WEST VIRGINIA LEGISLATURE **REGULAR SESSION, 1985**

ENROLLED Emmittee Substitute for SENATE BILL NO. 616

(By Mr. Leh

ENROLLED

COMMITTEE SUBSTITUTE

FOR

Senate Bill No. 616

(Mr. Loehr, original sponsor)

(Originating in the Committee on Health and Human Resources.)

[Passed April 13, 1985; in effect ninety days from passage.]

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

Be it enacted by the Legislature of West Virginia:

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

ARTICLE 2D. CERTIFICATE OF NEED.

§16-2D-2. Definitions.

- 1 As used in this article, unless otherwise indicated by the $\mathbf{2}$ context:
 - (a) "Affected person" means:
- 4 The applicant; (1)
- 5 (2) An agency or organization representing consumers:
- 6 (3) Any individual residing within the geographic area 7 served or to be served by the applicant;
- 8 (4) Any individual who regularly uses the health care 9 facilities within that geographic area;
- 10 (5) The health care facilities located in the applicable 11 health service area which provide services similar to the 12 services of the facility under review;
- 13 (6) The health care facilities which, prior to receipt by 14 the state agency of the proposal being reviewed, have 15 formally indicated an intention to provide similar services 16 in the future;
- 17 (7) Third party payers who reimburse any health care 18 facilities for services in the applicable health service area;
- 19 (8) Any agency which establishes rates for the health 20 care facilities located in the applicable health service area; 21or
- 22(9)Organizations representing health care providers.
- 23(b) "Ambulatory health care facility" means a facility, 24which is free-standing and not physically attached to a 25health care facility and which provides health care to 26 noninstitutionalized and nonhomebound persons on an 27outpatient basis. This definition does not include the 28 private office practice of any one or more health 29 professionals licensed to practice in this state pursuant to
- 30 the provisions of chapter thirty of this code: Provided, That
- such exemption from review of private office practice shall 31

not be construed to include such practices where major
medical equipment otherwise subject to review under the
provisions of this article is acquired, offered or developed.

- 35 "Ambulatory surgical facility" means a facility 36 which is free-standing and not physically attached to a 37 health care facility and which provides surgical treatment 38 to patients not requiring hospitalization. This definition 39 does not include the private office practice of any one or 40 more health professionals licensed to practice surgery in 41 this state pursuant to the provisions of chapter thirty of this 42 code: Provided, That such exemption from review of 43 private office practice shall not be construed to include 44 such practices where major medical equipment otherwise 45 subject to review under the provisions of this article is 46 acquired, offered or developed.
- "Annual implementation plan" means a plan 47 48 established, annually reviewed and amended as necessary 49 by a health systems agency in conformance with Section 1513(b)(3) of the Public Health Service Act, as amended, Title 42 United States Code section 3001-2(b)(3), which 51 describes objectives which will achieve the goals of the 52health systems plan, or, if those goals are amended by the 53 54 statewide health coordinating council when included in the 55 state health plan, as so amended, and priorities among the 56 objectives.
 - (e) "Applicable health service area" means a health service area, as defined in this section, in which a new institutional health service is proposed to be located.

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- 60 "Applicant" means: (1) The governing body or the 61 person proposing a new institutional health service who is, 62 or will be, the health care facility licensee wherein the new 63 institutional health service is proposed to be located, and (2) in the case of a proposed new institutional health service 64 65 not to be located in a licensed health care facility, the governing body or the person proposing to provide such 66 new institutional health service. Incorporators or 67 promoters who will not constitute the governing body or 68 persons responsible for the new institutional health service 69 70 may not be an applicant.
- 71 (g) "Bed capacity" means the number of beds for which 72 a license is issued to a health care facility, or, if a facility is 73 unlicensed, the number of adult and pediatric beds

74 permanently staffed and maintained for immediate use by 75 inpatients in patient rooms or wards. 76

"Capital expenditure" means an expenditure:

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

78 (A) Which (i) under generally accepted accounting 79 principles is not properly chargeable as an expense of operation and maintenance, or (ii) is made to obtain either 80 by lease or comparable arrangement any facility or part 81 thereof or any equipment for a facility or part; and (B) 82 83 which (i) exceeds the expenditure minimum, or (ii) is a 84 substantial change to the bed capacity of the facility with 85 respect to which the expenditure is made, or (iii) is a substantial change to the services of such facility. For 86 87 purposes of part (i), subparagraph (B), subdivision (2) of 88 this definition, the cost of any studies, surveys, designs, 89 plans, working drawings, specifications, and other 90 activities, including staff effort and consulting and other 91 services, essential to the acquisition, improvement, 92expansion, or replacement of any plant or equipment with 93 respect to which an expenditure described in subparagraph (B), subdivision (2) of this definition is made shall be 94 95 included in determining if such expenditure exceeds the 96 expenditure minimum. Donations of equipment or facilities 97 to a health care facility which if acquired directly by such facility would be subject to review shall be considered 98 capital expenditures, and a transfer of equipment or 99 facilities for less than fair market value shall be considered 100 101 a capital expenditure for purposes of such subdivisions if a 102 transfer of the equipment or facilities at fair market value would be subject to review. A series of expenditures, each 103 104 less than the expenditure minimum, which when taken 105 together are in excess of the expenditure minimum, may be determined by the state agency to be a single capital 106 107 expenditure subject to review. In making its determination, the state agency shall consider: Whether the expenditures 108 109 are for components of a system which is required to accomplish a single purpose; whether the expenditures are 110 111 to be made over a two-year period and are directed towards the accomplishment of a single goal within the health care 112facility's long-range plan; or, whether the expenditures are 113 to be made within a two-year period within a single 114 department such that they will constitute a significant 115 116 modernization of the department.

fourteen thousand dollars for the twelve-month period

119 beginning the first day of October, one thousand nine

120 hundred eighty-five. For each twelve-month period

thereafter, the state agency may, by regulations adopted pursuant to section eight of this article, adjust the

123 expenditure minimum to reflect the impact of inflation.

