

WEST VIRGINIA LEGISLATURE

2016 REGULAR SESSION

Introduced

Senate Bill 467

FISCAL
NOTE

BY SENATORS FERNS, ASHLEY, KARNES, LEONHARDT,
TAKUBO, TRUMP, WALTERS, LAIRD, PALUMBO, PLYMALE,
PREZIOSO, STOLLINGS AND UNGER

[Introduced February 2, 2016;

Referred to the Committee on Health and Human
Resources.]

1 A BILL to repeal §16-2D-4a, §16-2D-4b, §16-2D-5a, §16-2D-5b, §16-2D-5c, §16-2D-5d, §16-2D-
2 5e and §16-2D-7a of the Code of West Virginia, 1931, as amended; to amend and reenact
3 §16-2D-1, §16-2D-2, §16-2D-3, §16-2D-4, §16-2D-5, §16-2D-6, §16-2D-7, §16-2D-8, §16-
4 2D-9, §16-2D-10, §16-2D-11, §16-2D-12, §16-2D-13, §16-2D-14 and §16-2D-15 of said
5 code; and to amend said code by adding thereto six new sections, designated §16-2D-16,
6 §16-2D-17, §16-2D-18, §16-2D-19, §16-2D-20 and §16-2D-21, all relating to certificate of
7 need process; providing legislative findings; defining terms; providing powers to the
8 authority; providing duties to the authority; providing rule-making authority; continuing
9 special revenue account; providing process to update certificate of need standards;
10 providing process to update state health plan; providing process to review cost
11 effectiveness of the certificate of need standards; providing process for Health Care
12 Authority to review whether certificate of need is required; providing health services that
13 require a certificate of need; providing an exemption process; providing exemptions to
14 certificate of need requirement; providing criteria the authority shall use to determine
15 whether to grant certificate of need; changing the certificate of need process; requiring the
16 creation of process to review an uncontested certificate of need application; requiring the
17 authority to make certain findings to approve a certificate of need; providing an appeal
18 process; prohibiting the transfer of a certificate of need; permitting the authority to perform
19 a compliance review of an issued certificate of need; creating an injunction process;
20 establishing a statute of limitations: and establishing a civil penalty.

Be it enacted by the Legislature of West Virginia:

1 That §16-2D-4a, §16-2D-4b, §16-2D-5a, §16-2D-5b, §16-2D-5c, §16-2D-5d, §16-2D-5e
2 and §16-2D-7a, of the Code of West Virginia, 1931, as amended, be repealed; that §16-2D-1,
3 §16-2D-2, §16-2D-3, §16-2D-4, §16-2D-5, §16-2D-6, §16-2D-7, §16-2D-8, §16-2D-9, §16-2D-10,
4 §16-2D-11, §16-2D-12, §16-2D-13, §16-2D-14 and §16-2D-15 be amended and reenacted; and

5 that said code be amended by adding thereto six new sections, designated §16-2D-16, §16-2D-
6 17, §16-2D-18, §16-2D-19, §16-2D-20 and §16-2D-21, all to read as follows:

ARTICLE 2D. CERTIFICATE OF NEED.

§16-2D-1. Legislative findings.

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

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

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

§16-2D-2. Definitions.

1 As used in this article:

2 (1) "Affected person" means:

3 (A) The applicant;

4 (B) An agency or organization representing consumers;

5 (C) An individual residing within the geographic area served or to be served by the
6 applicant;

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

8 (E) A health care facility located within this state which provide services similar to the

9 services of the facility under review and which will be significantly affected by the proposed
10 project;

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

14 (G) Third-party payors who reimburse health care facilities within this state similar to those
15 proposed for services;

16 (H) An agency that establishes rates for health care facilities within this state similar to
17 those proposed; or

18 (I) An organization representing health care providers.

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

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

23 (4) "Applicant" means a person proposing a new health service;

24 (5) "Authority" means the West Virginia Health Care Authority as provided in article twenty-
25 nine-d of this chapter.

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

29 (7) "Behavioral health services" means services provided for the care and treatment of
30 persons with mental illness, mental retardation, developmental disabilities or alcohol or drug
31 abuse problems in an inpatient, residential or outpatient setting.

32 (8) "Birthing center" means a short-stay ambulatory health care facility designed for low-
33 risk births following normal uncomplicated pregnancy.

34 (9) "Campus" means the adjacent grounds and buildings, or grounds and buildings not

35 separated by more than a public right-of-way, of a health care facility.

