2D, Chapter 16 of the West Virginia Code received approval of a formal plan of development or expansion from the State comprehensive health planning agency (heretofore created by executive order of the governor of West Virginia):~~

- ~~a) The determination of whether a health care facility or health maintenance organization is exempt under GON Reg. §4.05 and the extent to which such exemption shall apply, shall be made by the State Agency, based upon satisfactory evidence and documentation submitted to the State Agency by health care providers, health care facilities or health maintenance organizations requesting an exemption.~~
- ~~b) All requests for an exemption because of a formal plan of development or prior approval of a plan by the State comprehensive health planning agency shall be submitted in writing to the State Agency no later than (30) days from the effective date of these regulations. The decision as to whether or not an exemption shall be granted shall be made within sixty (60) days of the receipt by the State Agency of the request and any supporting materials~~

~~requested by the State Agency.~~

e) ~~An exemption granted under Chapter 16, Article 2D or
GON-Reg. §4.05-(b) above shall be valid for one year from the
date it is issued.~~

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

§4.06. Any health care facility ~~or health maintenance organization~~ which has received ~~such~~ an exemption shall report the progress toward completion of the exempt ~~development or expansion~~ project to the State Agency ~~and request a renewal not more than ninety (90) nor less than~~ forty-five (45) days prior to the ~~expiration~~ anniversary date of the exemption. Failure to report progress ~~and/or failure to demonstrate that sufficient progress is being made toward completion of the~~ ~~exempt development~~ or a substantial change in the scope of the project as ~~approved~~ exempted ~~may will~~ be cause for the State Agency to ~~revoke~~ withdraw the exemption or to determine that the change is subject to review. ~~Abandonment of a project which has been granted an exemption or any substantial change in the plan shall be cause for revocation of the exemption.~~

~~d) Health care facilities and health maintenance organizations are required to have an exemption, whether original or renewed, until completion of the project. Exemptions may be renewed by the State Agency for additional periods of one year or less in order to expeditiously complete the project. Shelled in space is not considered completion unless explicitly provided for in the exemption decision.~~

e) Any person ~~or entity~~ whose exemption is ~~revoked~~ withdrawn and who wishes to proceed with ~~any development or expansion~~ that project must obtain a Certificate of Need, ~~in accordance with these regulations.~~

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CON Reg. §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.

~~CON Reg. §6. DELEGATION OF RESPONSIBILITY AND USE OF OTHER AGENCIES AND ORGANIZATIONS. The State Agency may seek the advice and assistance of other persons, agencies and organizations including the designated Health Systems Agency in the performance of the State Agency's responsibilities under the Certificate of Need program.~~

CON Reg. §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.

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).

CON Reg. §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 ~~standard~~ form published by the State Agency. Three copies and shall be submitted to the State Agency in as many copies as requested. Additional copies may be required by the designated applicable health systems agency. ~~for the area in which the proposed new institutional health service is located.~~

~~In the case of a proposed health care facility or health maintenance organization, incorporators or promoters who will not be the actual owner/operator or legally constituted governing body of the facility or organization once it is operational, shall not be the applicant.~~ One or more persons shall be officially authorized in writing by the governing body to sign for and act for the applicant during the review. ~~Where the operator is different from the owner the operator's name shall also be given on the application form.~~

§7.01. The information required on the application form shall include:

- a. ~~Identification of the applicant;~~
- b. ~~Description of the project;~~
- c. ~~The consistency of the project with the appropriate health systems plan and annual implementation plan and state health plan;~~
- d. ~~The relationship of the project to the applicant's current long range plan on file with the State Agency;~~
- e. ~~The need of the population to be served for the project;~~
- f. ~~A documented study and analysis of less costly or more effective alternatives to the project were considered by the applicant;~~
- g. ~~A documented study and analysis of the availability of resources, including staffing and funding;~~
- h. ~~The relationship of the project to support services;~~
- i. ~~A documented study and analysis of how the project will promote cost containment, including energy conservation;~~
- j. ~~A financial feasibility study;~~
- k. ~~In the case of research projects, health maintenance organizations, any new institutional health service proposed to be provided by or through an health maintenance organization, or projects serving persons outside the project's service area and/or the health service area, documentation of any special needs and circumstances;~~

- ~~l.---A-timetable-for-completion-of-the-project;~~
- ~~m.---Policies-for-patient-admission-and-medical-staff
membership;~~
- ~~n.---Any-endorsements-of-the-project-from-individuals-or
organizations-in-the-community.~~
- ~~o.---A-documented-study-and-analysis-of-the-need-of-medically
underserved-groups-in-the-service-area-for-the-type-of
new-institutional-health-service-proposed-and-an-explana-
tion-as-to-how-the-proposed-new-institutional-health
service-will-contribute-toward-meeting-that-need-and-in
meeting--the-needs--of--medically-underserved--groups
identified-in-the-applicable-health-systems-plan-and
annual-implementation-plan-as-deserving-of-priority.~~

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- (a) Identification of the applicant;
- (b) Copy of the governing body's resolution approving the proposal and the related capital expenditure 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;
- (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 applicable health systems plan and the State Health 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: (1) the State Department of Health; and, (2) accreditation organizations and other federal, State, and local inspection agencies, and copies of such survey reports shall be provided;
- (m) Documentation of the availability of resources including health care providers, management personnel, and funds for capital and operating needs;
- (n) Copies of existing or proposed policies with respect to employment of facility staff and, where applicable, admission to medical staff membership;
- (o) Preliminary financial feasibility study to include an analysis of historical and projected utilization, charges, source(s) of revenue, statements of revenues and expenses, statement of changes in fund balance and balance sheets;
- (p) Documentation of existing or proposed mechanism(s) of soliciting consumer input into the applicant's decision-making process;
- (q) If applicable, documented analysis of the needs and circumstances of entities such as health professional schools, multidisciplinary clinics and specialty centers which provide 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;

- (r) If applicable, documented analysis of the needs of and circumstances of health maintenance organizations;
- (s) If applicable, documented analysis of the need and circumstances of research projects; and
- (t) 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 as well as the impact on charges for similar services by other providers.

