WEST VIRGINIA CODE CHAPTER 16 ARTICLE 2D

§16-2D-1. Legislative findings.

It is declared to be the public policy of this state:

(1) That the offering or development of all health services shall be accomplished in a manner which is orderly, economical and consistent with the effective development of necessary and adequate means of providing for the health services of the people of this state and to avoid unnecessary duplication of health services, and to contain or reduce increases in the cost of delivering health services.

(2) That the general welfare and protection of the lives, health and property of the people of this state require that the type, level and quality of care, the feasibility of providing such care and other criteria as provided for in this article, including certificate of need standards and criteria developed by the authority pursuant to provisions of this article, pertaining to health services within this state, be subject to review and evaluation before any health services are offered or developed in order that appropriate and needed health services are made available for persons in the area to be served.

§16-2D-2. Definitions.

As used in this article:

(1) "Affected person" means:

(A) The applicant;

(B) An agency or organization representing consumers;

(C) An individual residing within the geographic area but within this state served or to be served by the applicant;

(D) An individual who regularly uses the health care facilities within that geographic area;

(E) A health care facility located within this state which provide services similar to the services of the facility under review and which will be significantly affected by the proposed project;

(F) A health care facility located within this state which, before receipt by the authority of the proposal being reviewed, has formally indicated an intention to provide similar services within this state in the future;

(G) Third-party payors who reimburse health care facilities within this state; or

(H) An organization representing health care providers;

(2) "Ambulatory health care facility" means a facility that provides health services to noninstitutionalized and nonhomebound persons on an outpatient basis;

(3) "Ambulatory surgical facility" means a facility not physically attached to a health care facility that provides surgical treatment to patients not requiring hospitalization;

(4) "Applicant" means a person applying for a certificate of need, exemption or determination of review;

(5) "Authority" means the West Virginia Health Care Authority as provided in §16-29B-1 *et seq*. of this code;

(6) "Bed capacity" means the number of beds licensed to a health care facility or the number of adult and pediatric beds permanently staffed and maintained for immediate use by inpatients in patient rooms or wards in an unlicensed facility;

(7) "Behavioral health services" means services provided for the care and treatment of persons with mental illness or developmental disabilities;

(8) "Birthing center" means a short-stay ambulatory health care facility designed for low-risk

births following normal uncomplicated pregnancy;

(9) "Campus" means the physical area immediately adjacent to the hospital's main buildings, other areas, and structures that are not strictly contiguous to the main buildings, but are located within 250 yards of the main buildings;

(10) "Capital expenditure" means:

(A) (i) An expenditure made by or on behalf of a health care facility, which:

(I) Under generally accepted accounting principles is not properly chargeable as an expense of operation and maintenance; or

(II) Is made to obtain either by lease or comparable arrangement any facility or part thereof or any equipment for a facility or part; and

(ii) (I) Exceeds the expenditure minimum;

(II) Is a substantial change to the bed capacity of the facility with respect to which the expenditure is made; or

(III) Is a substantial change to the services of such facility;

(B) The transfer of equipment or facilities for less than fair market value if the transfer of the equipment or facilities at fair market value would be subject to review; or

(C) A series of expenditures, if the sum total exceeds the expenditure minimum and if determined by the authority to be a single capital expenditure subject to review. In making this determination, the authority shall consider: Whether the expenditures are for components of a system which is required to accomplish a single purpose; or whether the expenditures are to be made within a two-year period within a single department such that they will constitute a significant modernization of the department.

(11) "Charges" means the economic value established for accounting purposes of the goods and services a hospital provides for all classes of purchasers;

(12) "Community mental health and intellectual disability facility" means a facility which provides comprehensive services and continuity of care as emergency, outpatient, partial hospitalization, inpatient or consultation and education for individuals with mental illness, intellectual disability;

(13) "Diagnostic imaging" means the use of radiology, ultrasound, and mammography;

(14)"Drug and Alcohol Rehabilitation Services" means a medically or psychotherapeutically supervised process for assisting individuals through the processes of withdrawal from dependency on psychoactive substances;

(15) "Expenditure minimum" means the cost of acquisition, improvement, expansion of any facility, equipment, or services including the cost of any studies, surveys, designs, plans, working drawings, specifications and other activities, including staff effort and consulting at and above $100 million;

(16) "Health care facility" means a publicly or privately owned facility, agency or entity that offers or provides health services, whether a for-profit or nonprofit entity and whether or not licensed, or required to be licensed, in whole or in part;

(17) "Health care provider" means a person authorized by law to provide professional health services in this state to an individual;

(18) "Health services" means clinically related preventive, diagnostic, treatment or rehabilitative services;

(19) "Home health agency" means an organization primarily engaged in providing professional nursing services either directly or through contract arrangements and at least one of the following services:

(A) Home health aide services;

(B) Physical therapy;

(C) Speech therapy;

(D) Occupational therapy;

(E) Nutritional services; or

(F) Medical social services to persons in their place of residence on a part-time or intermittent basis.

(20) "Hospice" means a coordinated program of home and inpatient care provided directly or through an agreement under the direction of a licensed hospice program which provides palliative and supportive medical and other health services to terminally ill individuals and their families.

(21) "Hospital" means a facility licensed pursuant to the provisions of §16-5B-1 *et seq*. of this code and any acute care facility operated by the state government, that primarily provides inpatient diagnostic, treatment or rehabilitative services to injured, disabled, or sick persons under the supervision of physicians.

(22) "Hospital services" means services provided primarily to an inpatient to include, but not be limited to, preventative, diagnostic, treatment, or rehabilitative services provided in various departments on a hospital’s campus;

(23) "Intermediate care facility" means an institution that provides health-related services to individuals with conditions that require services above the level of room and board, but do not require the degree of services provided in a hospital or skilled-nursing facility.

(24) "Inpatient" means a patient whose medical condition, safety, or health would be significantly threatened if his or her care was provided in a less intense setting than a hospital. This patient stays in the hospital overnight.

