APPROVED AND SIGNED BY THE GOVERNOR

Date 4-28-81
Time

WEST VIRGINIA LEGISLATURE
REGULAR SESSION, 1981

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ENROLLED

HOUSE BILL No. 1789

(By Mrs. Hartman)

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Passed April 11, 1981
In Effect July 1, 1981
AN ACT to amend and reenact sections two, three, four, five, six, seven, eight, nine, ten, eleven, twelve and thirteen, article two-d, chapter sixteen of the code of West Virginia, one thousand nine hundred thirty-one, as amended, all relating to public health and requiring a certificate of need prior to the acquiring, offering or development of all new institutional health services within this state; defining terms; requiring institutional health services to be subject to review; providing for exemptions; permitting the state health planning and development agency to administer the certificate of need program; providing for cooperation with the statewide health coordinating council and other persons; strengthening competition and allocating supply of health services; enumerating criteria for certificate of need program; providing for procedure for conducting a certificate of need review; providing for reconsideration hearings; providing for rules and regulations to be used in administering the certificate of need program; granting authority to promulgate additional regulations; providing for adoption of review data; giving power to render a final decision; authorizing power to issue a certificate of need where appropriate; requiring written findings; providing for a capital expenditure maximum; providing for appeals of certificate of need decisions; providing for the length of time a certificate of need is valid; providing for nontransference, compliance and withdrawal of certificates of need; providing for denial of license; providing for injunction relief and civil action; and providing for a civil penalty.
Be it enacted by the Legislature of West Virginia:

That sections two, three, four, five, six, seven, eight, nine, ten, eleven, twelve and thirteen, article two-d, chapter sixteen of the code of the West Virginia, one thousand nine hundred thirty-one, as amended, be amended and reenacted, all to read as follows:

ARTICLE 2D. CERTIFICATE OF NEED.

§16-2D-2. Definitions.

As used in this article, unless otherwise indicated by the context:

(a) "Affected person" means:

(1) The applicant;

(2) The applicable health systems agency;

(3) Health systems agencies serving the contiguous health service areas or located within the same standard metropolitan statistical area;

(4) Any individual residing within the geographic area served or to be served by the applicant;

(5) Any individual who regularly uses the health care facilities within that geographic area;

(6) The health care facilities located in the applicable health service area which provide services similar to the services of the facility under review;

(7) 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;

(8) Third party payers who reimburse any health care facilities for services in the applicable health service area; or

(9) Any agency which establishes rates for the health care facilities located in the applicable health service area;

(10) Organizations representing health care providers.

(b) "Ambulatory health care facility" means a facility,
which is freestanding 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: Provided, That this definition does not include the legally authorized provision of health care services by any one or more health professionals licensed to practice in this state pursuant to the provisions of chapter thirty of this code.

(c) “Ambulatory surgical facility” means a facility which is freestanding 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 legally authorized practice of surgery by any one or more persons in the private offices of any health care providers.

(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) “Applicable health systems agency” means a health systems agency for a health service area in which a proposed new institutional health service is to be located.

(g) “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 con-
stitute the governing body or persons responsible for the new
institutional health service may not be an applicant.

(h) "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 perma-
nently staffed and maintained for immediate use by inpatients
in patient rooms or wards.

(i) "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 opera-
tion 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), sub-
paragraph (B), subdivision (2) of this definition, the cost of any
studies, surveys, designs, plans, working drawings, specifi-
cations, and other activities, including staff effort and con-
sulting and other services, essential to the acquisition, improve-
ment, 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 in-
cluded in determining if such expenditure exceeds the ex-
penditure 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 capi-
tal expenditures, and a transfer of equipment or facilities for
less than fair market value shall be considered a capital ex-
penditure 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.

(j) “Expenditure minimum” means one hundred fifty thousand dollars for the twelve-month period beginning the first day of October, one thousand nine hundred seventy-nine. 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.

(k) “Health,” used as a term, includes physical and mental health.

(i) “Health care facility” is defined as including 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, rehabilitation facilities, and health maintenance organization; 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.

(m) “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.

(n) “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
(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 (B), subdivision (2) 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.

(o) “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 service 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.

(p) “Health services” means clinically related preventive, diagnostic, treatment or rehabilitative services, including alcohol, drug abuse and mental health services.

(q) “Health systems agency” means an entity which is conditionally or fully designated as such by the federal secretary of health and human services pursuant to section 1515 of the public health service act, as amended, Title 42 United States Code section 3001-4.