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

CON. Reg. §8. LONG RANGE PLANS. ~~Prior to the submission of an application for a Certificate of Need each existing or proposed health care facility and health maintenance organization shall have submitted a long range plan, to the State Agency, with a copy to the designated Health Systems Agency for the area in which it is located. The long range plan shall be updated and revised and resubmitted every two (2) years. Each plan shall have been formally adopted by the owner/operator or legally constituted governing body of such facility or organization.~~

§8.01. 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. Each long range plan as defined in Code §16-2D-2(v) shall consist of the overall plan for the health care facility or organization proposing a new institutional health service for at least the following three to 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 ~~institution~~ 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.

~~Any project for which a Certificate of Need is sought, must be consonant with the current long range plan for the facility or organization on file with the State Agency.~~

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

CON Reg. §9. LETTERS OF INTENT AND PRE-APPLICATION CONFERENCE.

~~Prior to submitting an application, a person proposing a new institutional health service shall submit a letter of intent to the State Agency, with a copy to the designated Health Systems Agency. Such~~
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.

CON Reg. §10. ~~STANDARD REVIEW PROCESS. The following regulations govern the standard review process.~~

§10.01. REVIEW FOR COMPLETENESS. ~~The applicant shall be notified by the State Agency within fifteen (15) days following receipt of an application for Certificate of Need that the application is accepted and complete, or it will specify the additional information that is required to complete the application before it can be accepted. The State Agency shall seek the advice of the designated Health Systems Agency in making its determination. No application shall be accepted for formal review until it has been determined to be complete.~~ 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 considered withdrawn, and a new letter of intent and application must be filed if the applicant desires to pursue the project.

(c) A long range plan, as defined in Code §16-2D-2(v), conforming to CON Reg. §8, and adopted by an applicant within the preceeding four years, must be on file with the State Agency before the State Agency can accept to review for completeness a standard Certificate of Need application submitted by such applicant.

(d) Under the authority of Code §16-2D-8(a)(2), the State Agency shall not 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 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 health facility has filed all reports required therein.

§10.02. REVIEW OF A COMPLETE APPLICATION. ~~The proposed schedule for review, the period within which a public hearing may be requested, and the manner in which notification will be provided of the time and place of any public hearing so requested shall be sent to the affected persons and~~ 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 review process shall be initiated upon such publication or upon notice being sent to the affected persons, whichever is later. A copy of the notice shall be sent to the designated Health Systems Agency.~~

~~A determination that an application is complete does not bar the State Agency or designated Health Systems Agency from requesting additional information from the applicant during the course of the review. Additional information received from the applicant which in the opinion of the State Agency constitutes a substantial change to the project as originally proposed may be cause for the State Agency to determine the application to be a new project subject to a new review cycle.~~

~~The application shall be concurrently reviewed by the designated Health Systems Agency and the State Agency.~~

~~The State Agency shall mail timely written notice to affected persons that a review has begun, the proposed schedule for review, the period within which a public hearing may be requested and the manner in which notification will be provided of the time and place of any public hearing so requested. For purposes of this regulation, the State Agency deems it appropriate in all reviews to include as "affected persons" the~~

~~health systems agencies contiguous to West Virginia in adjacent states.~~

~~As a part of the review process a public hearing shall be held by the State Agency if a request is made by one or more persons directly affected by the review to the State Agency.~~

(b) To be effective, a request for a public hearing during the review of an application must be made in writing and received within ~~thirty-five (35)~~ (30) days of the date of notification of the beginning of the review as provided in Code §16-2D-7(g).

~~initiation of the review process as described~~

~~above in this regulation.~~ The request shall be addressed to:

Director, Certificate of Need Program

West Virginia Department of Health

1800 Washington Street, East

Charleston, West Virginia 25305

~~Written notice of the date, place and time of a scheduled public hearing and where the application is available for inspection and copying prior to the hearing shall be sent by the State Agency to all affected persons and shall also be provided through newspapers of general circulation and other public information channels in the appropriate area. Notice of the public hearing shall be provided at least ten (10) days prior to the date of the public hearing. The primary purpose of a public hearing is to provide individuals or organizations an opportunity to express opinions about the proposed new institutional health service. It is not to constitute an appeal by, for, or against the applicant. Any person may present written or oral testimony. Public hearings shall be held in the community where the proposed new institutional health service is to be located, during generally accepted non-working hours. A record, either~~

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~~stenographic or tape, shall be made of the public hearing. The information, testimony, and submitted reports or exhibits for the hearing shall be considered in the review and shall be part of the record of the review.~~

~~The requirement for a public hearing shall be deemed satisfied if an opportunity for a public hearing with respect to the new institutional health service under review has been provided to all persons directly affected by the review by the designated Health Systems Agency.~~

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(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 other 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 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, 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 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 sixtieth (60) 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 evaluating 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.

