WEST VIRGINIA LEGISLATURE
REGULAR SESSION, 1985

ENROLLED
Committee Substitute for
SENATE BILL NO. 616

(By Mr. Lee)

PASSED April 13, 1985
In Effect upon enactment
AN ACT to amend and reenact sections two, three, four, five, seven, nine and thirteen, article two-d, chapter sixteen of the code of West Virginia, one thousand nine hundred thirty-one, as amended; and to further amend article two-d of said chapter by adding thereto two new sections, designated sections fourteen and fifteen, all relating to certificate of need; increasing the minimum levels for expenditures and major medical equipment subject to review and for health services exempted from review; providing for review of community mental health and retardation facilities and private office practice of licensed health professionals under certain circumstances, authorizing ninety-day agency imposed moratorium on applications involving new medical technology in absence of criteria for review; providing for imposition of conditions of operation for no longer than a three-year period with the issuance of a certificate of need; three-year statute of limitations for state agency to correct violations; previously approved rules and regulations to remain in force.
Be it enacted by the Legislature of West Virginia:

That sections two, three, four, five, seven, nine and thirteen, article two-d, chapter sixteen of the code of West Virginia, one thousand nine hundred thirty-one, as amended, be amended and reenacted; and that article two-d be further amended by adding thereto two new sections, designated sections fourteen and fifteen, all to read as follows:

ARTICLE 2D. CERTIFICATE OF NEED.

§16-2D-2. Definitions.

1 As used in this article, unless otherwise indicated by the context:
2 (a) “Affected person” means:
3 (1) The applicant;
4 (2) An agency or organization representing consumers;
5 (3) Any individual residing within the geographic area served or to be served by the applicant;
6 (4) Any individual who regularly uses the health care facilities within that geographic area;
7 (5) The health care facilities located in the applicable health service area which provide services similar to the services of the facility under review;
8 (6) The health care facilities which, prior to receipt by the state agency of the proposal being reviewed, have formally indicated an intention to provide similar services in the future;
9 (7) Third party payers who reimburse any health care facilities for services in the applicable health service area;
10 (8) Any agency which establishes rates for the health care facilities located in the applicable health service area;
11 or
12 (9) Organizations representing health care providers.
13 (b) “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 private office practice of any one or more health professionals licensed to practice in this state pursuant to the provisions of chapter thirty of this code: Provided, That such exemption from review of private office practice shall
not be construed to include such practices where major medical equipment otherwise subject to review under the provisions of this article is acquired, offered or developed.

(c) "Ambulatory surgical facility" means a facility which is free-standing and not physically attached to a health care facility and which provides surgical treatment to patients not requiring hospitalization. This definition does not include the private office practice of any one or more health professionals licensed to practice surgery in this state pursuant to the provisions of chapter thirty of this code: Provided, That such exemption from review of private office practice shall not be construed to include such practices where major medical equipment otherwise subject to review under the provisions of this article is acquired, offered or developed.

(d) "Annual implementation plan" means a plan established, annually reviewed and amended as necessary by a health systems agency in conformance with Section 1513(b)(3) of the Public Health Service Act, as amended, Title 42 United States Code section 3001-2(b)(3), which describes objectives which will achieve the goals of the health systems plan, or, if those goals are amended by the statewide health coordinating council when included in the state health plan, as so amended, and priorities among the objectives.

(e) "Applicable health service area" means a health service area, as defined in this section, in which a new institutional health service is proposed to be located.

(f) "Applicant" means: (1) The governing body or the person proposing a new institutional health service who is, or will be, the health care facility licensee wherein the new institutional health service is proposed to be located, and (2) in the case of a proposed new institutional health service not to be located in a licensed health care facility, the governing body or the person proposing to provide such new institutional health service. Incorporators or promoters who will not constitute the governing body or persons responsible for the new institutional health service may not be an applicant.

(g) "Bed capacity" means the number of beds for which a license is issued to a health care facility, or, if a facility is unlicensed, the number of adult and pediatric beds
(h) “Capital expenditure” means an expenditure:

(1) Made by or on behalf of a health care facility; and

(2) (A) Which (i) under generally accepted accounting principles is not properly chargeable as an expense of operation and maintenance, or (ii) is made to obtain either by lease or comparable arrangement any facility or part thereof or any equipment for a facility or part; and (B) which (i) exceeds the expenditure minimum, or (ii) is a substantial change to the bed capacity of the facility with respect to which the expenditure is made, or (iii) is a substantial change to the services of such facility. For purposes of part (i), subparagraph (B), subdivision (2) of this definition, the cost of any studies, surveys, designs, plans, working drawings, specifications, and other activities, including staff effort and consulting and other services, essential to the acquisition, improvement, expansion, or replacement of any plant or equipment with respect to which an expenditure described in subparagraph (B), subdivision (2) of this definition is made shall be included in determining if such expenditure exceeds the expenditure minimum. Donations of equipment or facilities to a health care facility which if acquired directly by such facility would be subject to review shall be considered capital expenditures, and a transfer of equipment or facilities for less than fair market value shall be considered a capital expenditure for purposes of such subdivisions if a transfer of the equipment or facilities at fair market value would be subject to review. A series of expenditures, each less than the expenditure minimum, which when taken together are in excess of the expenditure minimum, may be determined by the state agency to be a single capital expenditure subject to review. In making its determination, the state agency shall consider: Whether the expenditures are for components of a system which is required to accomplish a single purpose; whether the expenditures are to be made over a two-year period and are directed towards the accomplishment of a single goal within the health care facility’s long-range plan; or, whether 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.
(i) "Expenditure minimum" means seven hundred fourteen thousand dollars for the twelve-month period beginning the first day of October, one thousand nine hundred eighty-five. For each twelve-month period thereafter, the state agency may, by regulations adopted pursuant to section eight of this article, adjust the expenditure minimum to reflect the impact of inflation.

