

APPROVED AND SIGNED BY THE GOVERNOR

Date 4-28-81

Time _____

No: 1789

WEST VIRGINIA LEGISLATURE

REGULAR SESSION, 1981



ENROLLED

HOUSE BILL No. 1789

(By Mr. Hartman)



Passed April 11, 1981

In Effect July 1, 1981 ~~Passage~~



ENROLLED

H. B. 1789

(By MRS. HARTMAN)

[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.

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

3 (a) "Affected person" means:

4 (1) The applicant;

5 (2) The applicable health systems agency;

6 (3) Health systems agencies serving the contiguous health
7 service areas or located within the same standard metropoli-
8 tan statistical area;

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

11 (5) Any individual who regularly uses the health care fa-
12 cilities within that geographic area;

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

16 (7) The health care facilities which, prior to receipt by
17 the state agency of the proposal being reviewed, have form-
18 ally indicated an intention to provide similar services in the
19 future;

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

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

24 (10) Organizations representing health care providers.

25 (b) "Ambulatory health care facility" means a facility,

26 which is freestanding and not physically attached to a health
27 care facility and which provides health care to noninstitution-
28 alized and nonhomebound persons on an outpatient basis.
29 This definition does not include the legally authorized prac-
30 tice of medicine by any one or more persons in the private
31 offices of any health care providers: *Provided*, That this defi-
32 nition does not include the legally authorized provision of
33 health care services by any one or more health professionals
34 licensed to practice in this state pursuant to the provisions of
35 chapter thirty of this code.

36 (c) “Ambulatory surgical facility” means a facility which
37 is freestanding and not physically attached to a health care
38 facility and which provides surgical treatment to patients not
39 requiring hospitalization. This definition does not include
40 the legally authorized practice of surgery by any one or more
41 persons in the private offices of any health care providers.

42 (d) “Annual implementation plan” means a plan establish-
43 ed, annually reviewed and amended as necessary by a health
44 systems agency in conformance with section 1513 (b) (3) of
45 the public health service act, as amended, Title 42 United States
46 Code section 3001-2(b) (3), which describes objectives which
47 will achieve the goals of the health systems plan, or, if those
48 goals are amended by the statewide health coordinating coun-
49 cil when included in the state health plan, as so amended, and
50 priorities among the objectives.

51 (e) “Applicable health service area” means a health ser-
52 vice area, as defined in this section, in which a new institutional
53 health service is proposed to be located.

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

57 (g) “Applicant” means: (1) The governing body or the
58 person proposing a new institutional health service who is, or
59 will be, the health care facility licensee wherein the new
60 institutional health service is proposed to be located, and (2)
61 in the case of a proposed new institutional health service not
62 to be located in a licensed health care facility, the governing
63 body or the person proposing to provide such new institutional

64 health service. Incorporators or promoters who will not con-
65 stitute the governing body or persons responsible for the new
66 institutional health service may not be an applicant.

67 (h) "Bed capacity" means the number of beds for which a
68 license is issued to a health care facility, or, if a facility is
69 unlicensed, the number of adult and pediatric beds perma-
70 nently staffed and maintained for immediate use by inpatients
71 in patient rooms or wards.

72 (i) "Capital expenditure" means an expenditure:

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

74 (2) (A) Which (i) under generally accepted accounting
75 principles is not properly chargeable as an expense of opera-
76 tion and maintenance, or (ii) is made to obtain either by
77 lease or comparable arrangement any facility or part thereof
78 or any equipment for a facility or part; and (B) which (i)
79 exceeds the expenditure minimum, or (ii) is a substantial
80 change to the bed capacity of the facility with respect to
81 which the expenditure is made, or (iii) is a substantial change
82 to the services of such facility. For purposes of part (i), sub-
83 paragraph (B), subdivision (2) of this definition, the cost of any
84 studies, surveys, designs, plans, working drawings, specifi-
85 cations, and other activities, including staff effort and con-
86 sulting and other services, essential to the acquisition, improve-
87 ment, expansion, or replacement of any plant or equipment
88 with respect to which an expenditure described in subparagraph
89 (B), subdivision (2) of this definition is made shall be in-
90 cluded in determining if such expenditure exceeds the ex-
91 penditure minimum. Donations of equipment or facilities
92 to a health care facility which if acquired directly by such
93 facility would be subject to review shall be considered capi-
94 tal expenditures, and a transfer of equipment or facilities for
95 less than fair market value shall be considered a capital ex-
96 penditure for purposes of such subdivisions if a transfer
97 of the equipment or facilities at fair market value would be
98 subject to review. A series of expenditures, each less than the
99 expenditure minimum, which when taken together are in
100 excess of the expenditure minimum, may be determined by the
101 state agency to be a single capital expenditure subject to

102 review. In making its determination, the state agency shall
103 consider: Whether the expenditures are for components of a
104 system which is required to accomplish a single purpose;
105 whether the expenditures are to be made over a two-year
106 period and are directed towards the accomplishment of a
107 single goal within the health care facility's long range plan;
108 or, whether the expenditures are to be made within a two-
109 year period within a single department such that they will
110 constitute a significant modernization of the department.

111 (j) "Expenditure minimum" means one hundred fifty thou-
112 sand dollars for the twelve-month period beginning the first
113 day of October, one thousand nine hundred seventy-nine. For
114 each twelve-month period thereafter, the state agency may,
115 by regulations adopted pursuant to section eight of this article,
116 adjust the expenditure minimum to reflect the impact of
117 inflation.

118 (k) "Health," used as a term, includes physical and mental
119 health.

120 (i) "Health, care facility" is defined as including
121 hospitals, skilled nursing facilities, kidney disease treat-
122 ment centers, including freestanding hemodialysis units, inter-
123 mediate care facilities, ambulatory health care facilities,
124 ambulatory surgical facilities, home health agencies, re-
125 habilitation facilities, and health maintenance organiza-
126 tion; whether under public or private ownership, or as
127 a profit or nonprofit organization and whether or not
128 licensed or required to be licensed in whole or in part by
129 the state.