~~Except as otherwise provided, the State Agency shall issue its decision in writing within ninety (90) days of the initiation of the review process as described in CON Reg. §10.02. The decision may be a denial, approval, approval with conditions or, if the State Agency has received from the Secretary of Health and Human Services an exception for deferral decisions, a deferral. The State Agency shall issue written findings.~~

(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: provided, that 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:

- (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 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 organi-
zation, its institutional health services in a
reasonable and cost-effective manner which is consis-
tent with the basic method of operation of the
organization and which makes such services available
on a long-term basis through physicians and other
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 standards described in either CON Reg. §§10.03(a)(3)(A)(ii) or (iii).

(b) WRITTEN FINDING IF THE APPLICATION IS DISAPPROVED. This sub-
division 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 ~~and other material~~ shall be sent by certified mail to the applicant and sent or delivered to the designated health systems agency and shall be available to any 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.

CON Reg. §11. EXPEDITED APPLICATION FORM. This regulation supplements Code §16-2D-7(v). The purpose of the 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, ~~or health maintenance organization.~~ Such projects may include but are not limited to: ~~those which are in compliance with the Health Systems Plan and the State Health Plan (as defined in P.L. 93-641) and are:~~

- (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 ~~of less than \$250,000~~ which do not change the involve the renovation, replacement or substantial change to the bed capacity or a substantial change to the health services of the facility; ~~or organizations;~~ or
- (c) The replacement of ~~worn-out equipment;~~ ~~or facilities;~~ with equivalent equipment or facilities; or
- (d) ~~Transfer of ownership.~~ Acquisition of health care facilities; or
- (e) Substantial changes (as defined in CON Reg. §21) in a project after a CON has been issued for a particular project, 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 by persons that are not health care facilities; for example, projects for parking buildings and medical office buildings proposed by hospitals or the provision of personal care services by intermediate care facilities; or
- (i) Any other application within the discretion of the State Agency when there are no letters of intent on file for projects that are 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 a 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 ~~designated~~ applicable health systems agency.

If, in the judgment of the State Agency, ~~based on the information contained in the~~ 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.

~~A project determined to be eligible for an expedited application form by the State Agency shall receive a standard application form upon request of the applicant.~~

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. ~~process as described in CON Reg. §10.02.~~ If in the opinion of the State Agency there is cause to use the standard application form the review shall be stopped and, ~~a new review cycle begun using the~~ after the standard application form is declared complete, the application shall be included in the next review cycle.

~~The receipt of notice of an application considered competing will have the effect of stopping the review of the expedited application and instituting a review process in accordance with CON Reg. §16.~~

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§11.03. (DELETED). ~~REVIEW-FOR-COMPLETENESS:--Upon-receipt-of-a
completed-expedited-project-application-form,-the-State-Agency-will
review-it-for-completeness-in-accordance-with-CON-Reg.-§10.01-~~

§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. ~~except that for a request for a public hearing to be effective, it must be made within ten days after the initiation of the review process as described in CON Reg. §10.02.~~

§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, ~~process as described in CON Reg. §10-02,~~ the State Agency shall, unless CON Reg. §14 is invoked, issue its decision on or before the sixty ~~first~~ fifth (65th) day after the initiation of such review. ~~The decision may be a denial, approval, approval with conditions or, if the State Agency has received from the Secretary of Health and Human Services an exception for deferral decisions, a deferral.~~ The decision, findings and other material shall be sent to the applicant and to the designated Health Systems Agency and shall be available to any other persons upon request (at a cost set out in the fee schedule referred to in CON Reg. §17.) 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 at any time 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 invoked.

CON Reg. §12. ADDITIONAL INFORMATION AND AMENDMENTS TO AN 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
 - (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 ~~modifications-contained-in-an-amendment-to~~
~~an-application,~~ additional information received from an
applicant with respect to the impact on the project originally
accepted for review, ~~and-amendments-which-are-received-after~~
~~the-State-Agency-has-received-the-Health-Systems-Agency's~~
~~recommendation,~~ may be cause for the State Agency to determine
the application to be a new proposal, subject to a new review
cycle.

CON Reg. §13. WITHDRAWAL OF AN APPLICATION. Any applicant may withdraw an application at any time during the review process without prejudice. This notice of withdrawal ~~request~~ must be made in writing to the State Agency.

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CON Reg. §14. HOLDS AND EXTENSIONS OF 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 batch category of CON Reg. §16.01(a)(8), the State Agency may grant an applicant's ~~may~~ 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 batch categories in CON Reg. §16.01(a)(1) through (7) without the agreement of all applicants with applications in those batching categories of 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 time provided in CON Reg. §11.05, or in the case of a standard application, within ninety (90) days. ~~and~~ In such situations the State Agency may extend the review process ~~for up to an additional thirty (30) days but, if 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 shall be similarly extended.~~ ~~however, in the case of a review of a new institutional health service proposed by a health maintenance organization, the review process may not be extended.~~ Such situations shall include those in which:

~~a. --- Applications are judged competing as set forth in CON~~

~~Reg. §16~~

~~b. (a) A project is of such a comprehensive or far-reaching~~

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;

~~e.~~(b) Additional information related to the review criteria listed in ~~CON Reg. §18~~ is requested from the applicant ~~after the application has been judged complete in accordance with Code §16-2D-7(i),~~ and it is not provided by the applicant in ~~a timely fashion,~~ accordance with that Code section.