- 124 (j) "Health," used as a term, includes physical and 125 mental health.
- 126 (k) "Health care facility" is defined as including 127 hospitals, skilled nursing facilities, kidney disease
- 128 treatment centers, including free-standing hemodialysis
- 129 units, intermediate care facilities, ambulatory health care
- 130 facilities, ambulatory surgical facilities, home health
- 131 agencies, rehabilitation facilities, and health maintenance
- agencies, renabilitation facilities, and health maintenance
- 132 organizations, community mental health and mental
- 133 retardation facilities; whether under public or private
- 134 ownership, or as a profit or nonprofit organization and
- 135 whether or not licensed or required to be licensed in whole
- 136 or in part by the state. For purposes of this definition,
- 137 "community mental health and mental retardation facility"
- 138 means a private facility which provides such
- 139 comprehensive services and continuity of care as
- 140 emergency, outpatient, partial hospitalization, inpatient
- 141 and consultation and education for individuals with mental
- 142 illness, mental retardation or drug or alcohol addiction.
- 143 (l) "Health care provider" means a person, partnership, 144 corporation, facility or institution licensed or certified or
 - to polation, lacinty of institution feelibed of certified of
- 145 authorized by law to provide professional health care
- 146 service in this state to an individual during that individual's
- 147 medical care, treatment or confinement.
- 148 (m) "Health maintenance organization" means a public
- 149 or private organization, organized under the laws of this
- 150 state, which:

- 151 (1) Is a qualified health maintenance organization
- 152 under Section 1310(d) of the Public Health Service Act, as
- 153 amended, Title 42 United States Code Section 300e-9(d); or
- 154 (2) (A) Provides or otherwise makes available to
- 155 enrolled participants health care services, including
- 156 substantially the following basic health care services:
- 157 Usual physician services, hospitalization, laboratory, X-
- 158 ray, emergency and preventive services, and out-of-area
- 159 coverage; and

- (B) Is compensated except for copayments for the provision of the basic health care services listed in subparagraph (2)(A), subdivision (m) of this definition to enrolled participants on a predetermined periodic rate basis without regard to the date the health care services are provided and which is fixed without regard to the frequency, extent, or kind of health service actually provided: and
 - (C) Provides physicians' services primarily (i) directly through physicians who are either employees or partners of such organization, or (ii) through arrangements with individual physicians or one or more groups of physicians organized on a group practice or individual practice basis.
 - (n) "Health service area" means a geographic area designated by the Federal Secretary of Health and Human Services pursuant to Section 1511 of the Public Health Services Act, as amended, Title 42 United States Code Section 3001, with respect to which health systems agencies shall be designated under Section 1515 of such act, as amended. Title 42 United States Code Section 3001-4.
- 180 (o) "Health services" means clinically related 181 preventive, diagnostic, treatment or rehabilitative services, 182 including alcohol, drug abuse and mental health services. 183 (p) "Home health agency" is an organization primarily
 - (p) "Home health agency" is an organization primarily engaged in providing directly or through contract arrangements, professional nursing services, home health aide services, and other therapeutic and related services including, but not limited to, physical, speech and occupational therapy and nutritional and medical social services, to persons in their place of residence on a part-time or intermittent basis.
 - (q) "Hospital" means an institution which is primarily engaged in providing to inpatients, by or under the supervision of physicians, diagnostic and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons, or rehabilitation services for the rehabilitation of injured, disabled or sick persons. This term also includes psychiatric and tuberculosis hospitals.
- 199 (r) "Intermediate care facility" means an institution 200 which provides, on a regular basis, health-related care and 201 services to individuals who do not require the degree of care

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

- (s) "Long-range plan" means a document formally adopted by the legally constituted governing body of an existing health care facility or by a person proposing a new institutional health service. Each long-range plan shall consist of the information required by the state agency in regulations adopted pursuant to section eight of this article.
- 211 212 (t) "Major medical equipment" means a single unit of 213 medical equipment or a single system of components with 214 related functions which is used for the provision of medical 215 and other health services and which costs in excess of four 216 hundred thousand dollars, except that such term does not 217 include medical equipment acquired by or on behalf of a 218 clinical laboratory to provide clinical laboratory services if 219 the clinical laboratory is independent of a physician's office 220 and a hospital and it has been determined under Title XVIII 221 of the Social Security Act to meet the requirements of 222 paragraphs ten and eleven of Section 1861(s) of such act, 223 Title 42 United States Code Sections 1395x (10) and (11). In 224 determining whether medical equipment costs more than 225 four hundred thousand dollars, the cost of studies, surveys, 226 designs, plans, working drawings, specifications, and other 227 activities essential to the acquisition of such equipment 228 shall be included. If the equipment is acquired for less than 229 fair market value, the term "cost" includes the fair market 230 value.
- 231 "Medically underserved population" means the 232 population of an urban or rural area designated by the state 233agency as an area with a shortage of personal health 234 services or a population having a shortage of such services, 235 after taking into account unusual local conditions which 236 are a barrier to accessibility or availability of such services. 237 Such designation shall be in regulations adopted by the 238 state agency pursuant to section eight of this article, and the 239 population so designated may include the state's medically 240underserved population designated by the Federal 241 Secretary of Health and Human Services under Section 242330(b)(3) of the Public Health Service Act, as amended, 243 Title 42 United States Code Section 254(b)(3).

