

West Virginia Administrative Regulations **THIS DATE 3-12-80**
State Health Planning and Development Agency
Chapter 16-2D
Series I
Effective November 3, 1978
Amendments Effective _____

Subject: Certificate of Need

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WEST VIRGINIA ADMINISTRATIVE REGULATIONS
STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

CHAPTER 16 ARTICLE 2D
SERIES I

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.

§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. _____.

§1.04. FILING DATE. These amended regulations were filed in the Office of the Secretary of State on ~~March 8, 1978~~, _____, 1980.

§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. 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. 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 of West Virginia (1931), as amended, and that a need exists for the proposed new institutional health service.

§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 beds) and is not limited to the licensed beds of the health care facility.

§2.09. The term "conversion of beds" 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 (P.L. 93-641).

§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 (P.L. 93-641).

§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.

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, 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, whichever 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 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 organi-

zation 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 mainten-

ance 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.

CON Reg. §4. EXEMPTIONS. The following health care providers are exempt from coverage of the Certificate of Need program:

§4.01. Private offices of physicians, private clinics of physicians, dentists or other practitioners of the healing arts.

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

1) 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) 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) 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) 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;

§4.03. Establishments, such as motels, hotels and boarding houses which provide medical, nursing personnel and health related services;

§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;

§4.05. 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 CON 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.
- c) An exemption granted under Chapter 16, Article 2D or CON Reg. §4.05 (b) above shall be valid for one year from the date it is issued. 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 to the State Agency and request a renewal not more than ninety (90) nor less than forty-five (45) days prior to the expiration 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 change in the scope of the project as approved may be cause for the State Agency to revoke the exemption. 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 and who wishes to proceed with any development or expansion must obtain a Certificate of Need in accordance with these regulations.

CON Reg. §5. ACCESS TO INFORMATION AND FACILITIES. 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. §7. APPLICATION REQUIRED FOR CERTIFICATE OF NEED. An Application for a Certificate of Need shall be prepared on the standard

form published by the State Agency. Three copies shall be submitted to the State Agency. Additional copies may be required by the designated 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: but not be limited to:

- a. Identification of the applicant;
- b. Description of the project;
- c. The consistency of the project with the appropriate health systems plan and annual implementaton 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 explanation 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.

\$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. Each long range plan shall consist of the overall plan for the facility or organization 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 (e.g. construction, new service development, equipment purchase, sharing/merger arrangements, staff recruitment);
- c. 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.

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.

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 letter shall contain sufficient information to inform the State Agency of the approximate location, nature, scope, cost and timing of the project. In response to a letter of intent, the State Agency shall forward ~~an application form for~~ either a standard or an expedited application form. ~~a non-substantive review.~~ 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.

§10.02. REVIEW OF A COMPLETE APPLICATION. Written notification to the applicant by the State Agency of acceptance of a complete application ~~shall initiate the review process.~~ shall be sent to the applicant and 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 applicant, 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 provide 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 consider 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. To be effective, a request for a public hearing must be made within thirty-five (35) days of the date of initiation of the review process as described above in this regulation. ~~written notice to the applicant that the review has begun.~~ 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 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.

§10.03. DECISION.

(a) 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. ~~date of written notice to the applicant that the application has been determined to be complete and a review has begun.~~ 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 under 42 C.F.R. §123.408 for deferral decisions, a deferral. The State Agency shall

issue written findings. 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.).