(r) “Health systems plan” means a plan established by a health systems agency, under section 1513 (b)(2) of the public health service act, as amended, Title 42 United States Code section 3001-4.
Code section 3001-2 (b) (2), which is a detailed statement of goals describing a healthful environment and health systems of an area which, when developed will assure that quality health services will be available and accessible in a manner which assures continuity of care, at reasonable cost, for all residents of that area; which are responsive to the unique needs and resources of that area; and which take into account and are consistent with the national guidelines for health planning policy issued by the federal secretary of health and human services with respect to supply, distribution and organization of health resources and services.

(s) "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.

(t) "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.

(u) "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 and treatment which a hospital or skilled nursing facility is designed to provide, but who because of their mental or physical condition require health related care and services above the level of room and board.

(v) "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.
(w) "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 one hundred fifty 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 one hundred fifty 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.

(x) "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).

(y) "New institutional health service" means such service as described in section three of this article.

(z) "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.

(aa) "Person" means an individual, trust, estate, partnership, committee, corporation, association, and other orga-
zations 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.

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

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

(dd) "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.

(ee) "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.

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

(gg) "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.

(hh) "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.

(ii) "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 institutional health service may not be acquired, offered or developed within this state except upon application for and
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; or

(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 which will be owned by or located in a health care facility;

(i) (1) The acquisition of major medical equipment which will not be owned by or located in a health care facility unless:

(A) At least thirty days before any person enters into a contractual arrangement to acquire major medical equipment which will not be owned by or located in a health care facility, such person provides written notice to the state agency of such person's intent to acquire such equipment and of the use that will be made of the equipment; and

(B) Within thirty days after the date the state agency receives such notice, the state agency finds that the equipment will not be used to provide services for inpatients of a hospital.

(2) The notice provided for in part (A), subparagraph (1), subdivision (i) of this section shall contain all information the
state agency requires in accordance with subsections (e) and (u), section seven of this article.

(3) For purposes of subdivision (i) of this section, donations and leases of major medical equipment shall be considered acquisitions of such equipment, and an acquisition of medical equipment through a transfer of it for less than fair market value shall be considered an acquisition of major medical equipment if its fair market value is at least one hundred fifty thousand dollars.

(4) If major medical equipment not located in a health care facility is acquired without a certificate of need pursuant to section four of this article and at any time it is proposed to use that equipment to serve inpatients of a hospital, a certificate of need shall be issued before such equipment is so used, unless the use is one described in subparagraph (5), subdivision (i) of this section.

(5) For purposes of subdivision (i) of this section, an acquisition of major medical equipment is not required to be reviewed if its proposed use is to provide services to inpatients of a hospital only on a temporary basis in the case of a natural disaster, a major accident, or equipment failure. The state agency may, by regulations adopted pursuant to section eight of this article, specify additional circumstances under which acquisitions of major medical equipment which will not be owned or located in a health care facility are not required to be reviewed: Provided, That such additional circumstances are acceptable to the federal secretary of health and human services.

(6) The state agency may not make any requirement in addition to this subdivision for a certificate of need for an acquisition of major medical equipment which will not be owned or located in a health care facility;

(j) 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 (i) of 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 offices of physicians, private clinics of physicians, dentists or other practitioners of the healing arts; (2) 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; (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 or 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 or the obligation of a capital expenditure for the provisions 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; or
(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 and the appropriate health systems 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.
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 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 seventy-five thousand dollars for the twelve-month period beginning the first day of October, one thousand nine hundred seventy-nine, 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. Authority of state health planning and development agency; assistance of health systems agencies and other persons; cooperation with statewide health coordinating council and health systems agencies; strengthening competition and allocating supply of health services.

(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 and the designated health systems agencies for health service areas located in whole or in part within the state 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 the 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 health systems plans and 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 health systems plans and 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.

§16-2D-6. Minimum criteria for certificate of need reviews; promulgation of regulations regarding review criteria.