- 244 (v) "New institutional health service" means such 245 service as described in section three of this article.
- 246 (w) "Offer" when used in connection with health 247 services, means that the health care facility or health 248 maintenance organization holds itself out as capable of 249 providing, or as having the means for the provision of, 250 specified health services.
- 251 (x) "Person" means an individual, trust, estate, 252 partnership, committee, corporation, association and other 253 organizations such as joint-stock companies and insurance 254 companies, a state or a political subdivision or 255 instrumentality thereof or any legal entity recognized by 256 the state.
- 257 (y) "Physician" means a doctor of medicine or 258 osteopathy legally authorized to practice medicine and 259 surgery by the state.
- 260 (z) "Proposed new institutional health service" means 261 such service as described in section three of this article.
- 262 (aa) "Psychiatric hospital" means an institution which 263 primarily provides to inpatients, by or under the 264 supervision of a physician, specialized services for the 265 diagnosis, treatment and rehabilitation of mentally ill and 266 emotionally disturbed persons.
- 267 (bb) "Rehabilitation facility" means an inpatient 268 facility which is operated for the primary purpose of 269 assisting in the rehabilitation of disabled persons through 270 an integrated program of medical and other services which 271 are provided under competent professional supervision.
- 272 (cc) "Review agency" means an agency of the state 273 designated by the governor as the agency for the review of 274 state agency decisions.
- 275 (dd) "Skilled nursing facility" means an institution or a 276 distinct part of an institution which is primarily engaged in 277 providing to inpatients skilled nursing care and related 278 services for patients who require medical or nursing care, or 279 rehabilitation services for the rehabilitation of injured, 280 disabled or sick persons.
- 281 (ee) "State agency" means that agency of state 282 government selected by the governor and designated as the 283 state health planning and development agency in an 284 agreement entered into pursuant to Section 1521 of the 285 Public Health Service Act, as amended, Title 42 United 286 States Code Section 300m.

- 287 (ff) "State health plan" means the document approved 288 by the governor after preparation by the statewide health 289 coordinating council pursuant to Section 1524(c)(2) of the 290 Public Health Service Act, as amended, Title 42 United 291 States Code Section 300m-3(c)(2).
- 292 (gg) "Statewide health coordinating council" means the 293 body established pursuant to Section 1524 of the Public 294 Health Service Act, as amended, Title 42 United States 295 Code Section 300m-3, to advise the state agency.
- 296 (hh) "Substantial change to the bed capacity" of a
 297 health care facility means a change, with which a capital
 298 expenditure is associated, in any two-year period of ten or
 299 more beds or more than ten percent, whichever is less, of the
 300 bed capacity of such facility that increases or decreases the
 301 bed capacity, redistributes beds among various categories,
 302 or relocates beds from one physical facility or site to
 303 another. A series of changes to the bed capacity of a health
 304 care facility in any two-year period, each less than ten beds
 305 or ten percent of the bed capacity of such facility, but which
 306 when taken together comprise ten or more beds or more
 307 than ten percent of the bed capacity of such facility,
 308 whichever is less, is a substantial change to the bed
 309 capacity.
- 310 (ii) "Substantial change to the health services" of a 311 health care facility means the addition of a health service 312 which is offered by or on behalf of the health care facility 313 and which was not offered by or on behalf of the facility 314 within the twelve-month period before the month in which 315 the service is first offered, or the termination of a health 316 service which was offered by or on behalf of the facility.
- 317 (jj) "To develop," when used in connection with health 318 services, means to undertake those activities which, upon 319 their completion, will result in the offer of a new 320 institutional health service or the incurring of a financial 321 obligation, in relation to the offering of such a service.
- 322 (kk) "Tuberculosis hospital" means an institution 323 which is primarily engaged in providing to inpatients, by or 324 under the supervision of a physician, medical services for 325 the diagnosis and treatment of tuberculosis.

§16-2D-3. Certificate of need.

1 Except as provided in section four of this article, any new

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- institutional health service may not be acquired, offered or developed within this state except upon application for and 4 receipt of a certificate of need as provided by this article. Whenever a new institutional health service for which a certificate of need is required by this article is proposed for a health care facility for which, pursuant to section four of 8 this article, no certificate of need is or was required, a 9 certificate of need shall be issued before the new 10 institutional health service is offered or developed. No 11 person may knowingly charge or bill for any health services 12associated with any new institutional health service that is 13 knowingly acquired, offered or developed in violation of 14 this article, and any bill made in violation of this sentence is 15 legally unenforceable. For purposes of this article, a 16 proposed "new institutional health service" includes:
 - (a) The construction, development, acquisition or other establishment of a new health care facility or health maintenance organization;
 - (b) The partial or total closure of a health care facility or health maintenance organization with which a capital expenditure is associated;
 - (c) Any obligation for a capital expenditure incurred by or on behalf of a health care facility, except as exempted in section four of this article, or health maintenance organization in excess of the expenditure minimum or any obligation for a capital expenditure incurred by any person to acquire a health care facility. An obligation for a capital expenditure is considered to be incurred by or on behalf of a health care facility:
 - (1) When a contract, enforceable under state law, is entered into by or on behalf of the health care facility for the construction, acquisition, lease or financing of a capital asset;
- When the governing board of the health care facility takes formal action to commit its own funds for a construction project undertaken by the health care facility 38 as its own contractor; or
- 39 (3) In the case of donated property, on the date on which 40 the gift is completed under state law;
 - A substantial change to the bed capacity of a health care facility with which a capital expenditure is associated;
 - The addition of health services which are offered by

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- 44 or on behalf of a health care facility or health maintenance
- 45 organization and which were not offered on a regular basis
- by or on behalf of such health care facility or health
- 47 maintenance organization within the twelve-month period
- prior to the time such services would be offered; 48
- The deletion of one or more health services. 49 previously offered on a regular basis by or on behalf of a 50
- health care facility or health maintenance organization 51
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- which deletion is associated with a capital expenditure; 53 A substantial change to the bed capacity or health
- 54 services offered by or on behalf of a health care facility,
- whether or not the change is associated with a proposed 55
- capital expenditure, if the change is associated with a 56
- previous capital expenditure for which a certificate of need
- 58 was issued and if the change will occur within two years
- 59 after the date the activity which was associated with the
- previously approved capital expenditure was undertaken; 60
 - The acquisition of major medical equipment; and
- 62 A substantial change in an approved new
- institutional health service for which a certificate of need is 63
- in effect. For purposes of this subdivision "substantial 64
- change" shall be defined by the state agency in regulations
- adopted pursuant to section eight of this article.