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

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

138 (1) Is a qualified health maintenance organization under

139 section 1310(d) of the public health service act, as amended,
140 Title 42 United States Code section 300e-9(d); or

141 (2) (A) Provides or otherwise makes available to enrolled
142 participants health care services, including substantially the
143 following basic health care services: Usual physician services,
144 hospitalization, laboratory, X-ray, emergency and preventive
145 services and out-of-area coverage; and

146 (B) Is compensated except for copayments for the pro-
147 vision of the basic health care services listed in subparagraph
148 (B), subdivision (2) of this definition to enrolled participants
149 on a predetermined periodic rate basis without regard to the
150 date the health care services are provided and which is fixed
151 without regard to the frequency, extent, or kind of health
152 service actually provided; and

153 (C) Provides physicians' services primarily (i) directly
154 through physicians who are either employees or partners of
155 such organization, or (ii) through arrangements with indi-
156 vidual physicians or one or more groups of physicians organiz-
157 ed on a group practice or individual practice basis.

158 (o) "Health service area" means a geographic area de-
159 signated by the federal secretary of health and human services
160 pursuant to section 1511 of the public health service act, as
161 amended, Title 42 United States Code section 3001, with
162 respect to which health systems agencies shall be designated
163 under section 1515 of such act, as amended, Title 42 United
164 States Code section 3001-4.

165 (p) "Health services" means clinically related preventive,
166 diagnostic, treatment or rehabilitative services, including al-
167 cohol, drug abuse and mental health services.

168 (q) "Health systems agency" means an entity which is con-
169 ditionally or fully designated as such by the federal secre-
170 tary of health and human services pursuant to section 1515
171 of the public health service act, as amended, Title 42 United
172 States Code section 3001-4.

173 (r) "Health systems plan" means a plan established by a
174 health systems agency, under section 1513 (b)(2) of the pub-
175 lic health service act, as amended, Title 42 United States

176 Code section 3001-2 (b) (2), which is a detailed statement of
177 goals describing a healthful environment and health systems of
178 an area which, when developed will assure that quality health
179 services will be available and accessible in a manner which
180 assures continuity of care, at reasonable cost, for all resi-
181 dents of that area; which are responsive to the unique needs
182 and resources of that area; and which take into account and
183 are consistent with the national guidelines for health planning
184 policy issued by the federal secretary of health and human
185 services with respect to supply, distribution and organization
186 of health resources and services.

187 (s) "Home health agency" is an organization primarily en-
188 gaged in providing directly or through contract arrangements,
189 professional nursing services, home health aide services, and
190 other therapeutic and related services including, but not limit-
191 ed to, physical, speech and occupational therapy and nutritional
192 and medical social services, to persons in their place of resi-
193 dence on a part-time or intermittent basis.

194 (t) "Hospital" means an institution which is primarily en-
195 gaged in providing to inpatients, by or under the supervision
196 of physicians, diagnostic and therapeutic services for medical
197 diagnosis, treatment, and care of injured, disabled, or sick
198 persons, or rehabilitation services for the rehabilitation of in-
199 jured, disabled or sick persons. This term also includes psy-
200 chiatric and tuberculosis hospitals.

201 (u) "Intermediate care facility" means an institution which
202 provides, on a regular basis, health-related care and services
203 to individuals who do not require the degree of care and treat-
204 ment which a hospital or skilled nursing facility is designed to
205 provide, but who because of their mental or physical condition
206 require health related care and services above the level of
207 room and board.

208 (v) "Long-range plan" means a document formally adopted
209 by the legally constituted governing body of an existing
210 health care facility or by a person proposing a new institu-
211 tional health service. Each long-range plan shall consist of
212 the information required by the state agency in regulations
213 adopted pursuant to section eight of this article.

214 (w) "Major medical equipment" means a single unit of
215 medical equipment or a single system of components with
216 related functions which is used for the provision of medical
217 and other health services and which costs in excess of one
218 hundred fifty thousand dollars, except that such term does
219 not include medical equipment acquired by or on behalf of a
220 clinical laboratory to provide clinical laboratory services
221 if the clinical laboratory is independent of a physician's
222 office and a hospital and it has been determined under Title
223 XVIII of the social security act to meet the requirements of
224 paragraphs ten and eleven of section 1861 (s) of such act,
225 Title 42 United States Code sections 1395x (10) and (11).
226 In determining whether medical equipment costs more than one
227 hundred fifty thousand dollars, the cost of studies, surveys,
228 designs, plans, working drawings, specifications, and other
229 activities essential to the acquisition of such equipment shall
230 be included. If the equipment is acquired for less than fair
231 market value, the term "cost" includes the fair market value.

232 (x) "Medically underserved population" means the popu-
233 lation of an urban or rural area designated by the state agency
234 as an area with a shortage of personal health services or a
235 population having a shortage of such services, after taking
236 into account unusual local conditions which are a barrier to
237 accessibility or availability of such services. Such designation
238 shall be in regulations adopted by the state agency pursuant to
239 section eight of this article, and the population so designated
240 may include the state's medically underserved population
241 designated by the federal secretary of health and human ser-
242 vices under section 330(b) (3) of the public health service act,
243 as amended, Title 42 United States Code section 254(b) (3).

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

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

250 (aa) "Person" means an individual, trust, estate, partner-
251 ship, committee, corporation, association, and other organi-

252 zations such as joint-stock companies and insurance companies,
253 a state or a political subdivision or instrumentality thereof or
254 any legal entity recognized by the state.

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

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

260 (dd) "Psychiatric hospital" means an institution which pri-
261 marily provides to inpatients, by or under the supervision of a
262 physician, specialized services for the diagnosis, treatment
263 and rehabilitation of mentally ill and emotionally disturbed
264 persons.

265 (ee) "Rehabilitation facility" means an inpatient facility
266 which is operated for the primary purpose of assisting in the
267 rehabilitation of disabled persons through an integrated pro-
268 gram of medical and other services which are provided under
269 competent professional supervision.

270 (ff) "Review agency" means an agency of the state desig-
271 nated by the governor as the agency for the review of state
272 agency decisions.

273 (gg) "Skilled nursing facility" means an institution or a
274 distinct part of an institution which is primarily engaged in
275 providing to inpatients skilled nursing care and related services
276 for patients who require medical or nursing care, or rehabili-
277 tation services for the rehabilitation of injured, disabled or
278 sick persons.

279 (hh) "State agency" means that agency of state government
280 selected by the governor and designated as the state health
281 planning and development agency in an agreement entered in-
282 to pursuant to section 1521 of the public health service act, as
283 amended, Title 42 United States Code section 300m.

284 (ii) "State health plan" means the document approved by
285 the governor after preparation by the statewide health co-
286 ordinating council pursuant to section 1524 (c) (2) of the pub-
287 lic health service act, as amended, Title 42 United States
288 Code section 300m-3 (c) (2).