(b) If an exception for deferral decisions has been obtained as described in subsection (a), the State Agency may issue a deferral decision if:

- (1) The Health Systems Agency's recommendation is ambiguous; or,
- (2) The Health Systems Agency's recommendation contains conditions that are to be met by the applicant before the State Agency's decision is issued and the Health Systems Agency has not informed the State Agency whether those conditions have been met; or,
- (3) After the Health Systems Agency has considered the application there is new information or a change of circumstances that might affect the financial feasibility of the applicant's proposal or otherwise might affect the timely and efficient completion, or operation of the applicant's proposal, such as:
 - (A) Natural disaster;
 - (B) A change in federal or state or other reimbursement;
 - (C) A significant increase in construction costs or in the financing market;
 - (D) Construction material shortage;
 - (E) Strikes, wage settlements, or a government imposed freeze on wages and prices;
 - (F) Economic recession or depression;

- (G) Introduction of some form of national health insurance;
- (H) A road or bridge opening or closing;
- (I) A coal mine, plant or other industry closing;
- (J) Evidence of possible insufficient utility services; or,
- (K) Demonstration that official demographic statistics were not properly developed.

In the case of a deferral, the application shall be returned to the applicant with the opportunity to revise it or to the designated Health Systems Agency for reconsideration of its recommendation or to both. In the case of a return to the applicant, the State Agency shall state the terms of the deferral to the applicant and the designated Health Systems Agency. In the case of a return to the designated Health Systems Agency for reconsideration of its recommendation, the designated Health Systems Agency shall complete its reconsideration and submit a recommendation and findings to the State Agency within fifteen (15) days of the date of the notice that reconsideration is required. The State Agency shall issue its decision and findings within ten (10) days of receipt of the designated Health System Agency's recommendation and findings. Notification shall be sent to the applicant and the Health Systems Agency and to other persons upon request. The recommendation may not be returned again to the designated Health Systems Agency for reconsideration. In the case of a revision to applicant's application, the Health Systems Agency shall issue its recommendation and findings to the State Agency within ten (10) days of receipt of the revised application and

the State Agency shall issue its decision and findings within ten (10) days of receipt of the Health Systems Agency recommendation and findings.

CON Reg. §11. EXPEDITED APPLICATION FORM ~~NON-SUBSTANTIVE REVIEW~~
~~PROCESS.~~ The purpose of the expedited application form ~~non-substantive~~
~~review process~~ 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 bed capacity or 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.
- e. Changes (as defined in CON Reg. §21) in a project after a CON has been issued for a particular project.

§11.01. REQUEST FOR EXPEDITED APPLICATION FORM ~~NON-SUBSTANTIVE~~
~~REVIEW.~~ An applicant may request an expedited application form ~~a non-~~
~~substantive review~~ in the letter of intent. The State Agency will

forward a expedited ~~non-substantive~~ project application form, as appropriate, in response to a letter of intent.

§11.02. DETERMINATION OF ~~NON-SUBSTANTIVE~~ APPROPRIATENESS OF AN EXPEDITED APPLICATION FORM FOR A PROJECT. Meeting any or all of the categories in CON Reg. ~~§10~~ §11 does not automatically render a project ~~non-substantive~~ appropriate for an expedited application form. This determination is made by the State Agency after consultation with the designated Health Systems Agency.

If in the judgment of the State Agency, based on the information contained in the ~~non-substantive~~ expedited project application form, the project will require a standard application form, ~~review~~, the applicant will be required to complete a standard application form.

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

Any affected person may present reasons to the State Agency as to why the ~~application~~ applicant should be given a standard application form. ~~review~~. 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. ~~a notice that a non-substantive review has begun~~. If in the opinion of the State Agency there is cause to use the standard application form ~~review~~, the ~~non-substantive~~ review shall be stopped and a new review cycle begun using the standard application form. ~~review process~~.

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

§11.03. REVIEW FOR COMPLETENESS. Upon receipt of a completed ~~non-substantive~~ 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. NON-SUBSTANTIVE REVIEW PROCESS. 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. ~~Written notification to the applicant by the State Agency of acceptance of a complete non-substantive project application shall initiate the non-substantive review process. Notice shall be sent by the State Agency to all affected persons of the beginning of the review and that the applicant will receive a non-substantive review. A public hearing will not be required.~~

~~The designated Health Systems Agency shall make its recommendation, accompanied by its findings, on the proposed new institutional health service to the State Agency within thirty (30) days of the date of the notice to the applicant that the review has begun.~~

§11.05. DECISION ON AN EXPEDITED APPLICATION. The State Agency shall issue its decision and findings in writing within ~~forty five (45) days of the date of the notice to the applicant that the review has begun~~ ten (10) days after receiving the 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 issue its decision on the sixty-first 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 under 42 C.F.R. §123.408 for deferral decisions, a deferral. In the case of a deferral, CON reg. §10.03(b) applies. 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.).