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

- 1 Except as provided in subdivision (h), section three
- of this article, nothing in this article or the rules and 3
- regulations adopted pursuant to the provisions of this 4 article may be construed to authorize the licensure,
- 5 supervision, regulation or control in any manner of: (1)
- 6 Private office practice of any one or more health
- professionals licensed to practice in this state pursuant to
- 8 the provisions of chapter thirty of this code: Provided, That
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- such exemption from review of private office practice shall
- 10 not be construed to include such practices where major 11
- medical equipment otherwise subject to review under the 12 provisions of this article is acquired, offered or developed;
- 13 (2) dispensaries and first-aid stations located within
- 14 business or industrial establishments maintained solely for
- 15 the use of employees: Provided, however, That such facility
- 16 does not contain inpatient or resident beds for patients or
- 17 employees who generally remain in the facility for more

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- 18 than twenty-four hours; (3) establishments, such as motels, 19 hotels and boardinghouses, which provide medical, nursing 20 personnel and health related services; and (4) the remedial 21care or treatment of residents or patients in any home or 22institution conducted only for those who rely solely upon 23treatment by prayer or spiritual means in accordance with 24 the creed of tenets of any recognized church or religious 25 denomination.
 - (b) (1) A certificate of need is not required for the offering of an inpatient institutional health service or the acquisition of major medical equipment for the provision of an inpatient intitutional health service or the obligation of a capital expenditure for the provisions of an inpatient institutional health service, if with respect to such offering, acquisition, or obligation, the state agency has, upon application under subdivision (2), subsection (b) of this section, granted an exemption to:
- 35 (A) A health maintenance organization or a 36 combination of health maintenance organizations if (i) the 37 organization or combination of organizations has, in the 38 service area of the organization or the service areas of the 39 organizations in the combination, an enrollment of at least 40 fifty thousand individuals, (ii) the facility in which the 41 service will be provided is or will be geographically located 42so that the service will be reasonably accessible to such 43 enrolled individuals, and (iii) at least seventy-five percent 44 of the patients who can reasonably be expected to receive the institutional health service will be individuals enrolled 45 46 with such organization or organizations in the 47 combination:
- 48 (B) A health care facility if (i) the facility primarily 49 provides or will provide inpatient health services, (ii) the 50 facility is or will be controlled, directly or indirectly, by a health maintenance organization or a combination of 51 52 health maintenance organizations which has, in the service 53 area of the organization or service areas of the organizations in the combination, an enrollment of at least 54 fifty thousand individuals, (iii) the facility is or will be 55 56 geographically located so that the service will be 57 reasonably accessible to such enrolled individuals, and (iv) 58 at least seventy-five percent of the patients who can 59 reasonably be expected to receive the institutional health

service will be individuals enrolled with such organization or organizations in the combination; or

- (C) A health care facility, or portion thereof, if (i) the facility is or will be leased by a health maintenance organization or combination of health maintenance organizations which has, in the service area of the organization or the service areas of the organizations in the combination, an enrollment of at least fifty thousand individuals and on the date the application is submitted under subdivision (2), subsection (b) of this section, at least fifteen years remain in the term of the lease, (ii) the facility is or will be geographically located so that the service will be reasonably accessible to such enrolled individuals, and (iii) at least seventy-five percent of the patients who can reasonably be expected to receive the new institutional health service will be individuals enrolled with such organization.
 - (2) (A) A health maintenance organization, combination of health maintenance organizations, or other health care facility is not exempt under subdivision (1), subsection (b) of this section, from obtaining a certificate of need unless:
 - (i) It has submitted, at such time and in such form and manner as the state agency shall prescribe, an application for such exemption to the state agency;
 - (ii) The application contains such information respecting the organization, combination, or facility and the proposed offering, acquisition, or obligation as the state agency may require to determine if the organization or combination meets the requirements of subdivision (1), subsection (b) of this section, or the facility meets or will meet such requirements; and
 - (iii) The state agency approves such application.
 - (B) The state agency shall approve an application submitted under subparagraph (A), subdivision (2), subsection (b) of this section, if it determines that the applicable requirements of subdivision (1), subsection (b) of this section, are met or will be met on the date the proposed activity for which an exemption was requested will be undertaken.
- 100 (3) A health care facility, or any part thereof, or medical 101 equipment with respect to which an exemption was granted

- under subdivision (1), subsection (b) of this section, may not 103 be sold or leased and a controlling interest in such facility or 104 equipment or in a lease of such facility or equipment may 105 not be acquired and a health care facility described in subparagraph (C), subdivision (1), subsection (b) of this 106
- 107 section, which was granted an exemption under subdivision 108 (1), subsection (b) of this section, may not be used by any
- 109 person other than the lessee described in subparagraph (C), 110 subdivision (1), subsection (b) of this section, unless:
- 111 The state agency issues a certificate of need 112 approving the sale, lease, acquisition, or use; or
- 113 The state agency determines, upon application, that 114 the entity to which the facility or equipment is proposed to 115 be sold or leased, which intends to acquire the controlling 116 interest in or to use the facility is:
- 117 A health maintenance organization or a combination 118 of health maintenance organizations which meets the 119 enrollment requirements of part (i), subparagraph (A), 120 subdivision (1), subsection (b) of this section, and with 121 respect to such facility or equipment, the entity meets the 122 accessibility and patient enrollment requirements of parts 123 (ii) and (iii), subparagraph (A), subdivision (1), subsection 124 (b) of this section; or
- 125 (ii) A health care facility which meets the inpatient, 126 enrollment, and accessibility requirements of parts (i), (ii) 127 and (iii), subparagraph (B), subdivision (1), subsection (b) of 128 this section, and with respect to its patients meets the 129 enrollment requirements of part (iv), subparagraph (B), 130 subdivision (1), subsection (b) of this section.
- 131 In the case of a health maintenance organization or 132 an ambulatory care facility or health care facility which 133 ambulatory or health care facility is controlled, directly or 134 indirectly, by a health maintenance organization or a 135 combination of health maintenance organizations, the 136 certificate of need requirements apply only to the offering 137 of inpatient institutional health services, the acquisition of 138 major medical equipment, and the obligation of capital 139 expenditures for the offering of inpatient institutional 140 health services and then only to the extent that such 141 offering, acquisition, or obligation is not exempt under 142 subdivision (1), subsection (b) of this section.
- 143 The state agency shall establish the period within