289 (jj) "Statewide health coordinating council" means the body
290 established pursuant to section 1524 of the public health
291 service act, as amended, Title 42 United States Code section
292 300m-3, to advise the state agency.

293 (kk) "Substantial change to the bed capacity" of a health
294 care facility means a change, with which a capital expenditure
295 is associated, in any two-year period of ten or more beds or
296 more than ten percent, whichever is less, of the bed capacity
297 of such facility that increases or decreases the bed capacity,
298 redistributes beds among various categories, or relocates beds
299 from one physical facility or site to another. A series of
300 changes to the bed capacity of a health care facility in any
301 two-year period, each less than ten beds or ten percent of the
302 bed capacity of such facility, but which when taken together
303 comprise ten or more beds or more than ten percent of the
304 bed capacity of such facility, whichever is less, is a substantial
305 change to the bed capacity.

306 (ll) "Substantial change to the health services" of a health
307 care facility means the addition of a health service which is
308 offered by or on behalf of the health care facility and which
309 was not offered by or on behalf of the facility within the
310 twelve-month period before the month in which the service is
311 first offered, or the termination of a health service which was
312 offered by or on behalf of the facility.

313 (mm) "To develop," when used in connection with health ser-
314 vices, means to undertake those activities which upon their
315 completion will result in the offer of a new institutional health
316 service or the incurring of a financial obligation, in relation
317 to the offering of such a service.

318 (nn) "Tuberculosis hospital" means an institution which
319 is primarily engaged in providing to inpatients, by or under
320 the supervision of a physician, medical services for the diagnosis
321 and treatment of tuberculosis.

§16-2D-3. Certificate of need.

1 Except as provided in section four of this article, any new
2 institutional health service may not be acquired, offered or
3 developed within this state except upon application for and

4 receipt of a certificate of need as provided by this article.
5 Whenever a new institutional health service for which a certi-
6 ficate of need is required by this article is proposed for a
7 health care facility for which, pursuant to section four of this
8 article, no certificate of need is or was required, a certificate of
9 need shall be issued before the new institutional health service
10 is offered or developed. No person may, knowingly charge or
11 bill for any health services associated with any new institu-
12 tional health service that is knowingly acquired, offered, or
13 developed in violation of this article, and any bill made in
14 violation of this sentence is legally unenforceable. For purposes
15 of this article, a proposed "new institutional health service"
16 includes:

17 (a) The construction, development, acquisition or other
18 establishment of a new health care facility or health main-
19 tenance organization;

20 (b) The partial or total closure of a health care facility or
21 health maintenance organization with which a capital ex-
22 penditure is associated;

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

31 (1) When a contract, enforceable under state law, is enter-
32 ed into by or on behalf of the health care facility for the con-
33 struction, acquisition, lease or financing of a capital asset; or

34 (2) When the governing board of the health care facility
35 takes formal action to commit its own funds for a construction
36 project undertaken by the health care facility as its own con-
37 tractor; or

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

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

42 (e) The addition of health services which are offered by or
43 on behalf of a health care facility or health maintenance organi-
44 zation and which were not offered on a regular basis by or on
45 behalf of such health care facility or health maintenance or-
46 ganization within the twelve-month period prior to the time
47 such services would be offered;

48 (f) The deletion of one or more health services, previously
49 offered on a regular basis by or on behalf of a health care
50 facility or health maintenance organization which deletion is
51 associated with a capital expenditure;

52 (g) A substantial change to the bed capacity or health
53 services offered by or on behalf of a health care facility,
54 whether or not the change is associated with a proposed capital
55 expenditure, if the change is associated with a previous capi-
56 tal expenditure for which a certificate of need was issued and
57 if the change will occur within two years after the date the
58 activity which was associated with the previously approved
59 capital expenditure was undertaken;

60 (h) The acquisition of major medical equipment which
61 will be owned by or located in a health care facility;

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

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

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

73 (2) The notice provided for in part (A), subparagraph (1),
74 subdivision (i) of this section shall contain all information the

75 state agency requires in accordance with subsections (e) and
76 (u), section seven of this article.

77 (3) For purposes of subdivision (i) of this section, dona-
78 tions and leases of major medical equipment shall be con-
79 sidered acquisitions of such equipment, and an acquisition of
80 medical equipment through a transfer of it for less than fair
81 market value shall be considered an acquisition of major
82 medical equipment if its fair market value is at least one
83 hundred fifty thousand dollars.

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

91 (5) For purposes of subdivision (i) of this section, an ac-
92 quisition of major medical equipment is not required to be re-
93 viewed if its proposed use is to provide services to inpatients
94 of a hospital only on a temporary basis in the case of a natural
95 disaster, a major accident, or equipment failure. The state
96 agency may, by regulations adopted pursuant to section eight
97 of this article, specify additional circumstances under which
98 acquisitions of major medical equipment which will not be
99 owned or located in a health care facility are not required to
100 be reviewed: *Provided*, That such additional circumstances are
101 acceptable to the federal secretary of health and human ser-
102 vices.

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

107 (j) A substantial change in an approved new institutional
108 health service for which a certificate of need is in effect. For
109 purposes of this subdivision "substantial change" shall be
110 defined by the state agency in regulations adopted pursuant
111 to section eight of this article.

§16-2D-4. Exemptions from certificate of need program.

1 (a) Except as provided in subdivision (i) of section three
2 of this article, nothing in this article or the rules and regula-
3 tions adopted pursuant to the provisions of this article may
4 be construed to authorize the licensure, supervision, regulation
5 or control in any manner of: (1) Private offices of physicians,
6 private clinics of physicians, dentists or other practitioners of
7 the healing arts; (2) dispensaries and first aid stations located
8 within business or industrial establishments maintained solely
9 for the use of employees: *Provided*, That such facility does not
10 contain inpatient or resident beds for patients or employees
11 who generally remain in the facility for more than twenty-four
12 hours; (3) establishments, such as motels, hotels and boarding-
13 houses which provide medical, nursing personnel and health
14 related services; and (4) the remedial care or treatment of
15 residents or patients in any home or institution conducted only
16 for those who rely solely upon treatment by prayer or spiritual
17 means in accordance with the creed or tenets of any recognized
18 church or religious denomination.