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

~~Failure of the State Agency to make a decision within the time period specified for the review, shall have the effect of deeming the proposed new institutional health service not to be needed.~~

§14.03. 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 ~~extensions of the review process and the reasons, for which the agency has found such an extension to be necessary.~~

CON Reg. §15. (Deleted). ~~EMERGENCY APPLICATIONS. Situations posing an immediate threat to health and safety may arise which require reviewable changes to a health care facility or health maintenance organization. Such situations include but are not limited to: natural disasters, acts of God, acts of war, public riots, states of emergency declared as such by Federal or State Government and emergency life safety code violations. In such situations expedited application review procedures shall be followed in conformance with CON Reg. §§11.01 through 11.05.~~

~~GON-Reg. §16.---COMPETING APPLICATIONS.---An application shall be considered competing when it is received within thirty (30) days of the date that an application from a different applicant is judged complete, where the second applicant is requesting approval to provide the same or similar type of new institutional health services for the same or similar population as the first applicant; and where, in the opinion of the State Agency, with the advice of the Health Systems Agency, there may be a need for only a limited number of the new institutional health services proposed among the population to be served.~~

~~The State Agency shall notify both applicants in writing, upon receipt of the second application, that there are competing applications, who the competing applicants are, and the timetable to be used in reviewing the competing applications.---The State Agency shall stop the review process for the first applicant and begin new concurrent review cycles for the competing applicants, but only under GON-Reg. §14 may the commencement of the new review cycles be extended beyond ninety (90) days of the commencement of the first applicant's original review cycle. Competing applications shall always receive standard application reviews.~~

CON Reg. §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 in 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 and services;
 - (2) Psychiatric beds and services;
 - (3) Obstetric beds and services;
 - (4) Pediatric beds and services;
 - (5) Skilled nursing beds and services;
 - (6) Intermediate care beds and services;
 - (7) Proposed new institutional health services that do not fall in batching categories (1) through (6) but which directly relate to the provision of health services or to beds or to major medical equipment; and
 - (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. §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, and the State Agency's notice under CON Reg. §10.02 of the beginning of the review shall include notice of such determination.

§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 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.

CON Reg. §17. PUBLIC ACCESS TO INFORMATION. ~~All information, records, documents and data collected or produced under the Certificate of Need program shall be made readily available to any person for inspection and for copying for a fee, upon request, during regular working hours of the State Agency, provided that all information directly or indirectly identifying individual patients shall be deleted prior to disclosure of the information, unless a written consent for disclosure is received from the person so identified.~~

~~Information, records, documents and data is defined as all material, whether written, recorded, graphical, numerical, or pictorial, regardless of the physical form of storage which has been developed, recorded or received by the State Agency or designated Health Systems Agency in connection with the performance of their functions under the Certificate of Need and these regulations, including but not limited to long range plans, applications and supplementary material submitted by an applicant, decisions and finding of the State Agency and designated Health Systems Agency, procedures and criteria of the State Agency or Health Systems Agency for review, data received from health care providers, records of public meetings held by the State Agency or designated Health Systems Agency, staff reports, committee reports and consultant reports. 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 develop a fee schedule for copying material limited to reasonable, direct costs.~~ The State Agency shall provide copies of materials at a cost of 25¢ per page copied.~~

CON Reg. §18. REVIEW CRITERIA. ~~In making its determination as to whether a Certificate of Need shall be issued, the State Agency shall include in its consideration the following criteria, but in the case of health maintenance organizations for which assistance may be provided under Title XIII of the Health Maintenance Organization Act of 1973 the criteria shall be limited to those set forth in subparagraph l, except in the case of a new institutional health service which is proposed to be provided by or through an health maintenance organization for which assistance may be provided under Title XIII of the Act and which consists of (or includes) the construction, development or establishment of a new inpatient health care facility, the State Agency shall determine whether utilization of the facility by members of the applicant will account for at least 75 percent of the projected annual inpatient days, as determined in accordance with the recommended occupancy levels under the applicable health systems plan, and where the agency determines that these members will account for less than 75 percent of these patient days, it shall review the proposal in accordance with all the provisions of this regulation, except for subparagraph r, and where the agency determines that these members will account for a least 75 percent of the patient days, it shall review the proposal in accordance with the provisions of subparagraph r of this regulation.~~

- ~~a. The recommendation of the designated health systems agency for the health service area in which the proposed new institutional health service is to be located;~~
- ~~b. The relationship of the health service being reviewed to the applicable health systems plan and annual implementation plan adopted by the designated health systems agency~~

- ~~for the health service area in which the proposed new institutional health service is to be located;~~
- ~~e.---The relationship of services reviewed to the long range development plan of the person providing or proposing such services;~~
- ~~d.---The need that the population served or to be served by such services has for the services proposed to be offered or expanded, and the extent to which low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups are likely to have access to those services;~~
- ~~e.---The availability of less costly or more effective alternative methods of providing such services;~~
- ~~f.---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 person proposing the new institutional health service;~~
- ~~g.---The relationship of the services proposed to the existing health care system of the area in which such services are proposed to be provided;~~
- ~~h.---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 availability of alternative uses of such resources for the provision of other health services;~~

- ~~i.---The appropriate and nondiscriminatory utilization of existing and available health care providers;~~
- ~~j.---The relationship, including the organizational relationship, of the health services proposed to be provided to ancillary or support services;~~
- ~~k.---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.---Such entities may include medical and other health professional schools, multidisciplinary clinics and specialty centers;~~
- ~~l.---The special needs and circumstances of health maintenance organizations for which assistance may be provided under title XIII of P.L. 93-222 known as the Health Maintenance Organizations Act of 1973.---Such needs and circumstances shall be limited to:~~
- ~~(i)---The needs of enrolled members and reasonably anticipated new members of the health maintenance organization or proposed health maintenance organization for the new institutional health services proposed to be provided by the organization;~~
- ~~(ii)---The availability of the new health services from non-health maintenance organization providers or other health maintenance organizations in a reasonable and cost effective manner which is consistent with the basic method of operation of the health maintenance organization;~~