(25) "Like equipment" means medical equipment in which functional and technological capabilities are similar to the equipment being replaced; and the replacement equipment is to be used for the same or similar diagnostic, therapeutic, or treatment purposes as currently in use; and it does not constitute a substantial change in health service or a proposed health service.

(26) "Major medical equipment" means a single unit of medical equipment or a single system of components with related functions which is used for the provision of medical and other health services and costs in excess of the expenditure minimum. This term does not include medical equipment acquired by or on behalf of a clinical laboratory to provide clinical laboratory services if the clinical laboratory is independent of a physician’s office and a hospital and it has been determined under Title XVIII of the Social Security Act to meet the requirements of paragraphs ten and eleven, Section 1861(s) of such act, Title 42 U.S.C. § 1395x. In determining whether medical equipment is major medical equipment, the cost of studies, surveys, designs, plans, working drawings, specifications and other activities essential to the acquisition of such equipment shall be included. If the equipment is acquired for less than fair market value, the term "cost" includes the fair market value.

(27) "Medically underserved population" means the population of an area designated by the authority as having a shortage of a specific health service.

(28) "Nonhealth-related project" means a capital expenditure for the benefit of patients, visitors, staff or employees of a health care facility and not directly related to health services offered by the health care facility.

(29) "Offer" means the health care facility holds itself out as capable of providing, or as having the means to provide, specified health services.

(30) "Opioid treatment program" means as that term is defined in §16-5Y-1 *et seq*. of this code.

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

(32) "Personal care agency" means an entity that provides personal care services approved

by the Bureau of Medical Services.

(33) "Personal care services" means personal hygiene; dressing; feeding; nutrition; environmental support and health-related tasks provided by a personal care agency.

(34) "Physician" means an individual who is licensed to practice allopathic medicine by the Board of Medicine or licensed to practice osteopathic medicine by the Board of Osteopathic Medicine.

(35) "Proposed health service" means any service as described in §16-2D-8 of this code.

(36) "Purchaser" means an individual who is directly or indirectly responsible for payment of patient care services rendered by a health care provider, but does not include third-party payers.

(37) "Rates" means charges imposed by a health care facility for health services.

(38) "Records" means accounts, books and other data related to health service costs at health care facilities subject to the provisions of this article which do not include privileged medical information, individual personal data, confidential information, the disclosure of which is prohibited by other provisions of this code and the laws enacted by the federal government, and information, the disclosure of which would be an invasion of privacy.

(39) "Rehabilitation facility" means an inpatient facility licensed in West Virginia operated for the primary purpose of assisting in the rehabilitation of disabled persons through an integrated program of medical and other services.

(40) "Related organization" means an organization, whether publicly owned, nonprofit, tax-exempt or for profit, related to a health care facility through common membership, governing bodies, trustees, officers, stock ownership, family members, partners or limited partners, including, but not limited to, subsidiaries, foundations, related corporations and joint ventures. For the purposes of this subdivision "family members" means parents, children, brothers and sisters whether by the whole or half blood, spouse, ancestors, and lineal descendants.

(41) "Secretary" means the Secretary of the West Virginia Department of Health;

(42) "Skilled nursing facility" means an institution, or a distinct part of an institution, that primarily provides inpatient skilled nursing care and related services, or rehabilitation services, to injured, disabled or sick persons.

(43) "Standard'' means a health service guideline developed by the authority and instituted under §16-2D-6 of this code.

(44) "State health plan" means a document prepared by the authority that sets forth a strategy for future health service needs in this state.

(45) "Substantial change to the bed capacity" of a health care facility means any change, associated with a capital expenditure, that increases or decreases the bed capacity or relocates beds from one physical facility or site to another, but does not include a change by which a health care facility reassigns existing beds.

(46) "Substantial change to the health services" means:

(A) The addition of a health service offered by or on behalf of the health care facility which was not offered by or on behalf of the facility within the 12-month period before the month in which the service was first offered; or

(B) The termination of a health service offered by or on behalf of the facility but does not include the termination of ambulance service, wellness centers or programs, adult day care or respite care by acute care facilities.

(47) "Telehealth" means the use of electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health and health administration.

(48) "Third-party payor" means an individual, person, corporation or government entity responsible for payment for patient care services rendered by health care providers.

(49) "To develop" means to undertake those activities which upon their completion will result in the offer of a proposed health service or the incurring of a financial obligation in relation to the offering of such a service.

§16-2D-3. Powers and duties of the authority.

(a) The authority shall:

(1) Administer the certificate of need program;

(2) Review the state health plan, the certificate of need standards, and the cost effectiveness of the certificate of need program and make any amendments and modifications to each that it may deem necessary, no later than September 1, 2017, and biennially thereafter.

(3) Shall adjust the expenditure minimum annually and publish to its website the updated amount on or before December 31, of each year. The expenditure minimum adjustment shall be based on the DRI inflation index.

(4) Create a standing advisory committee to advise and assist in amending the state health plan, the certificate of need standards, and performing the state agencies' responsibilities.

(b) The authority may:

(1) (A) Order a moratorium upon the offering or development of a health service when criteria and guidelines for evaluating the need for the health service have not yet been adopted or are obsolete or when it determines that the proliferation of the health service may cause an adverse impact on the cost of health services or the health status of the public.

(B) A moratorium shall be declared by a written order which shall detail the circumstances requiring the moratorium. Upon the adoption of criteria for evaluating the need for the health service affected by the moratorium, or one hundred eighty days from the declaration of a moratorium, whichever is less, the moratorium shall be declared to be over and applications for certificates of need are processed pursuant to section eight.

(2) Approve an emerging health service or technology for one year.

(3) Exempt from certificate of need or annual assessment requirements to financially vulnerable health care facilities located in underserved areas that the state agency and the Office of Community and Rural Health Services determine are collaborating with other providers in the service area to provide cost effective health services.

§16-2D-4. Rulemaking.