(j) "Health," used as a term, includes physical and mental health.

(k) "Health care facility" is defined as including hospitals, skilled nursing facilities, kidney disease treatment centers, including free-standing hemodialysis units, intermediate care facilities, ambulatory health care facilities, ambulatory surgical facilities, home health agencies, rehabilitation facilities, and health maintenance organizations, 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. For purposes of this definition, "community mental health and mental retardation facility" means a 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.

(l) "Health care provider" means a person, partnership, corporation, facility or institution licensed or certified or authorized by law to provide professional health care service in this state to an individual during that individual's medical care, treatment or confinement.

(m) "Health maintenance organization" means a public or private organization, organized under the laws of this state, which:

(1) Is a qualified health maintenance organization under Section 1310(d) of the Public Health Service Act, as amended, Title 42 United States Code Section 300e-9(d); or

(2) (A) Provides or otherwise makes available to enrolled participants health care services, including substantially the following basic health care services: usual physician services, hospitalization, laboratory, X-ray, emergency and preventive services, and out-of-area coverage; and
B) Is compensated except for copayments for the provision of the basic health care services listed in subparagraph (2)(A), subdivision (m) of this definition to enrolled participants on a predetermined periodic rate basis without regard to the date the health care services are provided and which is fixed without regard to the frequency, extent, or kind of health service actually provided; and
C) Provides physicians' services primarily (i) directly through physicians who are either employees or partners of such organization, or (ii) through arrangements with individual physicians or one or more groups of physicians organized on a group practice or individual practice basis.
(n) "Health service area" means a geographic area designated by the Federal Secretary of Health and Human Services pursuant to Section 1511 of the Public Health Services Act, as amended, Title 42 United States Code Section 3001, with respect to which health systems agencies shall be designated under Section 1515 of such act, as amended, Title 42 United States Code Section 3001-4.
(o) "Health services" means clinically related preventive, diagnostic, treatment or rehabilitative services, including alcohol, drug abuse and mental health services.
(p) "Home health agency" is an organization primarily engaged in providing directly or through contract arrangements, professional nursing services, home health aide services, and other therapeutic and related services including, but not limited to, physical, speech and occupational therapy and nutritional and medical social services, to persons in their place of residence on a part-time or intermittent basis.
(q) "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. This term also includes psychiatric and tuberculosis hospitals.
(r) "Intermediate care facility" means an institution which provides, on a regular basis, health-related care and services to individuals who do not require the degree of care
(s) "Long-range plan" means a document formally adopted by the legally constituted governing body of an existing health care facility or by a person proposing a new institutional health service. Each long-range plan shall consist of the information required by the state agency in regulations adopted pursuant to section eight of this article.

(t) "Major medical equipment" means a single unit of medical equipment or a single system of components with related functions which is used for the provision of medical and other health services and which costs in excess of four hundred thousand dollars, except that such term does not include medical equipment acquired by or on behalf of a clinical laboratory to provide clinical laboratory services if the clinical laboratory is independent of a physician’s office and a hospital and it has been determined under Title XVIII of the Social Security Act to meet the requirements of paragraphs ten and eleven of Section 1861(s) of such act, Title 42 United States Code Sections 1395x(10) and (11). In determining whether medical equipment costs more than four hundred thousand dollars, the cost of studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the acquisition of such equipment shall be included. If the equipment is acquired for less than fair market value, the term “cost” includes the fair market value.

(u) “Medically underserved population” means the population of an urban or rural area designated by the state agency as an area with a shortage of personal health services or a population having a shortage of such services, after taking into account unusual local conditions which are a barrier to accessibility or availability of such services. Such designation shall be in regulations adopted by the state agency pursuant to section eight of this article, and the population so designated may include the state’s medically underserved population designated by the Federal Secretary of Health and Human Services under Section 330(b)(3) of the Public Health Service Act, as amended, Title 42 United States Code Section 254(b)(3).
(v) "New institutional health service" means such service as described in section three of this article.

(w) "Offer" when used in connection with health services, means that the health care facility or health maintenance organization holds itself out as capable of providing, or as having the means for the provision of, specified health services.

(x) "Person" means an individual, trust, estate, partnership, committee, corporation, association and other organizations such as joint-stock companies and insurance companies, a state or a political subdivision or instrumentality thereof or any legal entity recognized by the state.

(y) "Physician" means a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the state.