19 (b) (1) A certificate of need is not required for the offer-
20 ing of an inpatient institutional health service or the acquisition
21 of major medical equipment for the provision of an inpatient
22 institutional health service or the obligation of a capital ex-
23 penditure for the provisions of an inpatient institutional health
24 service, if with respect to such offering, acquisition, or obliga-
25 tion, the state agency has, upon application under subdivision
26 (2), subsection (b) of this section, granted an exemption to:

27 (A) A health maintenance organization or a combination
28 of health maintenance organizations if (i) the organization
29 or combination of organizations has, in the service area of the
30 organization or the service areas of the organizations in the
31 combination, an enrollment of at least fifty thousand indivi-
32 duals, (ii) the facility in which the service will be provided is or
33 will be geographically located so that the service will be reason-
34 ably accessible to such enrolled individuals, and (iii) at least
35 seventy-five percent of the patients who can reasonably be ex-
36 pected to receive the institutional health service will be in-
37 dividuals enrolled with such organization or organizations in
38 the combination; or

39 (B) A health care facility if (i) the facility primarily pro-
40 vides or will provide inpatient health services, (ii) the facility is
41 or will be controlled, directly or indirectly, by a health mainten-
42 ance organization or a combination of health maintenance or-
43 ganizations which has, in the service area of the organization or
44 service areas of the organizations in the combination, an enroll-
45 ment of at least fifty thousand individuals, (iii) the facility is or
46 will be geographically located so that the service will be reason-
47 ably accessible to such enrolled individuals, and (iv) at least
48 seventy-five percent of the patients who can reasonably be ex-
49 pected to receive the institutional health service will be indivi-
50 duals enrolled with such organization or organizations in the
51 combination; or

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

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

69 (i) It has submitted, at such time and in such form and
70 manner as the state agency shall prescribe, an application for
71 such exemption to the state agency and the appropriate health
72 systems agency;

73 (ii) The application contains such information respecting
74 the organization, combination, or facility and the proposed
75 offering, acquisition, or obligation as the state agency may
76 require to determine if the organization or combination meets

77 the requirements of subdivision (1), subsection (b) of this
78 section or the facility meets or will meet such requirements;
79 and

80 (iii) The state agency approves such application.

81 (B) The state agency shall approve an application sub-
82 mitted under subparagraph (A), subdivision (2), subsection
83 (b) of this section if it determines that the applicable require-
84 ments of subdivision (1), subsection (b) of this section are met
85 or will be met on the date the proposed activity for which
86 an exemption was requested will be undertaken.

87 (3) A health care facility, or any part thereof, or medical
88 equipment with respect to which an exemption was granted
89 under subdivision (1), subsection (b) of this section may not
90 be sold or leased and a controlling interest in such facility
91 or equipment or in a lease of such facility or equipment may
92 not be acquired and a health care facility described in sub-
93 paragraph (C), subdivision (1), subsection (b) of this section
94 which was granted an exemption under subdivision (1), sub-
95 section (b) of this section may not be used by any person other
96 than the lessee described in subparagraph (C), subdivision (1),
97 subsection (b) of this section unless:

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

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

104 (i) A health maintenance organization or a combination of
105 health maintenance organizations which meets the enroll-
106 ment requirements of part (i), subparagraph (A), subdivision
107 (1), subsection (b) of this section, and with respect to such
108 facility or equipment, the entity meets the accessibility and
109 patient enrollment requirements of parts (ii) and (iii), sub-
110 paragraph (A), subdivision (1), subsection (b) of this section;
111 or

112 (ii) A health care facility which meets the inpatient, en-
113 rollment, and accessibility requirements of parts (i), (ii) and

114 (iii), subparagraph (B), subdivision (1), subsection (b) of this
115 section and with respect to its patients meets the enrollment
116 requirements of part (iv), subparagraph (B), subdivision (1),
117 subsection (b) of this section.

118 (4) In the case of a health maintenance organization or
119 an ambulatory care facility or health care facility which
120 ambulatory or health care facility is controlled, directly
121 or indirectly, by a health maintenance organization or a
122 combination of health maintenance organizations, the cer-
123 tificate of need requirements apply only to the offering
124 of inpatient institutional health services, the acquisition
125 of major medical equipment, and the obligation of capital
126 expenditures for the offering of inpatient institutional health
127 services and then only to the extent that such offering, ac-
128 quisition, or obligation is not exempt under subdivision (1),
129 subsection (b) of this section.

130 (5) The state agency shall establish the period within
131 which approval or disapproval by the state agency of applica-
132 tions for exemptions under subdivision (1), subsection (b) of
133 this section shall be made.

134 (c) (1) A health care facility is not required to obtain
135 a certificate of need for the acquisition of major medical
136 equipment to be used solely for research, the addition of
137 health services to be offered solely for research, or the
138 obligation of a capital expenditure to be made solely for
139 research if the health care facility provides the notice re-
140 quired in subdivision (2), subsection (c) of this section and
141 the state agency does not find, within sixty days after it
142 receives such notice, that the acquisition, offering or obliga-
143 tion will, or will have the effect to:

144 (A) Affect the charges of the facility for the provision
145 of medical or other patient care services other than the services
146 which are included in the research;

147 (B) Result in a substantial change to the bed capacity of
148 the facility; or

149 (C) Result in a substantial change to the health services of
150 the facility.

151 (2) Before a health care facility acquires major medical
152 equipment to be used solely for research, offers a health
153 service solely for research, or obligates a capital expenditure
154 solely for research, such health care facility shall notify in
155 writing the state agency of such facility's intent and the use
156 to be made of such medical equipment, health service, or
157 capital expenditure.

158 (3) If major medical equipment is acquired, a health service
159 is offered, or a capital expenditure is obligated and a
160 certificate of need is not required for such acquisition, offer-
161 ing, or obligation as provided in subdivision (1), subsection
162 (c) of this section, such equipment or service or equipment
163 or facilities acquired through the obligation of such capital
164 expenditure may not be used in such a manner as to have
165 the effect or to make a change described in subparagraphs (A),
166 (B), and (C), subdivision (1), subsection (c) of this section
167 unless the state agency issues a certificate of need approving
168 such use.

169 (4) For purposes of this subsection, the term "solely for
170 research" includes patient care provided on an occasional and
171 irregular basis and not as part of a research program.