(a) The authority shall propose rules for legislative approval in accordance with the provisions of article three, chapter twenty-nine-a of this code, to implement the following:

(1) Information a person shall provide when applying for a certificate of need;

(2) Information a person shall provide when applying for an exemption;

(3) Process for the issuance of grants and loans to financially vulnerable health care facilities located in underserved areas;

(4) Information a person shall provide in a letter of intent;

(5) Process for an expedited certificate of need;

(6) Determine medically underserved population. The authority may consider unusual local conditions that are a barrier to accessibility or availability of health services. The authority may consider when making its determination of a medically underserved population designated by the federal Secretary of Health and Human Services under Section 330(b)(3) of the Public Health Service Act, as amended, Title 42 U.S.C. §254;

(7) Process to review an approved certificate of need; and

(8) Process to review approved proposed health services for which the expenditure maximum is exceeded or is expected to be exceeded.

(b) All of the authority's rules in effect and not in conflict with the provisions of this article, shall remain in effect until they are amended or rescinded.

§16-2D-4a

Repealed.

Acts, 2016 Reg. Sess., Ch. 195

§16-2D-4b

Repealed.

Acts, 2016 Reg. Sess., Ch. 195

§16-2D-5. Fee; special revenue account; administrative fines.

(a) All fees and other moneys, except administrative fines, received by the authority shall be deposited in a separate special revenue fund in the State Treasury which is continued and shall be known as the "Certificate of Need Program Fund". Expenditures from this fund shall be for the purposes set forth in this article and are not authorized from collections but are to be made only in accordance with appropriation by the Legislature and in accordance with the provisions of article three, chapter twelve of this code and upon fulfillment of the provisions of article two, chapter eleven-b of this code: Provided, That for the fiscal year ending June 30, 2017, expenditures are authorized from collections rather than pursuant to appropriation by the Legislature.

(b) Any amounts received as administrative fines imposed pursuant to this article shall be deposited into the General Revenue Fund of the State Treasury.

§16-2D-5a

Repealed.

Acts, 2016 Reg. Sess., Ch. 195

§16-2D-5b

Repealed.

Acts, 2016 Reg. Sess., Ch. 195

§16-2D-5c

Repealed.

Acts, 2016 Reg. Sess., Ch. 195

§16-2D-5d

Repealed.

Acts, 2016 Reg. Sess., Ch. 195

§16-2D-5e

Repealed.

Acts, 2016 Reg. Sess., Ch. 195

§16-2D-5f

Repealed

Acts, 2017 Reg. Sess., Ch. 185.

§16-2D-6. Changes to certificate of need standards.

(a) When the authority proposes a change to the certificate of need standards, it shall file with the Secretary of State, for publication in the State Register, a notice of proposed action, including the text of all proposed changes, and a date, time and place for receipt of general public comment. To comply with the public comment requirement of this section, the authority may hold a public hearing or schedule a public comment period for the receipt of written statements or documents.

(b) When changing the certificate of need standards, the authority shall identify relevant criteria contained in section twelve and apply those relevant criteria to the proposed health service in a manner that promotes the public policy goals and legislative findings contained in section one.

(c) The authority shall form task forces to assist it in satisfying its review and reporting requirements. The task forces shall be comprised of representatives of consumers, business, providers, payers and state agencies.

(d) The authority shall coordinate the collection of information needed to allow the authority to develop recommended modifications to certificate of need standards.

(e) The authority may consult with or rely upon learned treatises in health planning, recommendations and practices of other health planning agencies and organizations, recommendations from consumers, recommendations from health care providers, recommendations from third-party payors, materials reflecting the standard of care, the authority's own developed expertise in health planning, data accumulated by the authority or other local, state or federal agency or organization and any other source deemed relevant to the certificate of need standards proposed for change.

(f) All proposed changes to the certificate of need standards, with a record of the public hearing or written statements and documents received pursuant to a public comment period, shall be presented to the Governor. Within thirty days of receiving the proposed amendments or modifications, the Governor shall either approve or disapprove all or part of the amendments and modifications and, for any portion of amendments or modifications not approved, shall specify the reason or reasons for disapproval. Any portions of the amendments or modifications not approved by the Governor may be revised and resubmitted.

(g) The certificate of need standards adopted pursuant to this section which are applicable to the provisions of this article are not subject to article three, chapter twenty-nine-a of this code. The authority shall follow the provisions set forth in this section for giving notice to the public of its actions, holding hearings or receiving comments on the certificate of need standards. The certificate of need standards in effect on July 1, 2016, and all prior versions promulgated and adopted in accordance with the provisions of this section are and have been in full force and effect from each of their respective dates of approval by the Governor.

(h) After approval from the Governor, the authority shall prepare a report detailing its review findings and submit the report to the Legislative Oversight Commission on Health and Human Resources Accountability with its annual report before January 1, each year.

§16-2D-7. Determination of reviewability.

A person may make a written request to the authority for it to determine whether a proposed health service is subject to the certificate of need or exemption process. The authority may require that a person submit certain information in order to make this determination. A person shall pay a $100 fee to the authority to obtain this determination. A person is not required to obtain this determination before filing an application for a certificate of need or an exemption.

§16-2D-7a

Repealed.

Acts, 2016 Reg. Sess., Ch. 195

§16-2D-8. Proposed health services that require a certificate of need.

(a) Except as provided in §16-2D-9, §16-2D-10, and §16-2D-11 of this code, the following proposed health services may not be acquired, offered, or developed within this state except upon approval of and receipt of a certificate of need as provided by this article:

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

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

(3) (A) An obligation for a capital expenditure incurred by or on behalf of a health care facility in excess of the expenditure minimum; or

(B) An obligation for a capital expenditure incurred by a person to acquire a health care facility.

(4) An obligation for a capital expenditure is considered to be incurred by or on behalf of a health care facility:

(A) When a valid contract is entered into by or on behalf of the health care facility for the construction, acquisition, lease, or financing of a capital asset;

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

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

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

(6) The addition of ventilator services by a hospital;

(7) The elimination of health services previously offered on a regular basis by or on behalf of a health care facility which is associated with a capital expenditure;

(8) (A) A substantial change to the bed capacity or health services offered by or on behalf of a health care facility, whether or not the change is associated with a proposed capital expenditure;

(B) If the change is associated with a previous capital expenditure for which a certificate of need was issued; and

(C) If the change will occur within two years after the date the activity which was associated

with the previously approved capital expenditure was undertaken.