CON Reg. §12. AMENDMENT TO AN APPLICATION. ~~Amendments to an application may only be made by the applicant within the first thirty (30) days of a standard review cycle and the first ten (10) days of a non-substantive review cycle.~~ The extent of the modifications contained in an the amendment to an application, 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 withdrawal request must be made in writing to the State Agency.

CON Reg. §14. EXTENSION OF REVIEW PERIOD. At any time during a review, an applicant may request a tolling of the review period on its application.

The State Agency may find it would not be practicable to complete a review within ninety (90) days and may extend the review process for up to an additional thirty (30) days; however, in the case of a review of a new institutional health service proposed by a health maintenance organi-

zation, 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 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;
- c. Additional information related to the review criteria listed in CON Reg. §18 is requested from the applicant after the application has been judged complete and it is not provided by the applicant in a timely fashion.
- d. Weather conditions or other natural disasters have prevented the review process from taking place in a timely manner.

~~All extensions must be agreed to in writing by the applicant to be effective. If Failure of the State Agency to does not make a decision within the time period specified for the review, a certificate of need shall not be issued. ~~shall have the effect of deeming the proposed new institutional health service not to be needed, except in those cases where the State Agency has willfully neglected its responsibilities under Chapter 16, Article 2D.~~~~

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. EMERGENCY APPLICATIONS. Situations posing an immediate threat to health and safety may arise which require ~~immediate~~

reviewable changes to a health care facility or health maintenance organization. ~~which would normally require a Certificate of Need.~~ 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 those instances the State Agency may issue an emergency Certificate of Need.~~ In such situations expedited review procedures shall be followed in conformance with CON Reg. §§11 through 11.05.

~~§15.01. REQUEST FOR EMERGENCY CERTIFICATE OF NEED. Any health care facility requiring an emergency Certificate of Need, shall immediately contact the State Agency and promptly inform the State Agency in writing of the facts constituting the emergency situation. If upon receipt of this information the State Agency agrees that an emergency situation exists, the State Agency shall promptly issue an emergency Certificate of Need. In making its determination concerning a possible emergency situation, the State Agency shall consider if the particular facility or service is in conformance with areawide plans and if residents in the area will suffer hardship in the absence of prompt access to the facility or service.~~

~~§15.05. DURATION OF AN EMERGENCY CERTIFICATE OF NEED. The emergency Certificate of Need is temporary in nature and shall be issued for a period not to exceed one hundred eighty (180) days. Within the first thirty days following the issuance of an emergency Certificate, the health care facility or health maintenance organization shall submit an application for a Certificate of Need which shall then be subject to the review process, either standard or non-substantive, as determined by the State Agency.~~

CON 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 ~~in no case~~ only under CON 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 ~~substantive~~ standard application reviews.

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 State Agency shall develop a fee schedule for copying material limited to reasonable, direct costs.

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 1., 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;
- c. 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 ~~such~~ 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;

1. 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 ~~include the needs of and costs to members and projected members of the health maintenance organization in obtaining health services and the potential for a reduction in the use of inpatient care in the community through an extension of preventive health services and the provision of more systematic and comprehensive health services. The consideration of a new institutional health service proposed by a health maintenance organization shall also address the availability and cost of obtaining the proposed new institutional health service from the existing providers in the area that are not health maintenance organizations. The criteria established by the state agency pursuant to this subparagraph shall be consistent with standards and procedures established under section 1306 (c) of P.L. 93-222, known as the Health Maintenance Organizations Act of 1973; 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 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 (c) 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 ~~on~~ 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 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 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 intermediate care services, the addition will be con-

sistent 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.