(z) "Proposed new institutional health service" means such service as described in section three of this article.

(aa) "Psychiatric hospital" means an institution which primarily provides to inpatients, by or under the supervision of a physician, specialized services for the diagnosis, treatment and rehabilitation of mentally ill and emotionally disturbed persons.

(bb) "Rehabilitation facility" means an inpatient facility which is operated for the primary purpose of assisting in the rehabilitation of disabled persons through an integrated program of medical and other services which are provided under competent professional supervision.

(cc) "Review agency" means an agency of the state designated by the governor as the agency for the review of state agency decisions.

(dd) "Skilled nursing facility" means an institution or a distinct part of an institution which is primarily engaged in providing to inpatients skilled nursing care and related services for patients who require medical or nursing care, or rehabilitation services for the rehabilitation of injured, disabled or sick persons.

(ee) "State agency" means that agency of state government selected by the governor and designated as the state health planning and development agency in an agreement entered into pursuant to Section 1521 of the Public Health Service Act, as amended, Title 42 United States Code Section 300m.
“State health plan” means the document approved by the governor after preparation 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).

“Statewide health coordinating council” means the body established pursuant to Section 1524 of the Public Health Service Act, as amended, Title 42 United States Code Section 300m-3, to advise the state agency.

“Substantial change to the bed capacity” of a health care facility means a change, with which a capital expenditure is associated, in any two-year period of ten or more beds or more than ten percent, whichever is less, of the bed capacity of such facility that increases or decreases the bed capacity, redistributes beds among various categories, or relocates beds from one physical facility or site to another. A series of changes to the bed capacity of a health care facility in any two-year period, each less than ten beds or ten percent of the bed capacity of such facility, but which when taken together comprise ten or more beds or more than ten percent of the bed capacity of such facility, whichever is less, is a substantial change to the bed capacity.

“Substantial change to the health services” of a health care facility means the addition of a health service which is offered by or on behalf of the health care facility and which was not offered by or on behalf of the facility within the twelve-month period before the month in which the service is first offered, or the termination of a health service which was offered by or on behalf of the facility.

“To develop,” when used in connection with health services, means to undertake those activities which, upon their completion, will result in the offer of a new institutional health service or the incurring of a financial obligation, in relation to the offering of such a service.

“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.

§16-2D-3. Certificate of need.

Except as provided in section four of this article, any new
Whenever a new institutional health service for which a certificate of need is required by this article is proposed for a health care facility for which, pursuant to section four of this article, no certificate of need is or was required, a certificate of need shall be issued before the new institutional health service is offered or developed. No person may knowingly charge or bill for any health services associated with any new institutional health service that is knowingly acquired, offered or developed in violation of this article, and any bill made in violation of this sentence is legally unenforceable. For purposes of this article, a proposed "new institutional health service" includes:

(a) The construction, development, acquisition or other establishment of a new health care facility or health maintenance organization;

(b) The partial or total closure of a health care facility or health maintenance organization with which a capital expenditure is associated;

(c) Any obligation for a capital expenditure incurred by or on behalf of a health care facility, except as exempted in section four of this article, or health maintenance organization in excess of the expenditure minimum or any obligation for a capital expenditure incurred by any person to acquire a health care facility. An obligation for a capital expenditure is considered to be incurred by or on behalf of a health care facility:

(1) When a contract, enforceable under state law, is entered into by or on behalf of the health care facility for the construction, acquisition, lease or financing of a capital asset;

(2) When the governing board of the health care facility takes formal action to commit its own funds for a construction project undertaken by the health care facility as its own contractor; or

(3) In the case of donated property, on the date on which the gift is completed under state law;

(d) A substantial change to the bed capacity of a health care facility with which a capital expenditure is associated;

(e) The addition of health services which are offered by
or on behalf of a health care facility or health maintenance
organization and which were not offered on a regular basis
by or on behalf of such health care facility or health
maintenance organization within the twelve-month period
prior to the time such services would be offered;
(f) The deletion of one or more health services,
previously offered on a regular basis by or on behalf of a
health care facility or health maintenance organization
which deletion is associated with a capital expenditure;
(g) A substantial change to the bed capacity or health
services offered by or on behalf of a health care facility,
whether or not the change is associated with a proposed
capital expenditure, if the change is associated with a
previous capital expenditure for which a certificate of need
was issued and if the change will occur within two years
after the date the activity which was associated with the
previously approved capital expenditure was undertaken;
(h) The acquisition of major medical equipment; and
(i) A substantial change in an approved new
institutional health service for which a certificate of need is
in effect. For purposes of this subdivision “substantial
change” shall be defined by the state agency in regulations
adopted pursuant to section eight of this article.
§16-2D-4. Exemptions from certificate of need program.
(a) Except as provided in subdivision (h), section three
of this article, nothing in this article or the rules and
regulations adopted pursuant to the provisions of this
article may be construed to authorize the licensure,
supervision, regulation or control in any manner of: (1)
Private office practice of any one or more health
professionals licensed to practice in this state pursuant to
the provisions of chapter thirty of this code: Provided, That
such exemption from review of private office practice shall
not be construed to include such practices where major
medical equipment otherwise subject to review under the
provisions of this article is acquired, offered or developed;
(2) dispensaries and first-aid stations located within
business or industrial establishments maintained solely for
the use of employees: Provided, however, 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; (3) establishments, such as motels, hotels and boardinghouses, which provide medical, nursing personnel and health related services; and (4) 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 of tenets of any recognized church or religious denomination.