(9) The acquisition of major medical equipment;

(10) A substantial change in an approved health service for which a certificate of need is in effect;

(11) An expansion of the service area for hospice or home health agency regardless of the time period in which the expansion is contemplated or made; and

(12) The addition of health services offered by or on behalf of a health care facility which were not offered on a regular basis by or on behalf of the health care facility within the 12-month period prior to the time the services would be offered.

(b) The following health services are required to obtain a certificate of need regardless of the minimum expenditure:

(1) Providing radiation therapy;

(2) Providing computed tomography;

(3) Providing positron emission tomography;

(4) Providing cardiac surgery;

(5) Providing fixed magnetic resonance imaging;

(6) Providing comprehensive medical rehabilitation;

(7) Establishing an ambulatory care center;

(8) Establishing an ambulatory surgical center;

(9) Providing diagnostic imaging;

(10) Providing cardiac catheterization services;

(11) Constructing, developing, acquiring, or establishing kidney disease treatment centers, including freestanding hemodialysis units;

(12) Providing megavoltage radiation therapy;

(13) Providing surgical services;

(14) Establishing operating rooms;

(15) Adding acute care beds;

(16) Providing intellectual developmental disabilities services;

(17) Providing organ and tissue transplants;

(18) Establishing an intermediate care facility for individuals with intellectual disabilities;

(19) Providing inpatient services;

(20) Providing hospice services;

(21) Establishing a home health agency;

(22) Providing personal care services; and

(23) (A) Establishing no more than six four-bed transitional intermediate care facilities: *Provided*, That none of the four-bed sites shall be within five miles of another or adjacent to another behavioral health facility. This subdivision terminates upon the approval of the sixth four-bed intermediate care facility.

(B) Only individuals living in more restrictive institutional settings, in similar settings covered by state-only dollars, or at risk of being institutionalized will be given the choice to move, and they will be placed on the Individuals with Intellectual and Developmental Disabilities (IDD) Waiver Managed Enrollment List. Individuals already on the IDD Waiver Managed Enrollment List who live in a hospital or are in an out-of-state placement will continue to progress toward home- and community-based waiver status and will also be considered for all other community-based options, including, but not limited to, specialized family care and personal care.

(C) The department shall work to find the most integrated placement based upon an individualized assessment. Individuals already on the IDD waiver will not be considered for placement in the 24 new intermediate care beds.

(D) A monitoring committee of not more than 10 members, including a designee of Mountain State Justice, a designee of Disability Rights of West Virginia, a designee of the Statewide Independent Living Council, two members or family of members of the IDD waiver, the Developmental Disabilities Council, the Commissioner of the Bureau of Health and Health Facilities, the Commissioner of the Bureau for Medical Services, and the Commissioner of the Bureau for Children and Families. The secretary of the department shall chair the first meeting of the committee at which time the members shall elect a chairperson. The monitoring committee shall provide guidance on the department's transitional plans for residents in the 24 intermediate care facility beds and monitor progress toward home- and community-based waiver status and/or utilizing other community-based options and securing the most integrated setting for each individual.

(E) Any savings resulting from individuals moving from more expensive institutional care or out-of-state placements shall be reinvested into home- and community-based services for

individuals with intellectual developmental disabilities.

(c) A certificate of need previously approved under this article remains in effect unless revoked by the authority.

§16-2D-9. Health services that cannot be developed.

Notwithstanding §16-2D-8 and §16-2D-11 of this code, these health services require a certificate of need but the authority may not issue a certificate of need to:

(1) A health care facility adding intermediate care or skilled nursing beds to its current licensed bed complement, except as provided in §16-2D-11 of this code;

(2) A person developing, constructing, or replacing a skilled nursing facility except in the case of facilities designed to replace existing beds in existing facilities that may soon be deemed unsafe or facilities utilizing existing licensed beds from existing facilities which are designed to meet the changing health care delivery system;

(3) Add beds in an intermediate care facility for individuals with an intellectual disability, except that prohibition does not apply to an intermediate care facility for individuals with intellectual disabilities beds approved under the Kanawha County Circuit Court order of August 3, 1989, civil action number MISC-81-585 issued in the case of E.H. v. Matin, 168 W.V. 248, 284 S.E. 2d 232 (1981) including the 24 beds provided in §16-2D-8 of this code;

(4) An opioid treatment program: *Provided*, That an opioid treatment program that is an approved clinical trial, with institutional review board approval, for the study of office-based methadone versus buprenorphine to address retention in medication for opioid use disorder treatment may be developed for the limited purposes of conducting the clinical trial and shall be limited to the time frame set forth in the clinical trial, after registering with the Board of Pharmacy: *Provided, however*, That this exemption only permits one program to participate once in CTN-0131; and

(5) Add licensed substance abuse treatment beds in any county which already has greater than 250 licensed substance abuse treatment beds.

§16-2D-10. Exemptions from certificate of need.