172 (d) (1) The state agency may adopt regulations pursuant to
173 section eight of this article to specify the circumstances under
174 which a certificate of need may not be required for the obliga-
175 tion of a capital expenditure to acquire, either by purchase or
176 under lease or comparable arrangement, an existing health
177 care facility: *Provided*, That a certificate of need shall be
178 required for the obligation of a capital expenditure to
179 acquire, either by purchase or under lease or comparable ar-
180 rangement, an existing health care facility if:

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

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

199 (e) The state agency shall adopt regulations, pursuant
200 to section eight of this article, wherein criteria are established
201 to exempt from review the addition of certain health services,
202 not associated with a capital expenditure, that are projected
203 to entail annual operating costs of less than the expenditure
204 minimum for annual operating costs. For purposes of this
205 subsection, "expenditure minimum for annual operating costs"
206 means seventy-five thousand dollars for the twelve-month
207 period beginning the first day of October, one thousand nine
208 hundred seventy-nine, and for each twelve-month period
209 thereafter, the state agency may, by regulations adopted
210 pursuant to section eight of this article, adjust the expendi-
211 ture minimum for annual operating costs to reflect the impact
212 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 coordinat-
ing council and health systems agencies; strengthen-
ing competition and allocating supply of health serv-
ices.**

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

3 (b) The state agency shall cooperate with the statewide
4 health coordinating council and the designated health systems
5 agencies for health service areas located in whole or in part
6 within the state in developing rules and regulations for the
7 certificate of need program to the extent appropriate for the
8 achievement of efficiency in their reviews and consistency
9 in criteria for such reviews.

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

14 (d) For health services for which competition appropriately
15 allocates supply consistent with health systems plans and the
16 state health plan, the state agency shall, in the performance
17 of its functions under this article, give priority, where ap-
18 propriate to advance the purposes of quality assurance, cost
19 effectiveness, and access, to actions which would strengthen
20 the effect of competition on the supply of such services.

21 (e) For health services for which competition does not
22 or will not appropriately allocate supply consistent with
23 health systems plans and the state health plan, the state
24 agency shall, in the exercise of its functions under this
25 article, take actions, where appropriate to advance the pur-
26 poses of quality assurance, cost effectiveness, and access and
27 the other purposes of this article, to allocate the supply of such
28 services.

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

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

11 (1) The recommendation of the designated health systems
12 agency for the health service area in which the proposed
13 new institutional health service is to be located;

14 (2) The relationship of the health services being reviewed
15 to the state health plan and to the applicable health systems
16 plan and annual implementation plan adopted by the designated

17 health systems agency for the health service area in which
18 the proposed new institutional health service is to be located;

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

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

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

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

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

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

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

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

51 (11) Special needs and circumstances of those entities
52 which provide a substantial portion of their services or re-

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

89 the population presently served has for the service, the extent
90 to which that need will be met adequately by the proposed
91 relocation or by alternative arrangements, and the effect of the
92 reduction, elimination or relocation of the service on the
93 ability of low income persons, racial and ethnic minorities,
94 women, handicapped persons, and other medically underserved
95 population, and the elderly, to obtain needed health care;

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

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

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

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

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

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

124 (21) In the case of health services or facilities proposed
125 to be provided, the efficiency and appropriateness of the

126 use of existing services and facilities similar to those pro-
127 posed;

128 (22) In the case of existing services or facilities, the
129 quality of care provided by such services or facilities in
130 the past;

131 (23) In the case where an application is made by an
132 osteopathic or allopathic facility for a certificate of need
133 to construct, expand, or modernize a health care facility,
134 acquire major medical equipment, or add services, the need
135 for that construction, expansion, modernization, acquisition
136 of equipment, or addition of services shall be considered on
137 the basis of the need for and the availability in the com-
138 munity of services and facilities for osteopathic and allopathic
139 physicians and their patients. The state agency shall con-
140 sider the application in terms of its impact on existing and
141 proposed institutional training programs for doctors of osteo-
142 pathy and medicine at the student, internship, and residency
143 training levels;

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

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

155 (A) The extent to which medically underserved popula-
156 tions currently use the applicant's services in comparison to
157 the percentage of the population in the applicant's service area
158 which is medically underserved, and the extent to which
159 medically underserved populations are expected to use the
160 proposed services if approved;

161 (B) The performance of the applicant in meeting its
162 obligation, if any, under any applicable federal regulations

163 requiring provision of uncompensated care, community service,
164 or access by minorities and handicapped persons to programs
165 receiving federal financial assistance, including the existence
166 of any civil rights access complaints against the appli-
167 cant;

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

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

174 (26) The existence of a mechanism for soliciting con-
175 sumer input into the health care facility's decision making
176 process.

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

180 (c) Criteria for reviews may vary according to the pur-
181 pose for which a particular review is being conducted or the
182 types of health services being reviewed.

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

187 (e) In the case of any proposed new institutional health
188 service, the state agency may not grant a certificate of need
189 under its certificate of need program unless, after considera-
190 tion of the appropriateness of the use of existing facilities
191 providing services similar to those being proposed, the state
192 agency makes, in addition to findings required in section
193 nine of this article, each of the following findings in writing:

194 (1) That superior alternatives to such services in terms of
195 cost, efficiency and appropriateness do not exist and the
196 development of such alternatives is not practicable; (2) that
197 existing facilities providing services similar to those proposed
198 are being used in an appropriate and efficient manner; (3)
199 that in the case of new construction, alternatives to new con-

200 struction, such as modernization or sharing arrangements,
201 have been considered and have been implemented to the
202 maximum extent practicable; (4) that patients will experience
203 serious problems in obtaining care of the type proposed in the
204 absence of the proposed new service; and (5) that in the
205 case of a proposal for the addition of beds for the provision of
206 skilled nursing or intermediate care services, the addition
207 will be consistent with the plans of other agencies of the state
208 responsible for the provision and financing of long-term
209 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
2 of need, the state agency shall require the submission of long-
3 range plans by health care facilities with respect to the
4 development of proposals subject to review under this article.
5 The plans shall be in such form and contain such information
6 as the state agency shall require.

7 (b) An application for a certificate of need shall be
8 submitted to the state agency prior to the offering or develop-
9 ment of all new institutional services within this state. Per-
10 sons proposing new institutional health services shall submit
11 letters of intent not less than fifteen days prior to submitting
12 an application. The letters of intent shall be of such detail
13 as specified by the state agency.

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

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

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

21 (3) Except for proposed new institutional health services
22 which meet the requirements for consideration under sub-
23 section (g), section nine of this article with regard to the
24 elimination or prevention of certain imminent safety hazards
25 or to comply with certain licensure or accreditation standards,
26 provision for all completed applications pertaining to similar

27 types of services, facilities or equipment to be considered
28 in relation to each other, at least twice a year.

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

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

39 (f) Within fifteen days of receipt of application, the state
40 agency shall determine if the application is complete. The
41 state agency shall seek the advice of the designated health
42 systems agency for the area in which the proposed new insti-
43 tutional health service will be located to determine if the
44 application is complete and the state agency may request addi-
45 tional information from the applicant.