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- which approval or disapproval by the state agency of applications for exemptions under subdivision (1), subsection (b) of this section, shall be made.
- 147 (c) (1) A health care facility is not required to obtain a 148 certificate of need for the acquisition of major medical 149 equipment to be used solely for research, the addition of 150 health services to be offered solely for research, or the 151 obligation of a capital expenditure to be made solely for 152 research if the health care facility provides the notice 153 required in subdivision (2), subsection (c) of this section, 154 and the state agency does not find, within sixty days after it receives such notice, that the acquisition, offering or 155 156 obligation will, or will have the effect to:
 - (A) Affect the charges of the facility for the provision of medical or other patient care services other than the services which are included in the research:
- 160 (B) Result in a substantial change to the bed capacity of 161 the facility; or
 - (C) Result in a substantial change to the health services of the facility.
 - (2) Before a health care facility acquires major medical equipment to be used solely for research, offers a health service solely for research, or obligates a capital expenditure solely for research, such health care facility shall notify in writing the state agency of such facility's intent and the use to be made of such medical equipment, health service, or capital expenditure.
- 171 (3) If major medical equipment is acquired, a health 172service is offered, or a capital expenditure is obligated and a 173certificate of need is not required for such acquisition, 174 offering, or obligation as provided in subdivision (1), 175 subsection (c) of this section, such equipment or service or 176 equipment or facilities acquired through the obligation of 177 such capital expenditure may not be used in such a manner 178 as to have the effect or to make a change described in 179 subparagraphs (A), (B) and (C), subdivision (1), subsection 180 (c) of this section, unless the state agency issues a certificate 181 of need approving such use.
- 182 (4) For purposes of this subsection, the term "solely for 183 research" includes patient care provided on an occasional 184 and irregular basis and not as part of a research program.
 - (d) (1) The state agency may adopt regulations

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186 pursuant to section eight of this article to specify the 187 circumstances under which a certificate of need may not be 188 required for the obligation of a capital expenditure to 189 acquire, either by purchase or under lease or comparable 190 arrangement, an existing health care facility: Provided, 191 That a certificate of need shall be required for the 192 obligation of a capital expenditure to acquire, either by 193 purchase or under lease or comparable arrangement, an 194 existing health care facility if:

- (A) The notice required by subdivision (2), subsection (d) of this section, is not filed in accordance with that subdivision with respect to such acquisition; or (B) the state agency finds, within thirty days after the date it receives a notice in accordance with subdivision (2), subsection (d) of this section, with respect to such acquisition, that the services or bed capacity of the facility will be changed by reason of said acquisition.
- (2) Before any person enters into a contractual arrangement to acquire an existing health care facility, such person shall notify the state agency of his or her intent 206 to acquire the facility and of the services to be offered in the facility and its bed capacity. Such notice shall be made in writing and shall be made at least thirty days before contractual arrangements are entered into to acquire the 210 facility with respect to which the notice is given. The notice shall contain all information the state agency requires in 211 accordance with subsections (e) and (u), section seven of 213 this article.
- 214 The state agency shall adopt regulations, pursuant to 215 section eight of this article, wherein criteria are established 216 to exempt from review the addition of certain health 217 services, not associated with a capital expenditure, that are 218 projected to entail annual operating costs of less than the 219 expenditure minimum for annual operating costs. For 220 purposes of this subsection, "expenditure minimum for 221 annual operating costs" means two hundred ninety-seven 222 thousand five hundred dollars for the twelve-month period 223beginning the first day of October, one thousand nine 224 hundred eighty-five, and for each twelve-month period 225 thereafter, the state agency may, by regulations adopted 226 pursuant to section eight of this article, adjust the 227 expenditure minimum for annual operating costs to reflect 228 the impact of inflation.

§16-2D-5. Powers and duties of state health planning and development agency.

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- (a) The state agency is hereby empowered to administer the certificate of need program as provided by this article.
- 3 (b) The state agency shall cooperate with the statewide 4 health coordinating council in developing rules and 5 regulations for the certificate of need program to the extent 6 appropriate for the achievement of efficiency in their 7 reviews and consistency in criteria for such reviews.
- 8 (c) The state agency may seek advice and assistance of 9 other persons, organizations, and other state agencies in the 10 performance of the state agency's responsibilities under 11 this article.
 - (d) For health services for which competition appropriately allocates supply consistent with the state health plan, the state agency shall, in the performance of its functions under this article, give priority, where appropriate, to advance the purposes of quality assurance, cost effectiveness, and access, to actions which would strengthen the effect of competition on the supply of such services.
 - (e) For health services for which competition does not or will not appropriately allocate supply consistent with the state health plan, the state agency shall, in the exercise of its functions under this article, take actions, where appropriate, to advance the purposes of quality assurance, cost effectiveness, and access and the other purposes of this article, to allocate the supply of such services.
- 27 (f) The state agency is hereby empowered to order a 28 moratorium upon the processing of an application or 29 applications for the acquisition of major medical 30 equipment filed pursuant to section three of this article and 31 considered by the agency to be new medical technology, 32 when criteria and guidelines for evaluating the need for 33 such new medical technology have not yet been adopted. 34 Such moratoriums shall be declared by a written order which shall detail the circumstances requiring the 35 moratorium. Upon the adoption of criteria for evaluating 36 the need for the new medical technology affected by the 37moratorium, or ninety days from the declaration of a 38 moratorium, whichever is less, the moratorium shall be

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40 declared to be over and affected applications shall be 41 processed pursuant to section six of this article.