- q. 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:

~~1~~(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

~~2~~(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 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).

s. 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.

The State Agency may utilize and develop standards 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.

CON Reg. §19. DURATION OF CERTIFICATE OF NEED. A Certificate of Need shall be valid for a maximum 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, the person holding the Certificate shall submit in writing to the State Agency, with a copy to the designated Health Systems Agency, a report on the progress being made toward completion of the project. Such report shall be submitted not more than ninety (90) nor less than sixty (60) days prior to the expiration of the Certificate of Need. The person holding the Certificate shall submit any relevant additional information 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. Creation of shelled in space shall not be considered completion unless explicitly provided for in the decision. New conditions, unrelated to representations made by the applicant, may not be added to the project at the time of recertification.

The Certificate may be revoked by the State Agency 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.

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

CON Reg. §20. FINAL CONFORMANCE REVIEW. All new institutional health services shall receive a final conformance review by the State Agency immediately prior to their first use. No later than sixty (60) days prior to the first use or first receipt of patients, the applicant shall request in writing a final conformance review by the State Agency. A copy of the request shall be sent to the Health Systems Agency.

The State Agency shall issue findings as to the conformance on the basis of a site review within forty-five (45) days of the receipt of the request for a final review. In issuing such findings the State Agency

shall consider the recommendation of the Health Systems Agency. A finding that a project does not conform to its certification may be grounds for a revocation or denial of a license to operate the facility or for seeking an injunction against the use or operation of the facility.

CON Reg. §21. PROJECT CHANGES AFTER CERTIFICATION. 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. In making its determination of whether changes proposed are substantial, the State Agency shall consider whether any of the following have occurred:

- a. Change in location; or
- b. Change in ownership of the facility or organization; or
- c. Change in project scope, including but not limited to increases or decreases in:
 - 1) number and/or type of beds
 - 2) number and/or type of equipment (moveable or fixed)
 - 3) types and/or mix of services
 - 4) contracts for services
 - 5) square footage; or
- d. Change in method or cost of financing;

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

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. Failure to inform the State Agency of such a project change may result in revocation of the Certificate of Need by the State Agency.

No 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 require the submission of a new application for a Certificate of Need.

CON Reg. §22. TRANSFERABILITY. 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 transfer of a Certificate will result in its automatic revocation.

CON Reg. §23. 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.

§24.01. REQUEST FOR 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.

§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 admissability 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 reconsideration 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 under 42 C.F.R. §123.408 for deferral decisions, a deferral. In the case of a deferral, CON Reg. §10.03(b) applies.

§24.07. STATEMENT TO HSA. If the State Agency makes a decision regarding a proposed new institutional health service which is 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 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.

§25.01. REQUEST FOR HEARING. The HSA, when a final decision of SHPDA 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.

§25.02. 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 by the State Agency within 30 days of the date on which the person proposing the new institutional health services receives notice of the State Agency's written decision, if the request is made by such person. In all other cases, the written request for a hearing 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 HEARING OFFICERS. No person who has taken part in any prior consideration of or action upon the proposed capital expenditure 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. 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. (The question of the State Agency's adherence to its procedures may also be considered.)

§25.07. HOW HEARINGS CONDUCTED. Pending the decision of the appeals agency, the State Agency or the Hearing Officer may delay the enforcement 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 123, 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, all developed pursuant to the Public Health Service Act (P.L. 93-641) or the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963) 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 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.

§25.08. 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 under 42 C.F.R. §123.408 for deferral decisions, a deferral, or the hearing officer may remand the matter to the SHPDA for further action or consideration. In the case of a

deferral, CON Reg. §10.03(b) applies. 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.

§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.

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. §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 regulations are declared to be severable.

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