(b) (1) A certificate of need is not required for the offering of an inpatient institutional health service or the acquisition of major medical equipment for the provision of an inpatient institutional health service, if with respect to such offering, acquisition, or obligation, the state agency has, upon application under subdivision (2), subsection (b) of this section, granted an exemption to:

(A) A health maintenance organization or a combination of health maintenance organizations if (i) the organization or combination of organizations has, in the service area of the organization or the service areas of the organizations in the combination, an enrollment of at least fifty thousand individuals, (ii) the facility in which the service will be provided is or will be geographically located so that the service will be reasonably accessible to such enrolled individuals, and (iii) at least seventy-five percent of the patients who can reasonably be expected to receive the institutional health service will be individuals enrolled with such organization or organizations in the combination;

(B) A health care facility if (i) the facility primarily provides or will provide inpatient health services, (ii) the facility is or will be controlled, directly or indirectly, by a health maintenance organization or a combination of health maintenance organizations which has, in the service area of the organization or service areas of the organizations in the combination, an enrollment of at least fifty thousand individuals, (iii) the facility is or will be geographically located so that the service will be reasonably accessible to such enrolled individuals, and (iv) at least seventy-five percent of the patients who can reasonably be expected to receive the institutional health
service will be individuals enrolled with such organization or organizations in the combination; or

(C) A health care facility, or portion thereof, if (i) the facility is or will be leased by a health maintenance organization or combination of health maintenance organizations which has, in the service area of the organization or the service areas of the organizations in the combination, an enrollment of at least fifty thousand individuals and on the date the application is submitted under subdivision (2), subsection (b) of this section, at least fifteen years remain in the term of the lease, (ii) the facility is or will be geographically located so that the service will be reasonably accessible to such enrolled individuals, and (iii) at least seventy-five percent of the patients who can reasonably be expected to receive the new institutional health service will be individuals enrolled with such organization.

(2) (A) A health maintenance organization, combination of health maintenance organizations, or other health care facility is not exempt under subdivision (1), subsection (b) of this section, from obtaining a certificate of need unless:

(i) It has submitted, at such time and in such form and manner as the state agency shall prescribe, an application for such exemption to the state agency;

(ii) The application contains such information respecting the organization, combination, or facility and the proposed offering, acquisition, or obligation as the state agency may require to determine if the organization or combination meets the requirements of subdivision (1), subsection (b) of this section, or the facility meets or will meet such requirements; and

(iii) The state agency approves such application.

(B) The state agency shall approve an application submitted under subparagraph (A), subdivision (2), subsection (b) of this section, if it determines that the applicable requirements of subdivision (1), subsection (b) of this section, are met or will be met on the date the proposed activity for which an exemption was requested will be undertaken.

(3) A health care facility, or any part thereof, or medical equipment with respect to which an exemption was granted
under subdivision (1), subsection (b) of this section, may not be sold or leased and a controlling interest in such facility or equipment or in a lease of such facility or equipment may not be acquired and a health care facility described in subparagraph (C), subdivision (1), subsection (b) of this section, which was granted an exemption under subdivision (1), subsection (b) of this section, may not be used by any person other than the lessee described in subparagraph (C), subdivision (1), subsection (b) of this section, unless:

(A) The state agency issues a certificate of need approving the sale, lease, acquisition, or use; or

(B) The state agency determines, upon application, that the entity to which the facility or equipment is proposed to be sold or leased, which intends to acquire the controlling interest in or to use the facility is:

(i) A health maintenance organization or a combination of health maintenance organizations which meets the enrollment requirements of part (i), subparagraph (A), subdivision (1), subsection (b) of this section, and with respect to such facility or equipment, the entity meets the accessibility and patient enrollment requirements of parts (ii) and (iii), subparagraph (A), subdivision (1), subsection (b) of this section; or

(ii) A health care facility which meets the inpatient, enrollment, and accessibility requirements of parts (i), (ii) and (iii), subparagraph (B), subdivision (1), subsection (b) of this section, and with respect to its patients meets the enrollment requirements of part (iv), subparagraph (B), subdivision (1), subsection (b) of this section.

(4) In the case of a health maintenance organization or an ambulatory care facility or health care facility which ambulatory or health care facility is controlled, directly or indirectly, by a health maintenance organization or a combination of health maintenance organizations, the certificate of need requirements apply only to the offering of inpatient institutional health services, the acquisition of major medical equipment, and the obligation of capital expenditures for the offering of inpatient institutional health services and then only to the extent that such offering, acquisition, or obligation is not exempt under subdivision (1), subsection (b) of this section.