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

- 1 (a) Prior to submission of an application for a certificate of need, the state agency shall require the submission of long-range plans by health care facilities with respect to the development of proposals subject to review under this article. The plans shall be in such form and contain such information as the state agency shall require.
- 7 (b) An application for a certificate of need shall be 8 submitted to the state agency prior to the offering or 9 development of all new institutional services within this state. Persons proposing new institutional health services shall submit letters of intent not less than fifteen days prior 12 to submitting an application. The letters of intent shall be of such detail as specified by the state agency.
- 14 (c) The state agency may adopt regulations pursuant to 15 section eight of this article for:
 - (1) Provision for applications to be submitted in accordance with a timetable established by the state agency;
 - (2) Provision for such reviews to be undertaken in a timely fashion; and
 - (3) Except for proposed new institutional health services which meet the requirements for consideration under subsection (g), section nine of this article with regard to the elimination or prevention of certain imminent safety hazards or to comply with certain licensure or accreditation standards, provision for all completed applications pertaining to similar types of services, facilities or equipment to be considered in relation to each other, at least twice a year.
 - (d) An application for a certificate of need shall specify the time the applicant will require to make such service or equipment available or to obligate such expenditure and a timetable for making such service or equipment available or obligating such expenditure.
- 35 (e) The application shall be in such form and contain
 36 such information as the state agency shall establish by rule
 37 or regulation, but requests for information shall be limited

to only that information which is necessary for the state agency to perform the review.

- (f) Within fifteen days of receipt of application, the state agency shall determine if the application is complete. The state agency may request additional information from the applicant.
- The state agency shall provide timely written notice (g) to the applicant and to all affected persons of the beginning of the review, and to any person who has asked the state agency to place the person's name on a mailing list maintained by the state agency. Notification shall include the proposed schedule for review, the period within which a public hearing during the course of the review may be requested by affected persons, which period may not be less than thirty days from the date of the written notification of the beginning of the review required by this section, and the manner in which notification will be provided of the time and place of any public hearing so requested. For the purposes of this subsection, the date of notification is the date on which the notice is sent or the date on which the notice appears in a newspaper of general circulation, whichever is later.
 - (h) Written notification to members of the public and third-party payers may be provided through newspapers of general circulation in the applicable health service area and public information channels; notification to all other affected persons shall be by mail which may be as part of a newsletter.
 - (i) If, after a review has begun, the state agency requires the person subject to the review to submit additional information respecting the subject of the review, such person shall be provided at least fifteen days to submit the information and the state agency shall, at the request of such person, extend the review period by fifteen days. This extension applies to all other applications which have been considered in relation to the application for which additional information is required.
 - (j) The state agency shall adopt schedules for reviews which provide that no review may, to the extent practicable, take longer than ninety days from the date that notification, as described under subsection (g) of this section, is sent to the applicant to the date of the final

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decision of the state agency, and in the case of expedited applications, may by regulations adopted pursuant to section eight of this article provide for a shortened review period.

- (k) The state agency shall adopt criteria for determining when it would not be practicable to complete a review within ninety days.
- (l) The state agency shall provide a public hearing in the course of agency review if requested by any affected person and the state agency may on its own initiate such a public hearing:
- (1) The state agency shall, prior to such hearing, provide notice of such hearing and shall conduct such hearing in accordance with administrative hearing requirements in article five, chapter twenty-nine-a of this code, and its procedure adopted pursuant to this section.
- 96 (2) In a hearing any person has the right to be 97 represented by counsel and to present oral or written 98 arguments and evidence relevant to the matter which is the 99 subject of the hearing. Any person affected by the matter 100 which is the subject of the hearing may conduct reasonable 101 questioning of persons who make factual allegations 102 relevant to such matter.
- 103 (3) The state agency shall maintain a verbatim record of 104 the hearing.
 - (4) After the commencement of a hearing on the applicant's application and before a decision is made with respect to it, there may be no ex parte contacts between (a) the applicant for the certificate of need, any person acting on behalf of the applicant or holder of a certificate of need, or any person opposed to the issuance of a certificate for the applicant and (b) any person in the state agency who exercises any responsibility respecting the application.
- 113 (5) The state agency may not impose fees for such a 114 public hearing.
- 115 (m) If a public hearing is not conducted during the review of a new institutional health service, the state agency may, by regulations adopted pursuant to section eight of this article, provide for a file closing date during the review period after which date no other factual information or evidence may be considered in the determination of the application for the certificate of need.

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A detailed itemization of documents in the state agency file on a proposed new institutional health service shall, on request, be made available by the state agency at any time before the file closing date.

- The extent of additional information received by the state agency from the applicant for a certificate of need after a review has begun on the applicant's proposed new institutional health service, with respect to the impact on such new institutional health service and additional information which is received by the state agency from the applicant, may be cause for the state agency to determine the application to be a new proposal, subject to a new review cycle.
- The state agency shall in timely fashion notify, upon request, providers of health services and other persons subject to review under this article of the status of the state agency review of new institutional health services subject to review, findings made in the course of such review, and other appropriate information respecting such review.
- The state agency shall prepare and publish, at least annually, reports of reviews completed and being conducted, with general statements about the status of each review still in progress and the findings and rationale for each completed review since the publication of the last report.
- The state agency shall provide for access by the general public to all applications reviewed by the state agency and to all other pertinent written materials essential to agency review.
- (r) (1) Any person may request in writing a public 152 hearing for purposes of reconsideration of a state agency 153decision. No fees may be imposed by the state agency for the 154 hearing. For purposes of this section, a request for a public 155 hearing for purposes of reconsideration shall be deemed to 156 have shown good cause if, in a detailed statement, it:
 - (A) Presents significant, relevant information not previously considered by the state agency, and demonstrates that with reasonable diligence the information could not have been presented before the state agency made its decision;
- 162 (B) Demonstrates that there have been significant 163 changes in factors or circumstances relied upon by the state 164 agency in reaching its decision;