(a) Except as provided in subsections (f) and (g) of section nine of this article, in making its determination as to whether a certificate of need shall be issued, the state agency shall, at a minimum, consider all of the following criteria that are applicable, but in the case of a health maintenance organization or an ambulatory care facility or health care facility controlled, directly or indirectly, by a health maintenance organization or combination of health maintenance organizations, the criteria considered shall be only those set forth in subdivision (12) of this subsection:

(1) 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;

(2) The relationship of the health services being reviewed to the state health plan and 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;

(3) The relationship of services reviewed to the long-
range development plan of the person providing or proposing
such services;

(4) The need that the population served or to be served
by such services has for such services proposed to be offered
or expanded, and the extent to which all residents of the
area, and in particular low income persons, racial and ethnic
minorities, women, handicapped persons, other medically
underserved population, and the elderly, are likely to have
access to those services;

(5) The availability of less costly or more effective al-
ternative methods of providing such services to be offered,
expanded, reduced, relocated or eliminated;

(6) The immediate and long-term financial feasibility
of the proposal as well as the probable impact of the pro-
posal on the costs of and charges for providing health services
by the person proposing the new institutional health service;

(7) The relationship of the services proposed to the
existing health care system of the area in which such services
are proposed to be provided;

(8) In the case of health services proposed to be provided,
the availability of resources, including health care providers,
management personnel, and funds for capital and operating
needs, for the provision of the services proposed to be pro-
vided and the need for alternative uses of these resources as
identified by the state health plan, applicable health systems
plan and annual implementation plan;

(9) The appropriate and nondiscriminatory utilization
of existing and available health care providers;

(10) The relationship, including the organizational rela-
tionship, of the health services proposed to be provided to
ancillary or support services;

(11) Special needs and circumstances of those entitles
which provide a substantial portion of their services or re-
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53 sources, or both, to individuals not residing in the health service
54 areas in which the entities are located or in adjacent health
55 service areas. Such entities may include medical and other
56 health professional schools, multidisciplinary clinics and spe-
57 cialty centers.

58 (12) To the extent not precluded by subdivision (1),
59 subsection (f), section nine of this article, the special needs and
60 circumstances of health maintenance organizations. These
61 needs and circumstances shall be limited to:

62 (A) The needs of enrolled members and reasonably
63 anticipated new members of the health maintenance or-
64 ganization for the health services proposed to be provided
65 by the organization; and

66 (B) The availability of the new health services from
67 nonhealth maintenance organization providers or other health
68 maintenance organizations in a reasonable and cost-effective
69 manner which is consistent with the basic method of opera-
70 tion of the health maintenance organization. In assessing the
71 availability of these health services from these providers,
72 the agency shall consider only whether the services from these
73 providers:

74 (i) Would be available under a contract of at least five
75 years duration;
76 (ii) Would be available and conveniently accessible
77 through physicians and other health professionals associated
78 with the health maintenance organization;
79 (iii) Would cost no more than if the services were pro-
80 vided by the health maintenance organization; and
81 (iv) Would be available in a manner which is administra-
82 tively feasible to the health maintenance organization;

83 (13) The special needs and circumstances of biomedical
84 and behavioral research projects which are designed to meet
85 a national need and for which local conditions offer special
86 advantages;

87 (14) In the case of a reduction or elimination of a service,
88 including the relocation of a facility or a service, the need that
the population presently served has for the service, the extent
to which that need will be met adequately by the proposed
relocation or by alternative arrangements, and the effect of the
reduction, elimination or relocation of the service on the
ability of low income persons, racial and ethnic minorities,
women, handicapped persons, and other medically underserved
population, and the elderly, to obtain needed health care;

(15) In the case of a construction project: (A) The
cost and methods of the proposed construction, including
the costs and methods of energy provision and (B) the
probable impact of the construction project reviewed on the
costs of providing health services by the person proposing
such construction project and on the costs and charges to
the public of providing health services by other persons;

(16) In the case of health services proposed to be pro-
vided, the effect of the means proposed for the delivery
of proposed health services on the clinical needs of health
professional training programs in the area in which such
services are to be provided;

(17) In the case of health services proposed to be pro-
vided, if such services are to be available in a limited number
of facilities, the extent to which the schools in the area for
health professions will have access to the services for training
purposes;

(18) In the case of health services proposed to be pro-
vided, the extent to which such proposed services will be
accessible to all the residents of the area to be served by such
services;

(19) In accordance with section five of this article, the
factors influencing the effect of competition on the supply
of the health services being reviewed;

(20) Improvements or innovations in the financing and
delivery of health services which foster competition, in ac-
cordance with section five of this article, and serve to pro-
mote quality assurance and cost effectiveness;

(21) In the case of health services or facilities proposed
to be provided, the efficiency and appropriateness of the
(22) In the case of existing services or facilities, the quality of care provided by such services or facilities in the past;