Notwithstanding §16-2D-8 of this code, a person may provide the following health services without obtaining a certificate of need or applying to the authority for approval:

(1) The creation of a private office of one or more licensed health professionals to practice in this state pursuant to §30-1-1 *et seq*. of this code;

(2) Dispensaries and first-aid stations located within business or industrial establishments maintained solely for the use of employees that does not contain inpatient or resident beds for patients or employees who generally remain in the facility for more than 24 hours;

(3) A place that provides remedial care or treatment of residents or patients conducted only for those who rely solely upon treatment by prayer or spiritual means in accordance with the creed or tenets of any recognized church or religious denomination;

(4) Telehealth;

(5) A private office practice owned or operated by one or more health professionals authorized or organized pursuant to §30-1-1 *et seq*. or ambulatory health care facility may offer laboratory services or diagnostic imaging to patients regardless of the cost associated with the proposal. A private office practice owned or operated by one or more health professionals authorized or organized pursuant to chapter 30 of this code which has at least seven office practice locations may acquire and utilize one fixed-site magnetic resonance imaging scanner regardless of the cost associated with the proposal. To qualify for this exemption, 75 percent of the magnetic resonance imaging scans are for the patients of the private office practice of the total magnetic resonance imaging scans performed. To qualify for this exemption 75 percent of the laboratory services are for the patients of the practice or ambulatory health care facility of the total laboratory services performed and 75 percent of diagnostic imaging services are for the patients of the practice or ambulatory health care facility of the total imaging services performed. The authority may, at any time, request from the entity information concerning the number of patients who have been provided laboratory services diagnostic imaging, or magnetic resonance imaging services;

(6) (A) Notwithstanding the provisions of §16-2D-17, any hospital that holds a valid certificate of need issued pursuant to this article, may transfer that certificate of need to a person purchasing that hospital, or all or substantially all of its assets, if the hospital is financially distressed. A hospital is financially distressed if, at the time of its purchase:

(i) It has filed a petition for voluntary bankruptcy;

(ii) It has been the subject of an involuntary petition for bankruptcy;

(iii) It is in receivership;

(iv) It is operating under a forbearance agreement with one or more of its major creditors;

(v) It is in default of its obligations to pay one or more of its major creditors and is in violation of the material, substantive terms of its debt instruments with one or more of its major creditors; or

(vi) It is insolvent: evidenced by balance sheet insolvency and/or the inability to pay its debts as they come due in the ordinary course of business.

(B) A financially distressed hospital which is being purchased pursuant to the provisions of this subsection shall give notice to the authority of the sale 30 days prior to the closing of the transaction and shall file simultaneous with that notice evidence of its financial status. The financial status or distressed condition of a hospital shall be evidenced by the filing of any of the following:

(i) A copy of a forbearance agreement;

(ii) A copy of a petition for voluntary or involuntary bankruptcy;

(iii) Written evidence of receivership, or

(iv) Documentation establishing the requirements of subparagraph (v) or (vi), paragraph (A) of this subdivision. The names of creditors may be redacted by the filing party.

(C) Any substantial change to the capacity of services offered in that hospital made subsequent to that transaction would remain subject to the requirements for the issuance of a certificate of need as otherwise set forth in this article.

(D) Any person purchasing a financially distressed hospital, or all or substantially all of its assets, that has applied for a certificate of need after January 1, 2017, shall qualify for an exemption from certificate of need;

(7) The acquisition by a qualified hospital which is party to an approved cooperative agreement as provided in section §16-29B-28 of this code, of a hospital located within a distance of 20 highway miles of the main campus of the qualified hospital;

(8) The acquisition by a hospital of a physician practice group which owns an ambulatory surgical center as defined in this article;

(9) Hospital services performed at a hospital; and

(10) Constructing, developing, acquiring, or establishing a birthing center :*Provided*, That a hospital shall be deemed a trauma center, subject to the provisions of §55-7B-9c of this code, for any and all claims arising out of any medical services provided by a hospital or physician to an individual as a result of birth complications at a birthing center.

§16-2D-11. Exemptions from certificate of need which require the submission of information to the authority.

(a) To obtain an exemption under this section a person shall:

(1) File an exemption application; and

(2) Provide a statement detailing which exemption applies and the circumstances justifying the exemption.

(b) Notwithstanding §16-2D-8 of this code and §16-2D-10 of this code and except as provided in §16-2D-9 of this code, the Legislature finds that a need exists and these health services are exempt from the certificate of need process:

(1) The acquisition and utilization of one computed tomography scanner with a purchase price up to $750,000 that is installed in a private office practice where at minimum 75 percent of the scans are performed on the patients of the practice. The private office practice shall obtain and maintain accreditation from the American College of Radiology prior to, and at all times during, the offering of this service. The authority may at any time request from the private office practice information relating to the number of patients who have been provided scans and proof of active and continuous accreditation from the American College of Radiology. If a physician owns or operates a private office practice in more than one location, this exemption shall only apply to the physician's primary place of business and if a physician wants to expand the offering of this service to include more than one computed topography scanner, he or she shall be required to obtain a certificate of need prior to expanding this service. All current certificates of need issued for computed tomography services, with a required percentage threshold of scans to be performed on patients of the practice in excess of 75 percent, shall be reduced to 75 percent: *Provided*, That these limitations on the exemption for a private office practice with more than one location shall not apply to a private office practice with more than 20 locations in the state on April 8, 2017.

(2) (A) A health care facility acquiring major medical equipment, adding health services or obligating a capital expenditure to be used solely for research;

(B) To qualify for this exemption, the health care facility shall show that the acquisition, offering, or obligation will not:

(i) 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;

(ii) Result in a substantial change to the bed capacity of the facility; or

(iii) Result in a substantial change to the health services of the facility.

(C) For purposes of this subdivision, the term "solely for research" includes patient care

provided on an occasional and irregular basis and not as part of a research program;

(3) The obligation of a capital expenditure to acquire, either by purchase, lease or comparable arrangement, the real property, equipment or operations of a skilled nursing facility: *Provided*, That a skilled nursing facility developed pursuant to subdivision (15) of this section and subsequently acquired pursuant to this subdivision may not transfer or sell any of the skilled nursing home beds of the acquired skilled nursing facility until the skilled nursing facility has been in operation for at least 10 years.