(5) The state agency shall establish the period within
which approval or disapproval by the state agency of
applications for exemptions under subdivision (1),
subsection (b) of this section, shall be made.
(c) (1) A health care facility is not required to obtain a
certificate of need for the acquisition of major medical
equipment to be used solely for research, the addition of
health services to be offered solely for research, or the
obligation of a capital expenditure to be made solely for
research if the health care facility provides the notice
required in subdivision (2), subsection (c) of this section,
and the state agency does not find, within sixty days after it
receives such notice, that the acquisition, offering or
obligation will, or will have the effect to:
(A) Affect the charges of the facility for the provision of
medical or other patient care services other than the
services which are included in the research;
(B) Result in a substantial change to the bed capacity of
the facility; or
(C) Result in a substantial change to the health services
of the facility.
(2) Before a health care facility acquires major medical
equipment to be used solely for research, offers a health
service solely for research, or obligates a capital
expenditure solely for research, such health care facility
shall notify in writing the state agency of such facility's
intent and the use to be made of such medical equipment,
health service, or capital expenditure.
(3) If major medical equipment is acquired, a health
service is offered, or a capital expenditure is obligated and a
certificate of need is not required for such acquisition,
offering, or obligation as provided in subdivision (1),
subsection (c) of this section, such equipment or service or
equipment or facilities acquired through the obligation of
such capital expenditure may not be used in such a manner
as to have the effect or to make a change described in
subparagraphs (A), (B) and (C), subdivision (1), subsection
(c) of this section, unless the state agency issues a certificate
of need approving such use.
(4) For purposes of this subsection, the term "solely for
research" includes patient care provided on an occasional
and irregular basis and not as part of a research program.
(d) (1) The state agency may adopt regulations
pursuant to section eight of this article to specify the circumstances under which a certificate of need may not be required for the obligation of a capital expenditure to acquire, either by purchase or under lease or comparable arrangement, an existing health care facility: Provided, That a certificate of need shall be required for the obligation of a capital expenditure to acquire, either by purchase or under lease or comparable arrangement, an existing health care facility if:

(A) The notice required by subdivision (2), subsection (d) of this section, is not filed in accordance with that subdivision with respect to such acquisition; or (B) the state agency finds, within thirty days after the date it receives a notice in accordance with subdivision (2), subsection (d) of this section, with respect to such acquisition, that the services or bed capacity of the facility will be changed by reason of said acquisition.

(2) Before any person enters into a contractual arrangement to acquire an existing health care facility, such person shall notify the state agency of his or her intent to acquire the facility and of the services to be offered in the facility and its bed capacity. Such notice shall be made in writing and shall be made at least thirty days before contractual arrangements are entered into to acquire the facility with respect to which the notice is given. The notice shall contain all information the state agency requires in accordance with subsections (e) and (u), section seven of this article.

(e) The state agency shall adopt regulations, pursuant to section eight of this article, wherein criteria are established to exempt from review the addition of certain health services, not associated with a capital expenditure, that are projected to entail annual operating costs of less than the expenditure minimum for annual operating costs. For purposes of this subsection, “expenditure minimum for annual operating costs” means two hundred ninety-seven thousand five hundred dollars for the twelve-month period beginning the first day of October, one thousand nine hundred eighty-five, and for each twelve-month period thereafter, the state agency may, by regulations adopted pursuant to section eight of this article, adjust the expenditure minimum for annual operating costs to reflect the impact of inflation.
§16-2D-5. Powers and duties of state health planning and development agency.

(a) The state agency is hereby empowered to administer the certificate of need program as provided by this article.

(b) The state agency shall cooperate with the statewide health coordinating council in developing rules and regulations for the certificate of need program to the extent appropriate for the achievement of efficiency in their reviews and consistency in criteria for such reviews.

(c) The state agency may seek advice and assistance of other persons, organizations, and other state agencies in the performance of the state agency’s responsibilities under this article.

(d) For health services for which competition appropriately allocates supply consistent with the state health plan, the state agency shall, in the performance of its functions under this article, give priority, where appropriate, to advance the purposes of quality assurance, cost effectiveness, and access, to actions which would strengthen the effect of competition on the supply of such services.

(e) For health services for which competition does not or will not appropriately allocate supply consistent with the state health plan, the state agency shall, in the exercise of its functions under this article, take actions, where appropriate, to advance the purposes of quality assurance, cost effectiveness, and access and the other purposes of this article, to allocate the supply of such services.

(f) The state agency is hereby empowered to order a moratorium upon the processing of an application or applications for the acquisition of major medical equipment filed pursuant to section three of this article and considered by the agency to be new medical technology, when criteria and guidelines for evaluating the need for such new medical technology have not yet been adopted. Such moratoriums shall be declared by a written order which shall detail the circumstances requiring the moratorium. Upon the adoption of criteria for evaluating the need for the new medical technology affected by the moratorium, or ninety days from the declaration of a moratorium, whichever is less, the moratorium shall be
declared to be over and affected applications shall be processed pursuant to section six of this article.

§16-2D-7. Procedures for certificate of need reviews.

(a) Prior to submission of an application for a certificate of need, the state agency shall require the submission of long-range plans by health care facilities with respect to the development of proposals subject to review under this article. The plans shall be in such form and contain such information as the state agency shall require.