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

61 (h) Written notification to members of the public and
62 third-party payers may be provided through newspapers of
63 general circulation in the applicable health service area and
64 public information channels; notification to all other affected

65 persons shall be by mail which may be as part of a news-
66 letter.

67 (i) If, after a review has begun the state agency or the
68 health systems agency requires the person subject to the
69 review to submit additional information respecting the sub-
70 ject of the review, such person shall be provided at least
71 fifteen days to submit the information and the state agency
72 shall, at the request of such person, extend the review
73 period by fifteen days. This extension applies to all other
74 applications which have been considered in relation to the
75 application for which additional information is required.

76 (j) The state agency shall seek the recommendation of
77 the designated health systems agency for the health service
78 area in which the proposed new institutional health service
79 is to be located as to whether a certificate of need should
80 be issued. The state agency shall assist the designated health
81 systems agency in the review of applications by supplying
82 information and data on those proposed new institutional
83 services which have statewide implications.

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

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

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

103 (n) The state agency shall provide a public hearing in the
104 course of agency review if requested by any affected person
105 and the state agency may on its own initiate such a public
106 hearing.

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

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

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

121 (4) After the commencement of a hearing on the applicant's
122 application and before a decision is made with respect to it,
123 there may be no ex parte contracts between (a) the applicant
124 for the certificate of need, any person acting on behalf of
125 the applicant or holder of a certificate of need, or any person
126 opposed to the issuance of a certificate for the applicant and
127 (b) any person in the state agency who exercises any responsi-
128 bility respecting the application.

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

131 (o) If a public hearing is not conducted during the review
132 of a new institutional health service, the state agency may,
133 by regulations adopted pursuant to section eight of this article,
134 provide for a file closing date during the review period
135 after which date no other factual information or evidence
136 may be considered in the determination of the application
137 for the certificate of need, except that the file closing date
138 shall not be set prior to the date the state agency receives
139 the recommendation of the applicable health systems agency

140 with respect to the proposed new institutional health service
141 if the state agency receives such recommendation before the
142 sixty-first day for the review. A detailed itemization of
143 documents in the state agency file on a proposed new insti-
144 tutional health service shall, on request, be made available by
145 the state agency at any time before the file closing date.

146 (p) The extent of additional information received by the
147 state agency from the applicant for a certificate of need
148 after a review has begun on the applicant's proposed new
149 institutional health service, with respect to the impact on
150 such new institutional health service and additional informa-
151 tion which is received by the state agency from the applicant
152 after the state agency has received the applicable health systems
153 agency's recommendation, may be cause for the state agency
154 to determine the application to be a new proposal, subject
155 to a new review cycle.

156 (q) The state agency shall in timely fashion notify, upon
157 request, providers of health services and other persons subject
158 to review under this article of the status of the state agency
159 review of new institutional health services subject to review,
160 findings made in the course of such review, and other appro-
161 priate information respecting such review.

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

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

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

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

190 (B) Demonstrates that there have been significant changes
191 in factors or circumstances relied upon by the state agency
192 in reaching its decision;

193 (C) Demonstrates that the state agency has materially
194 failed to follow its adopted procedures in reaching its decision;
195 or

196 (D) Provides such other bases for a public hearing as
197 the state agency determines constitutes good cause.

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

203 (3) Notification of such public hearing shall be sent,
204 prior to the date of the hearing, to the person requesting the
205 hearing, the person proposing the new institutional health
206 service, and the health systems agency for the health service
207 area in which the new institutional health service is proposed
208 to be offered or developed, and shall be sent to others upon
209 request.

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

213 (A) Its adopted procedures;

214 (B) Ex parte contact provisions of subdivision (4), sub-
215 section (n) of this section; and

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

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

221 (8) A decision of the state agency following a reconsidera-
222 tion hearing shall be considered a decision of the state agency
223 for purposes of sections nine and ten of this article and for
224 purposes of the notification of the status of review, findings
225 and annual report provisions of subsections (q) and (r) of
226 this section.

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

232 (v) Notwithstanding other provisions of this article, the
233 state agency shall adopt rules and regulations for determining
234 when there is an application which warrants expedited review.
235 If procedures adopted by the state agency to handle expedited
236 applications do not conform to the provisions of this article,
237 such procedures shall be approved by the federal secretary
238 of health and human services and shall be adopted as regula-
239 tions pursuant to section eight of this article.

§16-2D-8. Agency to promulgate additional rules and regulations.

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

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

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

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

14 (1) The state agency shall distribute copies of its proposed
15 review rules and regulations, and proposed revisions thereof,
16 to statewide health agencies and organizations, the statewide

17 health coordinating council, and each health systems agency
18 for a health service area located in whole or in part within
19 the state and any agency which establishes rates for health
20 care facilities in the state.

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

28 (3) The state agency shall distribute copies of its adopted
29 review rules and regulations, and any revisions thereof, to the
30 agencies and organizations specified in this section and to the
31 secretary of health and human services, and shall provide
32 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.**

1 (a) Only the state agency, or the appropriate administra-
2 tive or judicial review body, may issue, deny or withdraw
3 certificates of need, grant exemptions from certificate of need
4 reviews, or determine that certificate of need reviews are not
5 required.

6 (b) Except as provided in subsection (f) of this section, a
7 certificate of need may only be issued if the proposed new in-
8 stitutional health service is:

9 (1) Found to be needed; and

10 (2) Except in emergency circumstances that pose a threat
11 to public health, consistent with the state health plan: *Pro-*
12 *vided*, That if a health care facility which is controlled, direct-
13 ly or indirectly, by a health maintenance organization applies
14 for a certificate of need for a proposed new institutional health
15 service, the state agency may not disapprove the application
16 solely because such an institutional health service is not dis-
17 cussed in the state health plan, applicable health systems plan,
18 or annual implementation plan.

19 (c) The state agency shall render a final decision on every
20 application for a certificate of need or application for exemp-
21 tion in the form of an approval, a denial, an approval with
22 conditions. Any decision of the state agency with respect to a
23 certificate of need, or exemption, shall be based solely on:

24 (1) The review of the state agency conducted in accordance
25 with procedures and criteria in this article and in regulations
26 adopted pursuant to section eight of this article; and

27 (2) The record established in administrative proceedings
28 held with respect to the certificate of need or exemption.