(4) Shared health services between two or more hospitals licensed in West Virginia providing health services made available through existing technology that can reasonably be mobile. This exemption does not include providing mobile cardiac catheterization;

(5) The acquisition, development, or establishment of a certified interoperable electronic health record or electronic medical record system;

(6) The addition of forensic beds in a health care facility;

(7) A behavioral health service selected by the Department of Human Services in response to its request for application for services intended to return children currently placed in out-of-state facilities to the state or to prevent placement of children in out-of-state facilities is not subject to a certificate of need;

(8) The replacement of major medical equipment with like equipment, only if the replacement major medical equipment cost is more than the expenditure minimum;

(9) Renovations within a hospital, only if the renovation cost is more than the expenditure minimum. The renovations may not expand the health care facility's current square footage, incur a substantial change to the health services, or a substantial change to the bed capacity;

(10) Renovations to a skilled nursing facility;

(11) The donation of major medical equipment to replace like equipment for which a certificate of need has been issued and the replacement does not result in a substantial change to health services. This exemption does not include the donation of major medical equipment made to a health care facility by a related organization;

(12) A person providing specialized foster care personal care services to one individual and those services are delivered in the provider's home;

(13) A hospital converting the use of beds except a hospital may not convert a bed to a skilled nursing home bed and conversion of beds may not result in a substantial change to health services provided by the hospital;

(14) The construction, renovation, maintenance, or operation of a state-owned veterans

skilled nursing facilities established pursuant to the provisions of §16-1B-1 *et seq*. of this code;

(15) To develop and operate a skilled nursing facility with no more than 36 beds in a county that currently is without a skilled nursing facility;

(16) A critical access hospital, designated by the state as a critical access hospital, after meeting all federal eligibility criteria, previously licensed as a hospital and subsequently closed, if it reopens within 10 years of its closure;

(17) The establishing of a heath care facility or offering of health services for children under one year of age suffering from Neonatal Abstinence Syndrome;

(18) The construction, development, acquisition, or other establishment of community mental health and intellectual disability facility;

(19) Providing behavioral health facilities and services;

(20) The construction, development, acquisition, or other establishment of kidney disease treatment centers, including freestanding hemodialysis units but only to a medically underserved population;

(21) The transfer, purchase or sale of intermediate care or skilled nursing beds from a skilled nursing facility or a skilled nursing unit of an acute care hospital to a skilled nursing facility providing intermediate care and skilled nursing services. The Department of Human Service or the Office of Health Facility Licensure and Certification may not create a policy which limits the transfer, purchase or sale of intermediate care or skilled nursing beds from a skilled nursing facility or a skilled nursing unit of an acute care hospital. The transferred beds shall retain the same certification status that existed at the nursing home or hospital skilled nursing unit from which they were acquired. If construction is required to place the transferred beds into the acquiring nursing home, the acquiring nursing home has one year from the date of purchase to commence construction;

(22) The construction, development, acquisition, or other establishment by a health care facility of a nonhealth related project, only if the nonhealth related project cost is more than the expenditure minimum;

(23) The construction, development, acquisition, or other establishment of an alcohol or drug treatment facility and drug and alcohol treatment services unless the construction, development, acquisition, or other establishment is an opioid treatment facility or programs as set forth in subdivision (4) of §16-2D-9 of this code;

(24) Assisted living facilities and services;

(25) The creation, construction, acquisition, or expansion of a community-based nonprofit organization with a community board that provides or will provide primary care services to

people without regard to ability to pay and receives approval from the Health Resources and Services Administration; and

(26) The acquisition and utilization of one computed tomography scanner and/or one magnetic resonance imaging scanner with a purchase price of up to $750,000 by a hospital.

§16-2D-12. Minimum criteria for certificate of need reviews.

(a) A certificate of need may only be issued if the proposed health service is:

(1) Found to be needed; and

(2) Consistent with the state health plan, unless there are emergency circumstances that pose a threat to public health.

(b) The authority may not grant a certificate of need unless, after consideration of the appropriateness of the use of existing facilities within this state providing services similar to those being proposed, the authority makes each of the following findings in writing:

(1) That superior alternatives to the services in terms of cost, efficiency and appropriateness do not exist within this state and the development of alternatives is not practicable;

(2) That existing facilities providing services within this state similar to those proposed are being used in an appropriate and efficient manner;

(3) That in the case of new construction, alternatives to new construction, such as modernization or sharing arrangements, have been considered and have been implemented to the maximum extent practicable; and

(4) That patients will experience serious problems in obtaining care within this state of the type proposed in the absence of the proposed health service.

(c) In addition to the written findings required in this section, the authority shall make a written finding regarding the extent to which the proposed health service meets the needs of the medically underserved population, except in the following cases:

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

(2) Where the proposed health service is a proposed capital expenditure not directly related to the provision of health services or to beds or to major medical equipment.

(d) Notwithstanding the review criteria in subsection (b), an application for a certificate of need shall be approved, if the authority finds that the facility or service with respect to which such capital expenditure is proposed to be made is needed and that the obligation of such capital expenditure is consistent with the state health plan, for a capital expenditure which is required:

(1) To eliminate or prevent imminent safety hazards as defined by federal, state or local fire building or life safety codes, statutes or rules.

(2) To comply with state licensure standards; or

(3) To comply with accreditation or certification standards. Compliance with which is required to receive reimbursement under Title XVIII of the Social Security Act or payments under the state plan for medical assistance approved under Title XIX of such act.

(e) In the case where an application is made by a health care facility to provide ventilator services which have not previously been provided for a nursing facility bed, the authority shall consider the application in terms of the need for the service and whether the cost exceeds the level of current Medicaid services. A facility providing ventilator services, may not provide a higher level of services for a nursing facility bed without demonstrating that the change in level of service by provision of the additional ventilator services will result in no additional fiscal burden to the state.

(f) The authority shall consider the total fiscal liability to the state for a submitted application.

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

(h) An application for a certificate of need may not be made subject to any criterion not contained in this article or in the certificate of need standards.

§16-2D-13. Procedures for certificate of need reviews.

(a) An application for a certificate of need shall be submitted to the authority prior to the offering or developing of a proposed health service.