(b) An application for a certificate of need shall be submitted to the state agency prior to the offering or development of all new institutional services within this state. Persons proposing new institutional health services shall submit letters of intent not less than fifteen days prior to submitting an application. The letters of intent shall be of such detail as specified by the state agency.

(c) The state agency may adopt regulations pursuant to section eight of this article for:

(1) Provision for applications to be submitted in accordance with a timetable established by the state agency;

(2) Provision for such reviews to be undertaken in a timely fashion; and

(3) Except for proposed new institutional health services which meet the requirements for consideration under subsection (g), section nine of this article with regard to the elimination or prevention of certain imminent safety hazards or to comply with certain licensure or accreditation standards, provision for all completed applications pertaining to similar types of services, facilities or equipment to be considered in relation to each other, at least twice a year.

(d) An application for a certificate of need shall specify the time the applicant will require to make such service or equipment available or to obligate such expenditure and a timetable for making such service or equipment available or obligating such expenditure.

(e) The application shall be in such form and contain such information as the state agency shall establish by rule or regulation, but requests for information shall be limited
to only that information which is necessary for the state agency to perform the review.

(f) Within fifteen days of receipt of application, the state agency shall determine if the application is complete. The state agency may request additional information from the applicant.

(g) The state agency shall provide timely written notice to the applicant and to all affected persons of the beginning of the review, and to any person who has asked the state agency to place the person's name on a mailing list maintained by the state agency. Notification shall include the proposed schedule for review, the period within which a public hearing during the course of the review may be requested by affected persons, which period may not be less than thirty days from the date of the written notification of the beginning of the review required by this section, and the manner in which notification will be provided of the time and place of any public hearing so requested. For the purposes of this subsection, the date of notification is the date on which the notice is sent or the date on which the notice appears in a newspaper of general circulation, whichever is later.

(h) Written notification to members of the public and third-party payers may be provided through newspapers of general circulation in the applicable health service area and public information channels; notification to all other affected persons shall be by mail which may be as part of a newsletter.

(i) If, after a review has begun, the state agency requires the person subject to the review to submit additional information respecting the subject of the review, such person shall be provided at least fifteen days to submit the information and the state agency shall, at the request of such person, extend the review period by fifteen days. This extension applies to all other applications which have been considered in relation to the application for which additional information is required.

(j) The state agency shall adopt schedules for reviews which provide that no review may, to the extent practicable, take longer than ninety days from the date that notification, as described under subsection (g) of this section, is sent to the applicant to the date of the final
decision of the state agency, and in the case of expedited applications, may by regulations adopted pursuant to section eight of this article provide for a shortened review period.

(k) The state agency shall adopt criteria for determining when it would not be practicable to complete a review within ninety days.

(i) The state agency shall provide a public hearing in the course of agency review if requested by any affected person and the state agency may on its own initiate such a public hearing:

(1) The state agency shall, prior to such hearing, provide notice of such hearing and shall conduct such hearing in accordance with administrative hearing requirements in article five, chapter twenty-nine-a of this code, and its procedure adopted pursuant to this section.

(2) In a hearing any person has the right to be represented by counsel and to present oral or written arguments and evidence relevant to the matter which is the subject of the hearing. Any person affected by the matter which is the subject of the hearing may conduct reasonable questioning of persons who make factual allegations relevant to such matter.

(3) The state agency shall maintain a verbatim record of the hearing.

(4) After the commencement of a hearing on the applicant's application and before a decision is made with respect to it, there may be no ex parte contacts between (a) the applicant for the certificate of need, any person acting on behalf of the applicant or holder of a certificate of need, or any person opposed to the issuance of a certificate for the applicant and (b) any person in the state agency who exercises any responsibility respecting the application.

(5) The state agency may not impose fees for such a public hearing.

(m) If a public hearing is not conducted during the review of a new institutional health service, the state agency may, by regulations adopted pursuant to section eight of this article, provide for a file closing date during the review period after which date no other factual information or evidence may be considered in the determination of the application for the certificate of need.
A detailed itemization of documents in the state agency file on a proposed new institutional health service shall, on request, be made available by the state agency at any time before the file closing date.

(n) The extent of additional information received by the state agency from the applicant for a certificate of need after a review has begun on the applicant's proposed new institutional health service, with respect to the impact on such new institutional health service and additional information which is received by the state agency from the applicant, may be cause for the state agency to determine the application to be a new proposal, subject to a new review cycle.

(o) The state agency shall in timely fashion notify, upon request, providers of health services and other persons subject to review under this article of the status of the state agency review of new institutional health services subject to review, findings made in the course of such review, and other appropriate information respecting such review.

(p) The state agency shall prepare and publish, at least annually, reports of reviews completed and being conducted, with general statements about the status of each review still in progress and the findings and rationale for each completed review since the publication of the last report.

(q) The state agency shall provide for access by the general public to all applications reviewed by the state agency and to all other pertinent written materials essential to agency review.