(23) In the case where an application is made by an osteopathic or allopathic facility for a certificate of need to construct, expand, or modernize a health care facility, acquire major medical equipment, or add services, the need for that construction, expansion, modernization, acquisition of equipment, or addition of services shall be considered on the basis of the need for and the availability in the community of services and facilities for osteopathic and allopathic physicians and their patients. The state agency shall consider the application in terms of its impact on existing and proposed institutional training programs for doctors of osteopathy and medicine at the student, internship, and residency training levels;

(24) The special circumstances of health care facilities with respect to the need for conserving energy;

(25) The contribution of the proposed service in meeting the health related needs of members of medically underserved populations which have traditionally experienced difficulties in obtaining equal access to health services, particularly those needs identified in the state health plan, applicable health systems plan and annual implementation plan, as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the state agency shall consider:

(A) The extent to which medically underserved populations currently use the applicant's services in comparison to the percentage of the population in the applicant's service area which is medically underserved, and the extent to which medically underserved populations are expected to use the proposed services if approved;

(B) The performance of the applicant in meeting its obligation, if any, under any applicable federal regulations
requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal financial assistance, including the existence of any civil rights access complaints against the applicant;

(C) The extent to which medicare, medicaid and medically indigent patients are served by the applicant; and

(D) The extent to which the applicant offers a range of means by which a person will have access to its services, including, but not limited to, outpatient services, admission by house staff and admission by personal physician.

(26) The existence of a mechanism for soliciting consumer input into the health care facility’s decision making process.

(b) The state agency may include additional criteria which it prescribes by regulations adopted pursuant to section eight of this article.

(c) Criteria for reviews may vary according to the purpose for which a particular review is being conducted or the types of health services being reviewed.

(d) An application for a certificate of need may not be made subject to any criterion not contained in this article or not contained in regulations adopted pursuant to section eight of this article.

(e) In the case of any proposed new institutional health service, the state agency may 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, in addition to findings required in section nine of this article, each of the following findings in writing:

(1) That superior alternatives to such services in terms of cost, efficiency and appropriateness do not exist and the development of such alternatives is not practicable; (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 con-
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200 struction, 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 consistent with the plans of other agencies of the state responsible for the provision and financing of long-term care facilities or services including home health services.

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

1 (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.

7 (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.

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

16 (1) Provision for applications, and recommendations from the health systems agencies, to be submitted in accordance with a timetable established by the state agency;

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

21 (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 shall seek the advice of the designated health systems agency for the area in which the proposed new institutional health service will be located to determine if the application is complete and 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 news-
letter.

(i) If, after a review has begun the state agency or the
health systems agency requires the person subject to the
review to submit additional information respecting the sub-
ject 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 seek 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 as to whether a certificate of need should
be issued. The state agency shall assist the designated health
systems agency in the review of applications by supplying
information and data on those proposed new institutional
services which have statewide implications.

(k) 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.

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

(m) The schedule shall set forth the period within which
the health systems agency shall complete its review and
provide its recommendation with respect to such new in-
stitutional health service to the state agency: Provided, That
the period allotted by the state agency to a health systems
agency for completion of its review and submission of its
recommendations may not be less than sixty days, except with
the written consent of the health systems agency.
(n) 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 section five of 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 contracts 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.

6. 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, except that the file closing date shall not be set prior to the date the state agency receives the recommendation of the applicable health systems agency.
with respect to the proposed new institutional health service
if the state agency receives such recommendation before the
sixty-first day for the review. A detailed itemization of
documents in the state agency file on a proposed new insti-
tutional health service shall, on request, be made available by
the state agency at any time before the file closing date.

(p) 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 informa-
tion which is received by the state agency from the applicant
after the state agency has received the applicable 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.

(q) 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 approp-
riate information respecting such review.

(r) 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.

(s) 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.

(t) (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 the health systems agency for the health service area in which the new institutional health service is proposed to be offered or developed, 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 (n) of this section; and

(C) The administrative procedures for contested cases contained in article five of chapter twenty-nine-a of this code.

(7) The state agency shall make written findings which state the basis for its decision within forty-five days after the conclusion of such hearing.
(8) 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 (q) and (r) of this section.

(u) 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.

(v) 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-8. Agency to promulgate additional rules and regulations.

(a) The state agency is hereby empowered to promulgate additional rules and regulations:

(1) To carry out the provisions of this article; and

(2) To assure hospitals' compliance with requests for information concerning rates charged for each of the twenty-five most frequently used hospital services in the state including the average semiprivate and private room rates.