(b) A person proposing a proposed health service shall:

(1) Submit a letter of intent ten days prior to submitting the certificate of need application. If the tenth day falls on a weekend or holiday, the certificate of need application shall be filed on the next business day. The information required within the letter of intent shall be detailed by the authority in legislative rule;

(2) Submit the appropriate application fee;

(A) Up to $1,500,000 a fee of $1,500.00;

(B) From $1,500,001 to $5,000,000 a fee of $5,000.00;

(C) From $5,000,001 to $25,000,000 a fee of $25,000.00; and

(D) From $25,000,001 and above a fee of $35,000.00.

(3) Submit to the Director of the Office of Insurance Consumer Advocacy a copy of the application;

(c) The authority shall determine if the submitted application is complete within ten days of receipt of the application. The authority shall provide written notification to the applicant of this determination. If the authority determines an application to be incomplete, the authority may request additional information from the applicant.

(d) Within five days of receipt of a letter of intent, the authority shall provide notification to the public through a newspaper of general circulation in the area where the health service is being proposed and by placing of copy of the letter of intent on its website. The newspaper notice shall contain a statement that, further information regarding the application is on the authority's web site.

(e) The authority may batch completed applications for review on the fifteenth day of the month or the last day of month in which the application is deemed complete.

(f) When the application is submitted, ten days after filing the letter of intent, the application shall be placed on the authority's website.

(g) An affected party has thirty days starting from the date the application is batched to request the authority hold an administrative hearing.

(1) A hearing order shall be approved by the authority within fifteen days from the last day

an affected person may requests an administrative hearing on a certificate of need application.

(2) A hearing shall take place no later than three months from that date the hearing order was approved by the authority.

(3) The authority shall conduct the administrative hearing in accordance with administrative hearing requirements in section twelve, article twenty-nine-b of this chapter and article five, chapter twenty-nine-a of this code.

(4) In the administrative hearing an affected person has the right to be represented by counsel and to present oral or written arguments and evidence relevant to the matter which is the subject of the public hearing. An affected person may conduct reasonable questioning of persons who make factual allegations relevant to its certificate of need application.

(5) The authority shall maintain a verbatim record of the administrative hearing.

(6) After the commencement of the administrative hearing on the 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 authority who exercises any responsibility respecting the application.

(7) The authority may not impose fees to hold the administrative hearing.

(8) The authority shall render a decision within forty-five days of the conclusion of the administrative hearing.

(h) If an administrative hearing is not conducted during the review of an application, the authority shall provide a file closing date five days after an affected party may no longer request an administrative hearing, after which date no other factual information or evidence may be considered in the determination of the application for the certificate of need. A detailed itemization of documents in the authority's file on a proposed health service shall, on request, be made available by the authority at any time before the file closing date.

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

(j) The authority shall have five days to provide the written status update upon written request by the applicant or an affected person. The status update shall include the findings

made in the course of the review and any other appropriate information relating to the review.

(k) (1) The authority shall annually prepare and publish to its website, a status report of each ongoing and completed certificate of need application reviews.

(2) For a status report of an ongoing review, the authority shall include in its report all findings made during the course of the review and any other appropriate information relating to the review.

(3) For a status report of a completed review, the authority shall include in its report all the findings made during the course of the review and its detailed reasoning for its final decision.

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

§16-2D-14. Procedure for an uncontested application for a certificate of need.

The authority shall review an uncontested certificate of need application within sixty days from the date the application is batched. An uncontested application is deemed approved if the review is not completed within sixty days from the date the application is batched, unless an extension, up to fifteen days is requested by the applicant.

§16-2D-15. Authority to render final decision; issue certificate of need; write findings; specify capital expenditure maximum.

(a) The authority shall render a final decision on an application for a certificate of need in the form of an approval, a denial or an approval with conditions. The final decision with respect to a certificate of need shall be based solely on:

(1) The authority's review conducted in accordance with procedures and criteria in this article and the certificate of need standards; and

(2) The record established in the administrative hearing held with respect to the certificate of need.

(b) Approval with conditions does not give the authority the ability to mandate a health service not proposed by the health care facility. Issuance of a certificate of need or exemption may not be made subject to any condition unless the condition directly relates to criteria in this article, or in the certificate of need standards. Conditions may be imposed upon the operations of the health care facility for not longer than a three-year period.

(c) The authority shall send its decision along with written findings to the person proposing the proposed health service or exemption and shall make it available to others upon request.

(d) In the case of a final decision to approve or approve with conditions a proposal for a proposed health service, the authority shall issue a certificate of need to the person proposing the proposed health service.

(e) The authority shall specify in the certificate of need the maximum amount of capital expenditures which may be obligated. The authority shall adopt legislative rules pursuant to section four to prescribe the method used to determine capital expenditure maximums and a process to review the implementation of an approved certificate of need for a proposed health service for which the capital expenditure maximum is exceeded or is expected to be exceeded.

§16-2D-16. Appeal of certificate of need a decision.

(a) An applicant or an affected person may appeal the authority's final decision in a certificate of need review to the Office of Judges. The request shall be received within thirty days after the date of the authority's decision. The appeal hearing shall commence within thirty days of receipt of the request.

(b) The Office of Judges shall conduct its proceedings in conformance with the West Virginia Rules of Civil Procedure for trial courts of record and the local rules for use in the civil courts of Kanawha County and shall review appeals in accordance with the provisions governing the judicial review of contested administrative cases in article five, chapter twenty-nine-a of this code.

(c) The decision of the Office of Judges shall be made in writing within forty-five days after the conclusion of the hearing.

(d) The written findings of the Office of Judges shall be sent to the person who requested the appeal, to the person proposing the proposed health service and to the authority, and shall be made available by the authority to others upon request.

(e) The decision of the Office of Judges shall be considered the final decision of the authority; however, the Office of Judges may remand the matter to the authority for further action or consideration.

(f) Upon the entry of a final decision by the Office of Judges, an affected person may within thirty days after the date of the decision of the Office of Judges make an appeal in the circuit court of Kanawha County. The decision of the Office of Judges shall be reviewed by the circuit court in accordance with the provisions for the judicial review of administrative decisions contained in article five, chapter twenty-nine-a of this code.

§16-2D-16a. Transfer of appellate jurisdiction to Intermediate Court of Appeals.