~~nance organization or proposed health maintenance organization. In assessing the availability of these health services from these providers, the agency shall consider only whether the services from these providers:~~

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

~~(B) Would be available and conveniently accessible through physicians and other health professionals associated with the health maintenance organization or proposed health maintenance organization. (For example whether physicians associated with the HMO have or will have full staff privileges at a non health maintenance organization hospital);~~

~~(C) Would cost no more than if the services were provided by the health maintenance or proposed health maintenance organization; and~~

~~(D) Would be available in a manner which is administratively feasible to the health maintenance organization or proposed health maintenance organization.~~

~~The criteria established by the state agency pursuant to this subparagraph shall be consistent with standards and procedures established under section 1306 (e) of P.L. 93-222, known as the Health Maintenance Organizations Act of 1973;~~

~~m.---The special needs and circumstances of biomedical and behavioral research projects which are designed to meet a national need and for which local conditions offer special advantages;~~

~~n.---In the case of the deletion or relocation of beds or services or the partial or total closure or relocation of a health care facility or health maintenance organization, the state agency shall consider the impact on the person proposing such new institutional health service, on other health care facilities or health maintenance organizations and the extent to which the needs of the population to be served or previously served 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, and other underserved groups to obtain needed health care;~~

~~o.---In the case of a construction project, the State Agency shall consider:~~

~~1)---The cost and methods of the proposed construction, including the costs and methods of energy provision and~~

~~2)---the probable impact of the construction project reviewed on the costs of providing health services by the person proposing such construction project.~~

~~p. In the case of any proposed new institutional health service, the state agency shall not grant a certificate of need under its certificate of need program, unless after consideration of the appropriateness of the use of existing facilities providing services similar to those being proposed the state agency makes a written finding as to the capital and operating costs (and their potential impact on patient charges), efficiency, and appropriateness of the proposed new institutional health service and makes each of the following findings in writing:~~

- ~~1) That superior alternatives to such services in terms of costs, efficiency and appropriateness do not exist and the development of such alternatives is not practicable;~~
- ~~2) That existing facilities providing services similar to those proposed are being used in an appropriate and efficient manner;~~
- ~~3) 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;~~
- ~~4) That patients will experience serious problems in terms of cost, availability, or accessibility in obtaining care of the type proposed in the absence of the proposed new service; and~~
- ~~5) That in the case of a proposal for the addition of beds for the provision of skilled nursing or inter-~~

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~~mediate-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;~~

~~g. In the case of any new institutional health service proposed to be provided by or through a health maintenance organization the state agency shall not deny a certificate of need with respect to such service (or otherwise make a finding under this section that such service is not needed):~~

~~(1) in those cases:~~

~~(i) When the state agency has granted a certificate of need which authorized the development of the service; or expenditures in preparation for such offering or development (or has otherwise made a finding that such development or expenditure is needed) and~~

~~(ii) When the offering of this new institutional health service will be consistent with the basic objectives, time schedules, and plans of the previously approved application; or~~

~~(2) solely because there is an health maintenance organization of the same type; as specified in section 1310(b) of the Health Maintenance Organizations Act of 1973, P.L. 93-222, (that is, (i) health maintenance organizations providing services through pro-~~

~~professionals who are members of the staff of the organization or a medical group (or groups), or (ii) health maintenance organizations providing services through an individual practice association (or associations)} in the same area, or solely because the services being reviewed are not discussed in the applicable health systems plan, annual implementation plan, State health plan, or State medical facilities plan;~~

~~r. In the case of any new institutional health service~~

~~proposed to be provided by or through an health maintenance organization for which assistance may be provided under Title XIII of the Health Maintenance Organizations Act of 1973, P.L. 93-222, the State Agency shall not deny a certificate of need with respect to the service unless the State Agency determines that the service is:~~

~~(1) Not needed by the enrolled or reasonably anticipated new members of the health maintenance organization or proposed health maintenance organization, or~~

~~(2) Available from non health maintenance organization providers or other health maintenance organizations in a reasonable and cost effective manner which is consistent with the basic method of operation of the health maintenance organization in accordance with CON-Reg. §18.1.(ii);~~

~~or The contribution of the proposed new institutional health service in meeting the health related needs of members of~~

~~medically underserved groups which have traditionally experienced difficulties in obtaining equal access to health services (for example, low income persons, racial and ethnic minorities, women, and handicapped persons), particularly those needs identified in the applicable health systems plan and annual implementation plan as deserving of priority;~~

~~t. The special circumstances of health care facilities and health maintenance organizations with respect to the need for conserving energy.~~ This regulation supplements Code §§16-2D-5(d) and (e), and 16-2D-6.

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

§18.02. 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 Code or these regulations 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 Statewide Health Coordinating Council.

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

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§18.04. Where the State Agency determines that a substantially competitive market exists or may be developed 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 non-competitive market; namely, the criteria in Code §§16-2D-6(a)(3), (5), (6), (7), (8), (10), (15), (21), (22), and (26).

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§18.05. 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 §§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.

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§18.06. The State Agency may utilize and develop standards relating to the review criteria in the Code and these regulations. ~~for review of projects.~~ 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.