(b) All rules and regulations shall be promulgated pursuant to chapter twenty-nine-a of this code and as described herein. In addition, before adopting proposed rules and regulations the state agency shall give interested persons an opportunity to offer written comments on the rules and regulations, or any revisions thereof, which it proposes to adopt, as follows:

(1) The state agency shall distribute copies of its proposed review rules and regulations, and proposed revisions thereof, to statewide health agencies and organizations, the statewide
health coordinating council, and each health systems agency for a health service area located in whole or in part within the state and any agency which establishes rates for health care facilities in the state.

(2) The state agency shall publish, in at least one newspaper in each planning and development region in this state, a notice stating that rules and regulations for review of certificate of need applications or any revisions thereof, have been proposed for adoption and are available at specified addresses for inspection and copying by interested persons. In addition, notice may be given through other public information channels;

(3) The state agency shall distribute copies of its adopted review rules and regulations, and any revisions thereof, to the agencies and organizations specified in this section and to the secretary of health and human services, and shall provide such copies to other persons upon request.

§16-2D-9. State 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, applicable health systems 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, 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.

(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 ex-
penditure 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; or

(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 (q), 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 to the health systems agency for the health service area in which the new service is proposed to be offered or developed and shall make it available to others upon request.

(2) In the case of a new institutional health service proposed by an health maintenance organization, the state agency shall send the written findings to the appropriate 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 makes a decision regarding a proposed new institutional health service which is inconsistent with a recommendation made with respect thereto by the applicable health systems agency or is inconsistent with the goals of the applicable health systems plan or the priorities of the applicable annual implementation plan, the state agency shall, if its decision does not include a written, detailed statement of the reasons for the inconsistency, provide such a statement to such health systems agency.

(l) 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 court solely because the state agency failed to reach a decision.

§16-2D-10. Appeal of certificate of need decisions.

(a) A final decision of the state agency, including a state agency decision issued after a reconsideration, if such reconsideration was requested and granted under subsection (l),
section seven, of this article, and the record upon which it was made, shall, upon request of any affected person, or the applicable health systems agency if the decision is inconsistent with a recommendation made by the applicable health systems agency to the state agency with respect to the certificate of need, be reviewed by an agency of the state (other than the state agency) designated by the governor. To be effective, such request 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.

(b) To the extent not inconsistent with this section, for the purpose of administrative reviews of state agency decisions, the review agency shall conduct its proceedings in conformance with the West Virginia rules of civil procedure for trial courts of record and the local rules for use in the civil courts of Kanawha County and shall review appeals in accordance with the provisions governing the judicial review of contested administrative cases in section (4), article five, chapter twenty-nine-a of this code, notwithstanding the exceptions of section five, article five, chapter twenty-nine-a of this code.

c) The decision of the reviewing agency shall be made in writing within forty-five days after the conclusion of such hearing.

d) The written findings of the review agency shall be sent to the person who requested the review, to the person proposing the new institutional health service, to the health systems agency requesting a review and to the state agency, and shall be made available by the state agency to others upon request.

e) The decision of the reviewing agency shall be considered the final decision of the state agency; however, the reviewing agency may remand the matter to the state agency for further action or consideration.

f) Upon the entry of a final decision by the reviewing agency the designated health systems agency, if the decision respecting the certificate of need is inconsistent with a recommendation made by that health systems agency to the state agency with respect to the certificate of need, and any other
“person adversely affected by the review” have standing in and may within thirty days after the date upon which all parties received notice of the decision of the review agency take an appeal at the election of the petitioner, in either the circuit court of Kanawha County, or in the circuit court of the county in which the petitioner or any of the petitioners resides or does business, from any decision of the state agency granting, with or without conditions, denying or withdrawing a certificate of need or exemption. The decision of the review agency shall be reviewed by such circuit court in accordance with the provisions for the judicial review of administrative decisions contained in section four, article five, chapter twenty-nine-a of this code. For the purposes of this subsection, “person adversely affected by the review” includes the state agency, any person who meets the definition of affected person in section two of this article, and any person who participated in the proceeding before the state agency.

§16-2D-11. Nontransference, time period compliance and withdrawal of certificate of need.