29 (d) Approval with conditions does not give the state agency
30 authority to mandate new institutional health services not
31 proposed by the health care facility or health maintenance
32 organization. Issuance of a certificate of need or exemption
33 may not be made subject to any condition unless the con-
34 dition directly relates to criteria in this article or in rules and
35 regulations adopted pursuant to section eight of this article.

36 (e) (1) For each proposed new institutional health service
37 it approves, the state agency shall, in addition to the written
38 findings required in subsection (e), section six of this article,
39 make a written finding, which shall take into account the
40 current accessibility of the facility as a whole, on the extent
41 to which the new institutional health service will meet the
42 criteria in subdivisions (4), (14), and (25), subsection (a),
43 section six of this article regarding the needs of medically
44 underserved population, except in the following cases:

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

49 (B) Where the new institutional health service is a proposed
50 capital expenditure not directly related to the provision of
51 health services or to beds or major medical equipment; or

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

55 (2) If the state agency disapproves a proposed new insti-
56 tutional health service for failure to meet the needs of medi-
57 cally underserved populations, it shall so state in a written
58 finding.

59 (f) (1) Notwithstanding review criteria in subdivision (12),
60 subsection (a), section six of this article, if a health care fa-
61 cility which is controlled, directly or indirectly, by a health
62 maintenance organization applies for a certificate of need,
63 such application shall be approved by the state agency if the
64 state agency finds, in accordance with criteria prescribed by
65 the state agency by regulations adopted pursuant to section
66 eight of this article, that:

67 (A) Approval of such application is required to meet the
68 needs of the members of the health maintenance organization
69 and of the new members which such organization can reason-
70 ably be expected to enroll; and

71 (B) The health maintenance organization is unable to pro-
72 vide, through services or facilities which can reasonably be ex-
73 pected to be available to the organization, its institutional
74 health services in a reasonable and cost-effective manner which
75 is consistent with the basic method of operation of the organi-
76 zation and which makes such services available on a long-
77 term basis through physicians and other health professionals
78 associated with it.

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

87 (g) (1) Notwithstanding review criteria in section six of this
88 article, an application for a certificate of need shall be ap-
89 proved, if the state agency finds that the facility or service with
90 respect to which such capital expenditure is proposed to be
91 made is needed and that the obligation of such capital ex-

92 penditure is consistent with the state health plan, for a capital
93 expenditure which is required:

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

97 (B) To comply with state licensure standards; or

98 (C) To comply with accreditation or certification stand-
99 ards, compliance with which is required to receive reimburse-
100 ments under Title XVIII of the social security act or pay-
101 ments under the state plan for medical assistance approved
102 under TitleXIX of such act.

103 (2) An application for a certificate of need approved un-
104 der this subsection shall be approved only to the extent that
105 the capital expenditure is required to eliminate or prevent the
106 hazards described in subparagraph (A), subdivision (1), sub-
107 section (q), or to comply with the standards described in
108 either subparagraph (B) or (C) of subdivision (1) subsection
109 (g), of this section.

110 (h) (1) The state agency shall send its decision along with
111 written findings to the person proposing the new institutional
112 health service or exemption and to the health systems agency
113 for the health service area in which the new service is pro-
114 posed to be offered or developed and shall make it available
115 to others upon request.

116 (2) In the case of a new institutional health service pro-
117 posed by an health maintenance organization, the state agency
118 shall send the written findings to the appropriate regional
119 office of the federal department of health and human ser-
120 vices at the time they are sent to the applicant.

121 (3) In any decision where the state agency finds that a
122 proposed new institutional health service does not satisfy the
123 criteria in subdivisions (4), (14), and (25), subsection (a), sec-
124 tion six, of this article regarding the needs of medically under-
125 served population, it shall so notify in writing the applicant
126 and the appropriate regional office of the federal department
127 of health and human services.

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

132 (j) The state agency shall specify in the certificate the
133 maximum amount of capital expenditures which may be ob-
134 ligated under such certificate. The state agency shall prescribe
135 the method used to determine capital expenditure maximums
136 and shall adopt regulations pursuant to section eight of this
137 article for the review of approved new institutional health ser-
138 vices for which the capital expenditure maximum is exceeded
139 or is expected to be exceeded.

140 (k) If the state agency makes a decision regarding a pro-
141 posed new institutional health service which is inconsistent
142 with a recommendation made with respect thereto by the ap-
143 plicable health systems agency or is inconsistent with the goals
144 of the applicable health systems plan or the priorities of the
145 applicable annual implementation plan, the state agency shall,
146 if its decision does not include a written, detailed statement
147 of the reasons for the inconsistency, provide such a statement
148 to such health systems agency.

149 (l) If the state agency fails to make a decision within the
150 time period specified for the review, the applicant may, within
151 one year following the expiration of such period, bring an
152 action, at the election of the applicant, in either the circuit
153 court of Kanawha County, or with the judge thereof in vaca-
154 tion, or in the circuit court of the county in which the applicant
155 or any one of the applicants resides or does business, or with
156 the judge thereof in vacation to require the state agency to ap-
157 prove or disapprove the application. An application for a pro-
158 posed new institutional health service or exemption may not be
159 approved or denied by the circuit court solely because the
160 state agency failed to reach a decision.

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

1 (a) A final decision of the state agency, including a state
2 agency decision issued after a reconsideration, if such recon-
3 sideration was requested and granted under subsection (t),

4 section seven, of this article, and the record upon which it
5 was made, shall, upon request of any affected person, or the
6 applicable health systems agency if the decision is inconsistent
7 with a recommendation made by the applicable health systems
8 agency to the state agency with respect to the certificate of
9 need, be reviewed by an agency of the state (other than the
10 state agency) designated by the governor. To be effective, such
11 request shall be received within thirty days after the date
12 upon which all parties received notice of the state agency de-
13 cision, and the hearing shall commence within thirty days of
14 receipt of the request.

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

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

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

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

37 (f) Upon the entry of a final decision by the reviewing
38 agency the designated health system agency, if the decision re-
39 specting the certificate of need is inconsistent with a recom-
40 mendation made by that health systems agency to the state
41 agency with respect to the certificate of need, and any other

42 “person adversely affected by the review” have standing in and
 43 may within thirty days after the date upon which all parties
 44 received notice of the decision of the review agency take an
 45 appeal at the election of the petitioner, in either the circuit court
 46 of Kanawha County, or in the circuit court of the county in
 47 which the petitioner or any of the petitioners resides or does
 48 business, from any decision of the state agency granting, with
 49 or without conditions, denying or withdrawing a certificate
 50 of need or exemption. The decision of the review agency shall
 51 be reviewed by such circuit court in accordance with the pro-
 52 visions for the judicial review of administrative decisions con-
 53 tained in section four, article five, chapter twenty-nine-a of this
 54 code. For the purposes of this subsection, “person adversely
 55 affected by the review” includes the state agency, any person
 56 who meets the definition of affected person in section two of
 57 this article, and any person who participated in the proceeding
 58 before the state agency.