(a) Notwithstanding any other provision of this article, effective July 1, 2022:

(1) The Office of Judges may not review a decision of the authority, issued after June 30, 2022, in a certificate of need review. On or before September 30, 2022, the Office of Judges shall issue a final decision in, or otherwise dispose of, each and every appeal, pending before the Office of Judges, of a decision by the authority in a certificate of need review.

(2) An appeal of a final decision in a certificate of need review, issued by the authority after June 30, 2022, shall be made to the West Virginia Intermediate Court of Appeals, pursuant to the provisions governing the judicial review of contested administrative cases in §29A-5-1 *et seq*. of this code.

(b) If the Office of Judges does not issue a final decision or otherwise dispose of any appeal of a decision of the authority in a certificate of need review on or before September 30, 2022, the appeal shall be transferred to the Intermediate Court of Appeals, as provided in §29A-5-4 of this code. For any appeal transferred pursuant to this subsection, the Intermediate Court of Appeals shall adopt any existing records of evidence and proceedings in the Office of Judges, conduct further proceedings as it considers necessary, and issue a final decision or otherwise dispose of the case pursuant to the provisions governing the judicial review of contested administrative cases in §29A-5-1 *et seq*. of this code.

§16-2D-17. Nontransference, time period compliance and withdrawal of certificate of need.

(a) A certificate of need is nontransferable and is valid for a maximum of one year from the date of issuance. Upon the expiration of the certificate or during the certification period, the person proposing the proposed health service shall provide the authority information on the development of the project as the authority may request. The authority shall periodically monitor capital expenditures obligated under certificates, determine whether sufficient progress is being made in meeting the timetable specified in the approved application for the certificate and whether there has been compliance with the application and any conditions of certification. The certificate of need may be extended by the authority for additional periods of time as are reasonably necessary to expeditiously complete the project.

(b) A certificate of need may no longer be in effect, and may no longer be required, after written notice of substantial compliance with the approved application and any conditions of certification is issued to the applicant, after the activity is undertaken for which the certificate of need was issued, and after the authority is provided written notice of such undertaking.

(c) A person proposing a proposed health service may not be issued a license, if applicable, until the authority has issued a written notice of substantial compliance with the approved application and any conditions of certification, nor may a proposed health service be used until the person has received such notice. A proposed health service may not be found to be in substantial compliance with the approved application and any conditions of certification if there is a substantial change in the approved proposed health service for which change a certificate of need has not been issued.

(d) (1) A certificate of need may be withdrawn by the authority for:

(A) Noncompliance with any conditions of certification;

(B) A substantial change in an approved proposed health service for which change a certificate of need has not been issued;

(C) Material misrepresentation by an applicant upon which the authority relied in making its decision; or

(D) Other reasons that may be established by the authority in legislative rules adopted pursuant to section four of this article.

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

(A) The provisions of this article and on legislative rules adopted in accordance with section four of this article; and

(B) The record established in administrative hearing held with respect to the authority's

proposal to withdraw the certificate.

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

(A) After commencement of an administrative hearing on the authority's proposal to withdraw a certificate of need and before a decision is made on withdrawal, there may be no ex parte contacts between:

(i) The holder of the certificate of need, any person acting on behalf of the holder, or any person in favor of the withdrawal; and

(ii) Any person in the authority who exercises responsibility respecting withdrawal of the certificate;

(B) The authority shall follow the review procedure established in section thirteen; and

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

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

§16-2D-18. Denial or revocation of license for operating without certificate.

A person who violates the provisions of this article is subject to denial or revocation of a license, in whole or in part, to operate a proposed health service or health care facility. Upon a showing to the authority that a person is offering or developing a proposed health service without having first obtained a certificate of need or that a person is otherwise in violation of the provisions of this article, the authority shall provide a person with written notice which shall state the nature of the violation and the time and place at which the person shall appear to show good cause why its license should not be revoked or denied, at which time and place the person shall be afforded a reasonable opportunity to present testimony and other evidence in support of the person’s position. If, thereafter, the authority determines that the person's license to operate the health service or health care facility should be revoked or denied, the authority shall issue a written order to the appropriate licensing agency of the state, requiring that the person's license to operate the proposed health service or health care facility be revoked or denied. The order is binding upon the licensing agency.

§16-2D-19. Injunctive relief; civil penalty.

(a) A person who acquires, offers or develops a proposed health service for which a certificate of need is required without first having a certificate of need therefore or violates any other provision of this article, or any legislative rule promulgated thereunder, the authority may maintain a civil action in the circuit court of the county where the violation has occurred, or where the person may be found, to enjoin, restrain or prevent the violation. An injunction bond is not required to be filed.

(b) The authority may assess a civil penalty for violation of this article.

(c) Upon the authority determining that there is probable cause to believe that a person is in violation of the provisions of this article, or any lawful rule promulgated thereunder, the authority shall provide the person with written notice which states the nature of the alleged violation and the time and place at which an administrative hearing shall take place. The hearing shall be conducted in accordance with the administrative hearing provisions of article five, chapter twenty-nine-a of this code.

(d) If the authority determines that the person is in violation of the provisions of this article or legislative rule, the authority shall assess a civil penalty of not less than $500 nor more than $25,000.

(e) In determining the amount of the penalty, the authority shall consider the degree and extent of harm caused by the violation and the cost of rectifying the damage.

(f) A person assessed shall be notified of the assessment in writing, and the notice shall specify the reasons for the assessment. If the person assessed fails to pay the amount of the assessment to the authority within thirty days, the authority may institute a civil action in the circuit court of the county where the violation has occurred, or where the person may be found to recover the amount of the assessment. In the civil action, the scope of the court's review of the authority’s action, which shall include a review of the amount of the assessment, shall be as provided in article five, chapter twenty-nine-a of this code for the judicial review of contested administrative cases.

§16-2D-20. Statute of limitations.

The authority has a period of three years to correct violations of the provisions of this article. The three-year period begins from the date the authority 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.