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CON Reg. §19. PROGRESS REPORTS AND EXTENSION OF THE DURATION OF A CERTIFICATE OF NEED. ~~A Certificate of Need shall be valid for a minimum of one (1) year from the date of issuance and may be issued for periods of less than one year. A certified new institutional health service is required to maintain a valid Certificate until such time as the new institutional health service is first used or patients first received. Upon timely notice by the State Agency to the person holding the Certificate of Need,~~ This regulation supplements Code §16-2D-11(a).

(a) The State Agency shall require the person holding the Certificate shall to submit in writing to the State Agency, with a copy to the designated 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 more than ninety (90) nor less than sixty (60) 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.

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(b) The person holding the Certificate shall submit any relevant additional information whenever requested by the State Agency.

~~The State Agency shall determine, in consultation with the designated Health Systems Agency, whether sufficient progress is being made on the development of the project and whether there has been compliance with the conditions of certification.~~

~~The Certificate of Need may be extended by the State Agency for additional periods of time of up to one year as are needed to expeditiously complete the project.~~

(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 ~~revoked~~ withdrawn by the State Agency in accordance with Code §16-2D-11(b) for failure to submit a complete and timely progress report. ~~insufficient progress, or for failure to comply with conditions of certification, at the end of the first certification period or at the end of any subsequent certification period.~~

(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; provided, that 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 in no case may a Certificate of Need be renewed for a project beyond eighteen (18) months if any obligation that is required to be incurred by this subsection has not been incurred within said eighteen (18) months of issuance of the Certificate of Need.

(g) If a ~~recertification~~ renewal review is underway but is not complete at the end of a certification period, the old Certificate shall automatically be extended until the ~~recertification~~ renewal is complete.

(h) Failure to request renewal of a Certificate of Need without a showing of good cause will result in the automatic expiration of the Certificate.

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CON Reg. §20. ~~FINAL-CONFORMANCE-REVIEW~~ NOTICE OF SUBSTANTIAL COMPLIANCE.

This regulation supplements Code §16-2D-11(a). All new institutional health services shall receive a ~~final-conformance~~ substantial compliance review by the State Agency. ~~immediately-prior-to their-first-use.~~ No later than ~~sixty-(60)~~ forty-five (45) days prior to ~~the-first-use-or-first-receipt of-patients,~~ licensure or undertaking of the activity for which the Certificate of Need was issued, the applicant shall request in writing a ~~final-conformance~~ 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 ~~the-conformance-on-the basis-of-a-site-review~~ substantial compliance within forty-five (45) days of the receipt of the request for a ~~final~~ substantial compliance review. ~~In-issuing-such-findings~~ The State Agency shall consider the recommendation of the applicable health systems agency. A finding that a project ~~does-not-conform-to~~ is not in substantial compliance with its certification Certificate of Need ~~may~~ will be grounds for a withdrawal of the Certificate of Need under Code §16-2D-11(b) and for a revocation or denial of a license to operate the facility or for seeking a fine or an 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 enforcement actions under Code §§16-2D-12 and 13.

CON Reg. §21. PROJECT CHANGES AFTER CERTIFICATION WHILE A CERTIFICATE OF NEED IS IN EFFECT. ~~Substantial changes to a certified project constitute a new project requiring a new Certificate of Need review. Should an applicant consider it desirable or necessary to make a change to a project as approved, after it is certified but before it is first used or patients are first admitted, prior to making the change, the applicant shall notify the State Agency in writing describing the change and shall request a determination by the State Agency as to the need for review. The applicant shall supply any additional information requested by the State Agency.~~
This regulation supplements Code §16-2D-11.

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

- a. Change in location; ~~or~~ 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. ~~Change in ownership of the facility or organization; or~~
- e. ~~Change in project scope, including increases or decreases in:~~
 - 1) (b) Addition in number and/or change in type of beds;
 - 2) (c) number and/or type of Acquisition of major medical equipment (moveable or fixed) not described in the application as part of the project;
 - 3) (d) types and/or mix of Addition of health services;
 - 4) ~~contracts for services~~

(e) Increase or decrease in square footage; or in excess of ten (10) percent, or one thousand (1,000) square feet, whichever is greater;

~~d. --- Change in method or cost of financing;~~

e. (f) Change in project cost of more than 20% or a million dollars per year whichever is less. 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.

~~An applicant shall notify the State Agency of any change to a project as certified, as set out in a through e, above, which information shall become part of the project file.~~

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

No proposed substantial project change set out in a through e, above, 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 in the project, as determined by the State Agency, shall 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 a Certificate of Need the changes.

CON Reg. §22. TRANSFERABILITY. This section supplements Code §16-2D-11(a). ~~A Certificate of Need shall be issued in the name of the owner/operator or the legally constituted governing body of the facility or organization the name of which was given on the application form as the applicant. Certificate of Need is non-transferable.~~ The A finding by the State Agency that a transfer of a Certificate of Need has occurred will result in its automatic revocation withdrawal pursuant to Code §16-2D-11(b).

The license of a health care facility may not be transferred from a subsidiary corporation to its parent corporation, or vice versa, without a Certificate of Need.

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CON Reg. §23. (Deleted). ~~MATERIAL MISREPRESENTATION. The State Agency reserves the right to revoke a Certificate of Need at any time if the State Agency finds that the applicant made a material misrepresentation, upon which the State Agency or the designated Health Systems Agency relied in making its decision or recommendation.~~

CON Reg. §24. RECONSIDERATION OF A FINAL DECISION OF THE STATE AGENCY BY THE STATE AGENCY. ~~These regulations cover the procedures to be utilized for requesting and conducting a reconsideration of a final decision of the State Agency pertaining to certificate of need. This regulation supplements Code §16-2D-7(t).~~

§24.01. REQUEST FOR RECONSIDERATION HEARING. ~~Any person directly affected by the review of the State Agency may for good cause shown, request in writing, within 30 days of any final decision of the State Agency, a public hearing for purposes of reconsideration of the decision.~~

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

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.