(r) (1) Any person may request in writing a public hearing for purposes of reconsideration of a state agency decision. No fees may be imposed by the state agency for the hearing. For purposes of this section, a request for a public hearing for purposes of reconsideration shall be deemed to have shown good cause if, in a detailed statement, it:

(A) Presents significant, relevant information not previously considered by the state agency, and demonstrates that with reasonable diligence the information could not have been presented before the state agency made its decision;

(B) Demonstrates that there have been significant changes in factors or circumstances relied upon by the state agency in reaching its decision;
(C) Demonstrates that the state agency has materially failed to follow its adopted procedures in reaching its decision; or (D) Provides such other bases for a public hearing as the state agency determines constitutes good cause.

(2) To be effective, a request for such a hearing shall be received within thirty days after the date upon which all parties received notice of the state agency decision, and the hearing shall commence within thirty days of receipt of the request.

(3) Notification of such public hearing shall be sent, prior to the date of the hearing, to the person requesting the hearing, the person proposing the new institutional health service, and shall be sent to others upon request.

(4) The state agency shall hold public reconsideration hearings in accordance with the provisions for administrative hearings contained in:

(A) Its adopted procedures;
(B) Ex parte contact provisions of subdivision (4), subsection (1) of this section; and
(C) The administrative procedures for contested cases contained in article five, chapter twenty-nine-a of this code.

(5) The state agency shall make written findings which state the basis for its decision within forty-five days after the conclusion of such hearing.

(6) A decision of the state agency following a reconsideration hearing shall be considered a decision of the state agency for purposes of sections nine and ten of this article and for purposes of the notification of the status of review, findings and annual report provisions of subsections (o) and (p) of this section.

(8) The state agency may adopt regulations pursuant to section eight of this article for reviews and such regulations may vary according to the purpose for which a particular review is being conducted or the type of health services being reviewed.

(1) Notwithstanding other provisions of this article, the state agency shall adopt rules and regulations for determining when there is an application which warrants expedited review. If procedures adopted by the state agency to handle expedited applications do not conform to the
provisions of this article, such procedures shall be approved
by the federal secretary of health and human services and
shall be adopted as regulations pursuant to section eight of
this article.

§16-2D-9. Agency to render final decision; issue certificate of
need; write findings; specify capital expenditure
maximum.

(a) Only the state agency, or the appropriate
administrative or judicial review body, may issue, deny or
withdraw certificates of need, grant exemptions from
certificate of need reviews, or determine that certificate of
need reviews are not required.
(b) Except as provided in subsection (f) of this section, a
certificate of need may only be issued if the proposed new
institutional health service is:
(1) Found to be needed; and
(2) Except in emergency circumstances that pose a threat to public health, consistent with the state health plan: Provided, That if a health care facility which is controlled, directly or indirectly, by a health maintenance organization applies for a certificate of need for a proposed new institutional health service, the state agency may not disapprove the application solely because such an institutional health service is not discussed in the state health plan or annual implementation plan.
(c) The state agency shall render a final decision on every application for a certificate of need or application for exemption in the form of an approval, a denial, or an approval with conditions. Any decision of the state agency with respect to a certificate of need, or exemption, shall be based solely on:
(1) The review of the state agency conducted in accordance with procedures and criteria in this article and in regulations adopted pursuant to section eight of this article; and
(2) The record established in administrative proceedings held with respect to the certificate of need or exemption.
(d) Approval with conditions does not give the state agency authority to mandate new institutional health services not proposed by the health care facility or health
maintenance organization. Issuance of a certificate of need or exemption may not be made subject to any condition unless the condition directly relates to criteria in this article or in rules and regulations adopted pursuant to section eight of this article. Conditions may be imposed upon the operations of the health care facility or health maintenance organization for no longer than a three-year period. Compliance with such conditions may be enforced through the mechanisms detailed in section thirteen of this article.

(e) (1) For each proposed new institutional health service it approves, the state agency shall, in addition to the written findings required in subsection (e), section six of this article, make 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 subdivisions (4), (14), and (25), subsection (a), section six of this article, regarding the needs of medically underserved population, except in the following cases:

(A) Where the proposed new institutional health service is one described in subsection (g) of this section to eliminate or prevent certain imminent safety hazards or to comply with certain licensure or accreditation standards; or

(B) 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; or

(C) Where the new institutional health service is proposed by or on behalf of a health care facility which is controlled, directly or indirectly, by a health maintenance organization.

(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.

(f) (1) Notwithstanding review criteria in subdivision (12), subsection (a), section six of this article, 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, in accordance with criteria prescribed by the state agency by regulations adopted pursuant to section eight of this article, that:
(A) Approval of such application is required to meet the needs of the members of the health maintenance organization and of the new members which such organization can reasonably be expected to enroll; and

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

(2) Except as provided in subdivision (1), subsection (b), section four of this article, a health care facility, or any part thereof, or medical equipment with respect to which a certificate of need was issued under this subsection, may not be sold or leased, and a controlling interest in such facility or equipment or in a lease of such facility or equipment may not be acquired unless the state agency issues a certificate of need approving the sale, acquisition or lease.