- 165 (C) Demonstrates that the state agency has materially 166 failed to follow its adopted procedures in reaching its 167 decision; or
- 168 (D) Provides such other bases for a public hearing as the 169 state agency determines constitutes good cause.
- 170 (2) To be effective, a request for such a hearing shall be 171 received within thirty days after the date upon which all 172 parties received notice of the state agency decision, and the 173 hearing shall commence within thirty days of receipt of the 174 request.
- 175 (3) Notification of such public hearing shall be sent, 176 prior to the date of the hearing, to the person requesting the 177 hearing, the person proposing the new institutional health 178 service, and shall be sent to others upon request.
- 179 (4) The state agency shall hold public reconsideration 180 hearings in accordance with the provisions for 181 administrative hearings contained in:
- 182 (A) Its adopted procedures;
- 183 (B) Ex parte contact provisions of subdivision (4), 184 subsection (1) of this section; and
- 185 (C) The administrative procedures for contested cases 186 contained in article five, chapter twenty-nine-a of this 187 code.
- 188 (5) The state agency shall make written findings which 189 state the basis for its decision within forty-five days after 190 the conclusion of such hearing.
- 191 (6) A decision of the state agency following a 192 reconsideration hearing shall be considered a decision of 193 the state agency for purposes of sections nine and ten of this 194 article and for purposes of the notification of the status of 195 review, findings and annual report provisions of 196 subsections (o) and (p) of this section.
- 197 (s) The state agency may adopt regulations pursuant to 198 section eight of this article for reviews and such regulations 199 may vary according to the purpose for which a particular 200 review is being conducted or the type of health services 201 being reviewed.
- 202 (t) Notwithstanding other provisions of this article, the 203 state agency shall adopt rules and regulations for 204 determining when there is an application which warrants 205 expedited review. If procedures adopted by the state agency 206 to handle expedited applications do not conform to the

207 provisions of this article, such procedures shall be approved
208 by the federal secretary of health and human services and
209 shall be adopted as regulations pursuant to section eight of
210 this article.

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

- 1 (a) Only the state agency, or the appropriate 2 administrative or judicial review body, may issue, deny or 3 withdraw certificates of need, grant exemptions from 4 certificate of need reviews, or determine that certificate of 5 need reviews are not 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 8 institutional health service is:
 - (1) Found to be needed; and

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- 10 (2) Except in emergency circumstances that pose a 11 threat to public health, consistent with the state health 12 plan: Provided. That if a health care facility which is 13 controlled, directly or indirectly, by a health maintenance 14 organization applies for a certificate of need for a proposed 15 new institutional health service, the state agency may not 16 disapprove the application solely because such an 17 institutional health service is not discussed in the state 18 health plan or annual implementation plan. 19
 - (c) The state agency shall render a final decision on every application for a certificate of need or application for exemption in the form of an approval, a denial, or an approval with conditions. Any decision of the state agency with respect to a certificate of need, or exemption, shall be based solely on:
- 25 (1) The review of the state agency conducted in
 26 accordance with procedures and criteria in this article and
 27 in regulations adopted pursuant to section eight of this
 28 article; and
- (2) The record established in administrative
 proceedings held with respect to the certificate of need or
 exemption.
 (d) Approval with conditions does not give the state
- 32 (d) Approval with conditions does not give the state
 33 agency authority to mandate new institutional health
 34 services not proposed by the health care facility or health

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35 maintenance organization. Issuance of a certificate of need 36 or exemption may not be made subject to any condition 37unless the condition directly relates to criteria in this article 38 or in rules and regulations adopted pursuant to section eight of this article. Conditions may be imposed upon the 39 40 operations of the health care facility or health maintenance 41 organization for no longer than a three-year period. 42 Compliance with such conditions may be enforced through 43 the mechanisms detailed in section thirteen of this article.

- 44 (1) For each proposed new institutional health 45 service it approves, the state agency shall, in addition to the 46 written findings required in subsection (e), section six of 47 this article, make a written finding, which shall take into 48 account the current accessibility of the facility as a whole, 49 on the extent to which the new institutional health service 50 will meet the criteria in subdivisions (4), (14), and (25), 51 subsection (a), section six of this article, regarding the needs 52 of medically underserved population, except in the 53 following cases:
- 54 (A) Where the proposed new institutional health service
 55 is one described in subsection (g) of this section to eliminate
 56 or prevent certain imminent safety hazards or to comply
 57 with certain licensure or accreditation standards; or
- 58 (B) Where the new institutional health service is a 59 proposed capital expenditure not directly related to the 60 provision of health services or to beds or major medical 61 equipment; or 62 (C) Where the new institutional health service is
 - (C) Where the new institutional health service is proposed by or on behalf of a health care facility which is controlled, directly or indirectly, by a health maintenance organization.
 - (2) If the state agency disapproves a proposed new institutional health service for failure to meet the needs of medically underserved populations, it shall so state in a written finding.
- 70 (f) (1) Notwithstanding review criteria in subdivision 71 (12), subsection (a), section six of this article, if a health care 72 facility which is controlled, directly or indirectly, by a 73 health maintenance organization applies for a certificate of 74 need, such application shall be approved by the state 75 agency if the state agency finds, in accordance with criteria 76 prescribed by the state agency by regulations adopted 77 pursuant to section eight of this article, that:

- 78 (A) Approval of such application is required to meet the 79 needs of the members of the health maintenance 80 organization and of the new members which such 81 organization can reasonably be expected to enroll; and
- 82 The health maintenance organization is unable to 83 provide, through services or facilities which can reasonably 84 be expected to be available to the organization, its 85 institutional health services in a reasonable and cost-86 effective manner which is consistent with the basic method 87 of operation of the organization and which makes such 88 services available on a long-term basis through physicians 89 and other health professionals associated with it.
- 90 (2) Except as provided in subdivision (1), subsection (b). section four of this article, a health care facility, or any part 91 92thereof, or medical equipment with respect to which a certificate of need was issued under this subsection, may 93 94 not be sold or leased, and a controlling interest in such facility or equipment or in a lease of such facility or 96 equipment may not be acquired unless the state agency 97 issues a certificate of need approving the sale, acquisition or 98 lease.
- 99 (g) (1) Notwithstanding review criteria in section six of this article, an application for a certificate of need shall 100 101 be approved, if the state agency finds that the facility or 102 service with respect to which such capital expenditure is 103 proposed to be made is needed and that the obligation of 104 such capital expenditure is consistent with the state health 105 plan, for a capital expenditure which is required:
- (A) To eliminate or prevent imminent safety hazards as 106 107 defined by federal, state or local fire, building or life safety 108 codes or regulations:
 - To comply with state licensure standards; or

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- To comply with accreditation or certification standards, compliance with which is required to receive reimbursements under Title XVIII of the Social Security Act or payments under the state plan for medical assistance approved under Title XIX of such act.
- 115 (2) An application for a certificate of need approved 116 under this subsection shall be approved only to the extent 117 that the capital expenditure is required to eliminate or 118 prevent the hazards described in subparagraph (A), 119 subdivision (1), subsection (g), or to comply with the

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- 120 standards described in either subparagraph (B) or (C) of 121 subdivision (1), subsection (g) of this section.
- 122 (h) (1) The state agency shall send its decision along 123 with written findings to the person proposing the new institutional health service or exemption and shall make it 124 125 available to others upon request.
- 126 (2) In the case of a new institutional health service 127 proposed by a health maintenance organization, the state 128 agency shall send the written findings to the appropriate 129 regional office of the federal department of health and 130 human services at the time they are sent to the applicant.
 - (3) In any decision where the state agency finds that a proposed new institutional health service does not satisfy the criteria in subdivisions (4), (14), and (25), subsection (a), section six of this article, regarding the needs of medically underserved population, it shall so notify in writing the applicant and the appropriate regional office of the federal department of health and human services.
 - In the case of a final decision to approve or approve with conditions a proposal for a new institutional health service, the state agency shall issue a certificate of need to the person proposing the new institutional health service.
- (j) The state agency shall specify in the certificate the maximum amount of capital expenditures which may be obligated under such certificate. The state agency shall prescribe the method used to determine capital expenditure 146 maximums and shall adopt regulations pursuant to section eight of this article for the review of approved new institutional health services for which the capital 149 expenditure maximum is exceeded or is expected to be exceeded.
- 151 (k) If the state agency fails to make a decision within the 152 time period specified for the review, the applicant may, 153 within one year following the expiration of such period, 154 bring an action, at the election of the applicant, in either the 155 circuit court of Kanawha County, or with the judge thereof 156 in vacation, or in the circuit court of the county in which the 157 applicant or any one of the applicants resides or does 158 business, or with the judge thereof in vacation to require the 159 state agency to approve or disapprove the application. An 160 application for a proposed new institutional health service 161 or exemption may not be approved or denied by the circuit

court solely because the state agency failed to reach a

163 decision.

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

- (a) In addition to all other remedies, and aside from various penalties provided by law, if any person acquires. 3 offers or develops any new institutional health service for 4 which a certificate of need is required under this article without first having a certificate of need therefor as herein provided, or violates any other provision of this article or any lawful rule or regulation promulgated thereunder, 7 affected persons, as defined in section two of this article, 8 9 and the state agency shall request that the attorney general 10 maintain a civil action in the circuit court of the county 11 wherein such violation has occurred, or wherein such 12 person may be found, to enjoin, restrain or prevent such 13 violation. No injunction bond shall be required to be filed in 14 any such proceeding.
- 15 (b) The state agency may assess a civil penalty for 16 violation of this article. Upon the state agency determining 17 that there is probable cause to believe that any person is knowingly offering, developing, or has acquired any new 18 19 institutional health service subject to certificate of need 20 review without having first obtained a certificate of need 21therefor or that any person is otherwise in violation of the 22 provisions of this article, or any lawful rule or regulation 23 promulgated thereunder, the state agency shall provide 24 such person with written notice which shall state the nature 25 of the alleged violation and the time and place at which such 26 person shall appear to show good cause why a civil penalty 27 should not be imposed, at which time and place such person 28 shall be afforded an opportunity to cross-examine the state 29 agency's witnesses and afforded an opportunity to present 30 testimony and other evidence in support of his position. The 31 hearing shall be conducted in accordance with the 32 administrative hearing provisions of section four, article 33 five, chapter twenty-nine-a of this code. If, after reviewing 34 the record of such hearing, the state agency director 35 determines that such person is in violation of the certificate of need law, the state agency shall assess a civil penalty of 36 not less than five hundred dollars nor more than twenty-37 five thousand dollars. In determining the amount of 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 43
- pay the amount of the assessment to the state agency within 44
- thirty days, the attorney general may institute a civil action 45
- in the circuit court of the county wherein such violation has 46
- 47 occurred, or wherein such person may be found to recover
- the amount of the assessment. In any such civil action, the 48
- scope of the court's review of the state agency's action, 49
- which shall include a review of the amount of the 50
- assessment, shall be as provided in section four, article five, 51
- 52 chapter twenty-nine-a of this code for the judicial review of
- contested administrative cases. 53

§16-2D-14. Statute of limitations.

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

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

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

The Joint Committee on Enrolled Bills hereby certifies that the

foregoing bill is correctly enrolled.
Narul alames
Chairman Senate Committee
Chairman Aguse Committee
Originated in the Senate.
In effect ninety days from passage.
Sold C. Willes Clerk of the Senate
Clerk of the House of Delegates
President of the Senate
Speaker House of Delegates
The within Approved this the 2nd
day of May 1985. Aucha Phaness.
Governor

PRESENTED TO THE

GOVERNOR

Date 4/19/85

Yama 8:52 p.m.