§24.02. ~~RECEIPT OF REQUEST. The written request for a public hearing for reconsideration of the State Agency's decision shall state the basis upon which the reconsideration is requested and must be received by the State Agency within 30 days of the date of the State Agency's written decision.~~

§24.03. ~~NOTICE OF HEARING. Notice of the date, time and place of~~

~~such hearing, containing a short, plain statement of the matters asserted, shall be sent by the State Agency at least 10 days prior to the date of commencement of such hearing to the person requesting the hearing, the person proposing the new institutional health service, the HSA, to any person directly affected by the review, and to others upon request.~~

~~§24.04.---COMMENCEMENT OF HEARING.---The hearing shall be held in the county of location of the proposed new institutional health service and/or capital expenditure and shall commence within 30 days of the receipt by the State Agency of the written request for such hearing.---No fees will be imposed by the State Agency for the hearing.~~

~~§24.05.---HOW HEARINGS CONDUCTED.---At the hearing, an opportunity shall be afforded all parties to present evidence and argument with respect to the matters and issues involved.---All testimony and evidence at the hearing shall be reported by stenographic notes and characters or by mechanical means, including tape recordings.---All rulings by the hearing officer on the admissibility of testimony and evidence shall be reported.---The State Agency shall prepare an official record, which shall include reported testimony and exhibits and all agency staff memoranda and data used in consideration of the case.---Copies of such record shall be available to the public for inspection and copying.~~

~~§24.06.---DECISION WHEN MADE:---FORM.---The State Agency shall make a decision accompanied by findings and conclusions stating the basis for its decision on reconsideration within 45 days after the conclusion of the hearing and shall within said time period serve a copy of the decision and findings and conclusions upon each party and each party's attorney of record, if any.---The decision of the State Agency on recon-~~

~~sideration shall be in the form of an approval, a denial, an approval with conditions or, if the State Agency has received from the Secretary of Health and Human Services an exception for deferral decisions, a deferral.~~

~~§24.07. STATEMENT TO HSA. If the State Agency makes a decision regarding a proposed new institutional health service which inconsistent with the recommendaton made with respect thereto by the HSA or is inconsistent with the goals of the health systems plan or the priorities of the annual implementation plan of the HSA, the State Agency shall submit to the HSA a written, detailed statement of the reasons for the inconsistency.~~

CON Reg. §25. REVIEW HEARING OF ANY FINAL DECISION OF THE STATE AGENCY BY THE STATE APPEALS REVIEW AGENCY DESIGNATED BY THE GOVERNOR. ~~These regulations cover the procedures to be utilized for requesting and conducting a hearing for review of any final decision of the State Agency pertaining to certificate of need by a separate appeals agency of the state designated by the Governor.~~ This regulation supplements Code §16-2D-10.

§25.01. REQUEST FOR REVIEW AGENCY HEARING. ~~The HSA, when a final decision of the State Agency is inconsistent with a recommendation made by the HSA, the person proposing the new institutional health service, and any person directly affected by the review may request a hearing for review of the State Agency's decision by the appeals agency of the State as designated by the Governor to carry out such reviews.~~

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. through §25.04 (Deleted) ~~RECEIPT OF REQUEST. The written request for a hearing by the appeals agency of the State designated by the Governor shall state the basis upon which the hearing is requested and must be received within 30 days of the date of the State Agency's written decision.~~

~~§25.03.---NOTICE OF HEARING.---Notice of the date, time and place of such hearing, containing a clear statement of the matters asserted, shall be sent by the appeals agency at least 10 days prior to the commencement of the hearing to the person requesting the hearing, the person proposing the new institutional health service, the State Agency, the HSA, to any person directly affected by the review, to any other party, and to others upon request.~~

~~§25.04.---COMMENCEMENT OF HEARING.---The hearing shall be held in county of location of the proposed new institutional health service and/or capital expenditure, and shall commence within 30 days of the receipt by the State Agency of the written request for such hearing (or later at the option of the person proposing the new institutional health service if such person has requested the review) and shall be open to the public and publicized through local newspapers and public information channels.~~

§25.05. DESIGNATION OF REVIEW AGENCY HEARING OFFICERS. No person who has taken part in any ~~prior~~ State Agency or applicable health systems agency consideration of or action upon the proposed-capital expenditure--application may conduct a hearing pursuant to these regulations. ~~The designation of hearing officers shall be made by the Governor, through his designation of the appeals agency of the State responsible for conducting reviews of the State Agency's decisions.~~

§25.06. ~~(Deleted) SUBSTANCE-OF-HEARING.--The hearing is for the hearing officer to determine whether the proposed new institutional health service and/or capital expenditure is consistent with the standards, criteria and plans specified in the certificate of need law and regulations.--(The question of the State Agency's adherence to its procedures may also be considered.)~~

§25.07. HOW REVIEW AGENCY HEARINGS CONDUCTED. Pending the decision of the ~~appeals~~ Review Agency, the State Agency or the Hearing Officer may delay the ~~enforcement~~ effect of the State Agency Decision.