(g) (1) Notwithstanding review criteria in section six of this article, an application for a certificate of need shall be approved, if the state agency finds that the facility or service with respect to which such 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:

(A) To eliminate or prevent imminent safety hazards as defined by federal, state or local fire, building or life safety codes or regulations;

(B) To comply with state licensure standards; or

(C) 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.

(2) 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 subparagraph (A), subdivision (1), subsection (g), or to comply with the
standards described in either subparagraph (B) or (C) of subdivision (1), subsection (g) of this section.

(h) (1) The state agency shall send its decision along with written findings to the person proposing the new institutional health service or exemption and shall make it available to others upon request.

(2) In the case of a new institutional health service proposed by a health maintenance organization, the state agency shall send the written findings to the appropriate [122]

regional office of the federal department of health and human services at the time they are sent to the applicant.

(3) In any decision where the state agency finds that a proposed new institutional health service does not satisfy the criteria in subdivisions (4), (14), and (25), subsection (a), section six of this article, regarding the needs of medically underserved population, it shall so notify in writing the applicant and the appropriate regional office of the federal department of health and human services.

(i) In the case of a final decision to approve or approve with conditions a proposal for a new institutional health service, the state agency shall issue a certificate of need to the person proposing the new institutional health service.

(j) The state agency shall specify in the certificate the maximum amount of capital expenditures which may be obligated under such certificate. The state agency shall prescribe the method used to determine capital expenditure maximums and shall adopt regulations pursuant to section eight of this article for the review of approved new institutional health services for which the capital expenditure maximum is exceeded or is expected to be exceeded.

(k) If the state agency fails to make a decision within the time period specified for the review, the applicant may, within one year following the expiration of such period, bring an action, at the election of the applicant, in either the circuit court of Kanawha County, or with the judge thereof in vacation, or in the circuit court of the county in which the applicant or any one of the applicants resides or does business, or with the judge thereof in vacation to require the state agency to approve or disapprove the application. An application for a proposed new institutional health service or exemption may not be approved or denied by the circuit
§16-2D-13. Injunctive relief; civil penalty.

(a) In addition to all other remedies, and aside from various penalties provided by law, if any person acquires, offers or develops any new institutional health service for which a certificate of need is required under this article without first having a certificate of need therefor as herein provided, or violates any other provision of this article or any lawful rule or regulation promulgated thereunder, affected persons, as defined in section two of this article, and the state agency shall request that the attorney general maintain a civil action in the circuit court of the county wherein such violation has occurred, or wherein such person may be found, to enjoin, restrain or prevent such violation. No injunction bond shall be required to be filed in any such proceeding.

(b) The state agency may assess a civil penalty for violation of this article. Upon the state agency determining that there is probable cause to believe that any person is knowingly offering, developing, or has acquired any new institutional health service subject to certificate of need review without having first obtained a certificate of need therefor or that any person is otherwise in violation of the provisions of this article, or any lawful rule or regulation promulgated thereunder, the state agency shall provide such person with written notice which shall state the nature of the alleged violation and the time and place at which such person shall appear to show good cause why a civil penalty should not be imposed, at which time and place such person shall be afforded an opportunity to cross-examine the state agency’s witnesses and afforded an opportunity to present testimony and other evidence in support of his position. The hearing shall be conducted in accordance with the administrative hearing provisions of section four, article five, chapter twenty-nine-a of this code. If, after reviewing the record of such hearing, the state agency director determines that such person is in violation of the certificate of need law, the state agency shall assess a civil penalty of not less than five hundred dollars nor more than twenty-five thousand dollars. In determining the amount of the
penalty, the state agency shall consider the degree and extent of harm caused by the violation and the cost of rectifying the damage. Any person assessed shall be notified of the assessment in writing, and the notice shall specify the reasons for the assessment. If the person assessed fails to pay the amount of the assessment to the state agency within thirty days, the attorney general may institute a civil action in the circuit court of the county wherein such violation has occurred, or wherein such person may be found to recover the amount of the assessment. In any such civil action, the scope of the court’s review of the state agency’s action, which shall include a review of the amount of the assessment, shall be as provided in section four, article five, chapter twenty-nine-a of this code for the judicial review of contested administrative cases.


1 The state agency shall have a period of three years in which to take actions as provided in this article to correct violations of the provisions of this article. The three-year period shall begin to run from the date the state agency knows or should have known of the violation. Each new act of a continuing violation shall provide a basis for restarting the calculation of the limitations period.

§16-2D-15. Previously approved rules and regulations.

1 All rules and regulations previously promulgated to implement this article shall continue in force following the amendments to this article; except that, where such previous rules and regulations differ from the requirements of the amendments to this article, then such part of those rules and regulations are hereby abrogated and shall have no further legal effect. The state agency shall commence a review of such rules and regulations and shall promulgate revised rules and regulations.
The Joint Committee on Enrolled Bills hereby certifies that the foregoing bill is correctly enrolled.

Chairman Senate Committee

Chairman House Committee

Originated in the Senate.

In effect ninety days from passage.

Clerk of the Senate

Clerk of the House of Delegates

President of the Senate

Speaker House of Delegates

The within ...................... approved this the ......................

day of ...................... May, 1985.

Governor