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

1 (a) A certificate of need is nontransferable and shall be
 2 valid for a maximum of one year from the date of issuance.
 3 Upon the expiration of the certificate or during the certifica-
 4 tion period the person proposing the new institutional health
 5 service shall provide the state agency such information on
 6 the development of the project as the state agency may request.
 7 The state agency shall periodically monitor capital expendi-
 8 tures obligated under certificates, determine whether suf-
 9 ficient progress is being made in meeting the timetable
 10 specified in the approved application for the certificate
 11 and whether there has been compliance with the application
 12 and any conditions of certification. The state agency shall
 13 take in account recommendations made by the health systems
 14 agency in making its determination. The certificate of need
 15 may be extended by the state agency for additional periods
 16 of time as are reasonably necessary to expeditiously com-
 17 plete the project. A certificate of need may no longer be
 18 in effect, and may no longer be required, after written
 19 notice of substantial compliance with the approved application
 20 and any conditions of certification is issued to the applicant,

21 after the activity is undertaken for which the certificate
22 of need was issued, and after the state agency is provided
23 written notice of such undertaking. The person proposing
24 a new institutional health service may not be issued a license
25 therefor until the state agency has issued a written notice of
26 substantial compliance with the approved application and
27 any conditions of certification, nor may a new institutional
28 health service be used until such person has received such
29 notice. A new institutional health service may not be found
30 to be in substantial compliance with the approved application
31 and any conditions of certification if there is a substantial
32 change, as defined in regulations adopted pursuant to sub-
33 section (j), section three, of this article, in the approved new
34 institutional health service for which change a certificate
35 of need has not been issued.

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

38 (A) Insufficient progress in meeting the timetable specified
39 in the approved application for the certificate and for not
40 making a good faith effort to meet it in developing the pro-
41 ject; or

42 (B) Noncompliance with any conditions of certification; or

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

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

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

52 (2) Any decision of the state agency to withdraw a cer-
53 tificate of need shall be based solely on:

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

56 (B) The record established in administrative proceedings

57 held with respect to the state agency's proposal to withdraw
58 the certificate.

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

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

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

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

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

§16-2D-12. Licensing prohibited.

1 Any person acquiring, offering or developing any new
2 institutional health service for which a certificate of need
3 is required under this article without first obtaining a certificate
4 of need therefor as herein provided, or who violates any of
5 the provisions of this article is subject to denial or revoca-

6 tion of a license, in whole or in part, to operate such in-
7 stitutional health service or facility. Upon a showing to the
8 state agency that any person is offering or developing any
9 new institutional health service within the meaning of this
10 article without having first obtained a certificate of need
11 therefor as provided herein or that such person is otherwise
12 in violation of the provisions of this article, the state agency
13 shall provide such person with written notice which notice shall
14 state the nature of the violation and the time and place at which
15 such person shall appear to show good cause why its license
16 should not be revoked or denied, at which time and place such
17 person shall be afforded a reasonable opportunity to present
18 testimony and other evidence in support of its position. If,
19 thereafter, the state agency determines that such person's
20 license to operate such institutional health service or facility
21 should be revoked or denied, the state agency shall issue an
22 order, in writing, to the appropriate responsible licensing
23 agency of the state, requiring that such person's license to
24 operate such institutional health service or facility be revoked
25 or denied, which order shall be binding upon such licensing
26 agency.

§16-2D-13. Injunctive relief; civil penalty.

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

15 (b) The state agency may assess a civil penalty for viola-
16 tion of this article. Upon the state agency determining that
17 there is probable cause to believe that any person is knowingly

18 offering, developing, or has acquired any new institutional
19 health service subject to certificate of need review without
20 having first obtained a certificate of need therefor or that any
21 person is otherwise in violation of the provisions of this article,
22 or any lawful rule or regulation promulgated thereunder, the
23 state agency shall provide such person with written notice
24 which shall state the nature of the alleged violation and the
25 time and place at which such person shall appear to show
26 good cause why a civil penalty should not be imposed, at
27 which time and place such person shall be afforded an op-
28 portunity to cross-examine the state agency's witnesses and af-
29 farded an opportunity to present testimony and other evidence
30 in support of his position. The hearing shall be conducted
31 in accordance with the administrative hearing provisions of
32 section four, article five, chapter twenty-nine-a of this code.
33 If, after reviewing the record of such hearing, the state
34 agency director determines that such person is in violation of
35 the certificate of need law, the state agency shall assess a
36 civil penalty of not less than five hundred dollars nor more than
37 twenty-five thousand dollars. In determining the amount of
38 the penalty, the state agency shall consider the degree and
39 extent of harm caused by the violation and the cost of
40 rectifying the damage. Any person assessed shall be notified
41 of the assessment in writing, and the notice shall specify the
42 reasons for the assessment. If the person assessed fails to pay
43 the amount of the assessment to the state agency within thirty
44 days, the attorney general may institute a civil ac-
45 tion in the circuit court of the county wherein such
46 violation has occurred, or wherein such person may be found
47 to recover the amount of the assessment. In any such civil
48 action, the scope of the court's review of the state agency's
49 action, which shall include a review of the amount of the
50 assessment, shall be as provided in section four, article five,
51 chapter twenty-nine-a of this code for the judicial review of
52 contested administrative cases.

The Joint Committee on Enrolled Bills hereby certifies that the foregoing bill is correctly enrolled.

R. P. Bayler
Chairman Senate Committee

Tony E. Whitlow
Chairman House Committee

Originated in the House.

Takes effect July 1, 1981.

Loebel C. Skellis
Clerk of the Senate

C. A. Blankenship
Clerk of the House of Delegates

Warren R. McIsaac
President of the Senate

Lyle H. Lee, Jr.
Speaker House of Delegates

The within *is approved* this the *22*
day of *April*, 1981.

John D. Ralston
Governor

RECEIVED

APR 27 12 16 PM '81

OFFICE OF THE GOVERNOR

RECEIVED

81 APR 29 P 4: 35

OFFICE
OF STATE
SECY. OF STATE