~~Within fifteen days after receipt by the State Agency of the written request for a hearing by the appeals agency, or within such further time as the Hearing Office may allow, the State Agency shall provide to the Hearing Officer a certified copy of the entire record of the proceeding under review, including a transcript of all testimony and all applications, long range plans, drawings, letters, staff memoranda and other documents submitted in connection with the decision of the State Agency, and a statement of matters officially noted. By agreement of all parties to the hearing, the record may be shortened. The State Agency shall furnish to any person a copy of the record at the cost of reproduction.~~

The person requesting the hearing, as part of the request, shall include an assignment of the errors of law or procedure. ~~(including any clear failure of the State Agency to make its certificate of need decision in conformity with the standards and criteria in the certificate of need law or clear failure of the State Agency to make its recommendation under Section 1122 of the Social Security Act in conformity with that Section of the Act, with 42 C.F.R. Part 100, with the Section 1122 Agreement between the Secretary of Health, Education, and Welfare and the State of West Virginia, with the State health plan, and with the Division of Comprehensive Health Planning's DPA Manual and Section 1122 Notices) made by the State Agency that appear on the record that do not require an evidentiary hearing on appeal.~~

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

~~The Hearing Officer may hear oral arguments and require written briefs. Errors not argued in the request for the hearing or by brief may be disregarded, but the Hearing Officer may consider and decide errors which are not assigned or argued.~~

~~The review shall be conducted by the Hearing Officer and shall be upon the record made before the State Agency, except that in cases of alleged irregularities in procedure before the State Agency, not shown in the record, testimony thereon may be taken before the Hearing Officer.~~

~~The Hearing Officer may apply the administrative hearing provisions of Chapter 29A, Article 5, Sections 1 thru 3 of the West Virginia Code and Local Rule 21, governing appellate procedure, of the Local Rules for Use in the Civil Courts of Kanawha County.~~

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). ~~DECISION:--WHEN MADE.--The appeals agency shall make a decision accompanied by findings and conclusions stating the basis for its decision not more than 45 days after the conclusion of the hearing, and within said 45 days after the conclusion of the hearing, the hearing officer shall serve a copy of the decision and a concise, explicit statement of the findings of fact and conclusions of law upon the person who requested the hearing, the person proposing the new institutional health service and/or capital expenditure, the State Agency, the HSA, all other parties, the attorney of record of each party, if any, and other interested persons at the discretion of the hearing officer.--The decision shall be published through local newspapers and public information channels.~~

§25.09. FORM OF DECISION. ~~The decision of the hearing officer shall be in the form of an approval, a denial, approval with conditions, or if the State Agency has received from the Secretary of Health and Human Services an exception for deferral decisions, a deferral, or the hearing officer may remand the matter to the State Agency for further action or consideration.~~ 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 ~~or recommendations~~ of the State Agency are reversed or revised. ~~Where a party has proposed in writing findings of fact and conclusions of law, the decision shall include a ruling on each proposed finding and conclusion.~~

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~~§25.10.---INFORMAL-DISPOSITION,---Where there is informal disposition of the case, the hearing officer is not relieved of the requirements of §25.09.~~

~~§25.11.---WHEN-THE-STATE-AGENCY'S-DECISION-MAY-BE-REVERSED-OR-REVISED.---The hearing officer may reverse or revise the decision of the State Agency if the substantial rights of a party have been prejudiced because the State Agency's findings, inferences, conclusions or decision are:~~

- ~~1.---In violation of statutory or regulatory provisions; or~~
- ~~2.---in excess of the statutory or regulatory authority or jurisdiction of the agency; or~~
- ~~3.---made upon unlawful procedures; or~~
- ~~4.---clearly wrong in view of the reliable, probative, and substantial evidence on the whole record; or~~
- ~~5.---arbitrary or capricious or characterized by abuse of discretion or clearly unwarranted exercise of discretion.~~

~~§25.12.---DECISION-CONSIDERED-THE-STATE-AGENCY'S-FINAL-DECISION. The decision of the appeals agency shall be considered the final decision of the State Agency.---To the extent that a decision of the appeals agency reverses or revises the findings or recommendations of the State Agency, the decision shall supersede the findings and recommendations of the State Agency.~~

~~§25.13.---STATEMENT-TO-HSA,---Where a hearing has been conducted pursuant to a request made by the HSA, if the appeals agency makes a decision regarding a new institutional health service which is not consistent with the recommendation made with respect thereto by the HSA~~

~~or is not consistent with the goals of the health systems plan or the priorities of the annual implementation plan, the appeals agency shall submit to the HSA a written, detailed statement of the reasons for the inconsistency.~~

~~§25.14.---APPLICATION OF CHAPTER 29A.---All the provisions of Chapter 29A, Article 5, of the West Virginia Code not specifically set out herein shall apply to hearings conducted by the appeals agency.~~

§25.10. REVIEW AGENCY REGULATIONS AND PROCEDURES. The Review Agency may adopt regulations and procedures for the conduct of reviews of State Agency decisions; provided that, the Review Agency's regulations and procedures are not 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, Title 42 Code of Federal Regulations Part 123.

~~CON Reg. §26. ENTRY OF FINAL DECISION BY APPEALS AGENCY. Upon the entry of a final decision by the appeals agency, the designated health systems agency, the person proposing the new institutional health service and any other "person directly affected by the review" as defined in Chapter 16, Article 2D, Section 7 shall have standing in and may take an appeal to the circuit court of Kanawha county from any decision of the state agency granting, with or without conditions, denying or revoking a certificate of need.~~

CON Reg. §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.

CON Reg. §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 ~~this~~ these regulations are declared to be severable.

CON Reg. §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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