(a) A certificate of need is nontransferable and shall be valid for a maximum of one year from the date of issuance. Upon the expiration of the certificate or during the certification period the person proposing the new institutional health service shall provide the state agency such information on the development of the project as the state agency may request. The state agency shall periodically monitor capital expenditures obligated under certificates, determine whether sufficient progress is being made in meeting the timetable specified in the approved application for the certificate and whether there has been compliance with the application and any conditions of certification. The state agency shall take in account recommendations made by the health systems agency in making its determination. The certificate of need may be extended by the state agency for additional periods of time as are reasonably necessary to expeditiously complete the project. A certificate of need may no longer be in effect, and may no longer be required, after written notice of substantial compliance with the approved application and any conditions of certification is issued to the applicant,
after the activity is undertaken for which the certificate of need was issued, and after the state agency is provided written notice of such undertaking. The person proposing a new institutional health service may not be issued a license therefor until the state agency has issued a written notice of substantial compliance with the approved application and any conditions of certification, nor may a new institutional health service be used until such person has received such notice. A new institutional health service may not be found to be in substantial compliance with the approved application and any conditions of certification if there is a substantial change, as defined in regulations adopted pursuant to subsection (j), section three, of this article, in the approved new institutional health service for which change a certificate of need has not been issued.

(b) (1) The certificate of need may be withdrawn by the state agency for:

(A) Insufficient progress in meeting the timetable specified in the approved application for the certificate and for not making a good faith effort to meet it in developing the project; or

(B) Noncompliance with any conditions of certification; or

(C) A substantial change, as defined in regulations adopted pursuant to subsection (j), section three of this article, in an approved new institutional health service for which change a certificate of need has not been issued; or

(D) Material misrepresentation by an applicant upon which the state agency relied in making its decision; or

(E) Other reasons that may be established by the state agency in regulations adopted pursuant to section eight of this article.

(2) Any decision of the state agency to withdraw a certificate of need shall be based solely on:

(A) The provisions of this article and on regulations adopted in accordance with section eight of this article; and

(B) The record established in administrative proceedings
held with respect to the state agency's proposal to withdraw the certificate.

(3) In the case of a proposed withdrawal of a certificate of need:

(A) After commencement of a hearing on the state agency's proposal to withdraw a certificate of need and before a decision is made on withdrawal, there may be no ex parte contacts between (i) the holder of the certificate of need, any person acting on behalf of the holder, or any person in favor of the withdrawal and (ii) any person in the state agency who exercises responsibility respecting withdrawal of the certificate;

(B) The state agency shall follow the notification of review provisions of subsections (g) and (h), the public hearing provisions of subsection (n), the notification of the status of review and findings provisions of subsection (g), the annual report provisions of subsection (r), and the reconsideration provisions of subsection (t), all of section seven of this article, and the conditional decision provisions of subsection (d), the notification of decision and findings provisions of subsection (h), and the statement to the applicable health systems agency provisions of subsection (k), all of section nine of this article; and

(C) Appeals of withdrawals of certificates of need shall be made pursuant to section ten of this article.

(4) A new institutional health service may not be acquired, offered, or developed within this state if a certificate of need authorizing that new institutional health service has been withdrawn by the state agency and the acquisition, offering, or development of the new institutional health service is subject to review under this article.

§16-2D-12. Licensing prohibited.

Any person acquiring, offering or developing any new institutional health service for which a certificate of need is required under this article without first obtaining a certificate of need therefor as herein provided, or who violates any of the provisions of this article is subject to denial or revoca-
tion of a license, in whole or in part, to operate such institutional health service or facility. Upon a showing to the state agency that any person is offering or developing any new institutional health service within the meaning of this article without having first obtained a certificate of need therefor as provided herein or that such person is otherwise in violation of the provisions of this article, the state agency shall provide such person with written notice which notice shall state the nature of the violation and the time and place at which such person shall appear to show good cause why its license should not be revoked or denied, at which time and place such person shall be afforded a reasonable opportunity to present testimony and other evidence in support of its position. If, thereafter, the state agency determines that such person's license to operate such institutional health service or facility should be revoked or denied, the state agency shall issue an order, in writing, to the appropriate responsible licensing agency of the state, requiring that such person's license to operate such institutional health service or facility be revoked or denied, which order shall be binding upon such licensing agency.

§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 applicable health systems agency may maintain 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.
The Joint Committee on Enrolled Bills hereby certifies that the foregoing bill is correctly enrolled.

Chairman Senate Committee

Chairman House Committee

Originated in the House.

Takes effect July 1, 1981.

Clerk of the Senate

Clerk of the House of Delegates

President of the Senate

Speaker House of Delegates

The within is approved this the 20th day of April, 1981.

Governor