36 (10) "Capital expenditure" means:

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

38 (i) Under generally accepted accounting principles is not properly chargeable as an
39 expense of operation and maintenance; or (ii) is made to obtain either by lease or comparable
40 arrangement any facility or part thereof or any equipment for a facility or part; and

41 (B)(i) Exceeds the expenditure minimum; (ii) is a substantial change to the bed capacity
42 of the facility with respect to which the expenditure is made; or (iii) is a substantial change to the
43 services of such facility;

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

46 (D) A series of expenditures, if the sum total exceeds the expenditure minimum and if
47 determined by the state agency to be a single capital expenditure subject to review. In making
48 this determination, the state agency shall consider: Whether the expenditures are for components
49 of a system which is required to accomplish a single purpose; whether the expenditures are to be
50 made over a two-year period and are directed towards the accomplishment of a single goal within
51 the health care facility's long-range plan; or whether the expenditures are to be made within a
52 two-year period within a single department such that they will constitute a significant
53 modernization of the department.

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

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

60 (13) "Diagnostic imagining" means the use of radiology, ultrasound, mammography,

61 fluoroscopy, nuclear imaging, densitometry to create a graphic depiction of the body parts;

62 (14) “Drug and Alcohol Rehabilitation Services” means a medically or
63 psychotherapeutically supervised process for assisting individuals on an inpatient or outpatient
64 basis through the processes of withdrawal from dependency on psychoactive substances.

65 (15) “Expenditure minimum” means the cost of acquisition, improvement, expansion of
66 any facility, equipment, or services including the cost of any studies, surveys, designs, plans,
67 working drawings, specifications and other activities, including staff effort and consulting at and
68 above \$5 million.

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

72 (17) “Health care provider” means a person authorized by law to provide professional
73 health service in this state to an individual.

74 (18) “Health services” means clinically related preventive, diagnostic, treatment or
75 rehabilitative services.

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

79 (A) Home health aide services;

80 (B) Physical therapy;

81 (C) Speech therapy;

82 (D) Occupational therapy;

83 (E) Nutritional services; or

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

86 (20) “Hospice” means a coordinated program of home and inpatient care provided directly

87 or through an agreement under the direction of a licensed hospice program which provides
88 palliative and supportive medical and other health services to terminally ill individuals and their
89 families.

90 (21) "Hospital" means a facility licensed pursuant to the provisions of article five-b of this
91 chapter and any acute care facility operated by the state government, that primarily provides
92 inpatient diagnostic, treatment or rehabilitative services to injured, disabled or sick persons under
93 the supervision of physicians.

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

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

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

112 (25) "Medically underserved population" means the population of an area designated by

113 the authority as having a shortage of a specific health service.

114 (26) "New health service" means a service as described in section three of this article.

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

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

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

124 (30) "Physician" means an individual who is licensed by the Board of Medicine or the Board
125 of Osteopathy to practice in West Virginia.

126 (31) "Proposed new health service" means any service as described in section six of this
127 article.

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

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

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

137 (35) "Rehabilitation facility" means an inpatient facility licensed in West Virginia operated
138 for the primary purpose of assisting in the rehabilitation of disabled persons through an integrated

139 program of medical and other services.

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

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

149 (38) "Standard" means a health service guideline developed by the authority and instituted
150 under section six.

151 (39) "State health plan" means a document prepared by the authority that sets forth a
152 strategy for future health care needs in the state.

153 (40) "Substantial change to the bed capacity" of a health care facility means any change,
154 associated with a capital expenditure, that increases or decreases the bed capacity or relocates
155 beds from one physical facility or site to another, but does not include a change by which a health
156 care facility reassigns existing beds as swing beds between acute care and long-term care
157 categories or a decrease in bed capacity in response to federal rural health initiatives.

158 (41) "Substantial change to the health services" means:

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

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

165 (42) “Third-party payor” means an individual, person, corporation or government entity
166 responsible for payment for patient care services rendered by health care providers.

167 (43) “To develop” means to undertake those activities which upon their completion will
168 result in the offer of a new health service or the incurring of a financial obligation in relation to the
169 offering of such a service.

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

1 (a) The authority shall:

2 (1) Administer the certificate of need program;

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

6 (3) Shall adjust the expenditure minimum annually and publish to its website the updated
7 amount on or before December 31, of each year. The expenditure minimum adjustment shall be
8 based on the DRI inflation index published in the Global Insight DRI/WEFA Health Care Cost
9 Review.

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

12 (b) The authority may:

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

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

21 certificates of need are processed pursuant to section eight.

22 (2) Issue grants and loans to financially vulnerable health care facilities located in
23 underserved areas that the authority and the Office of Community and Rural Health Services
24 determine are collaborating with other providers in the service area to provide cost effective health
25 services.

26 (3) Approve an emerging health care service or technology for one year.

§16-2D-4. Rule-making Authority.

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

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

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

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

7 (4) The required information in a letter of intent;

8 (5) Process for an expedited certificate of need;

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

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

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

17 (b) The authority shall propose emergency rules by July 1, 2016, to effectuate the changes
18 to this article.

19 (c) All of the authority's rules in effect and not in conflict with the provisions of this article,

20 shall remain in effect until they are amended or rescinded.

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

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

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

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

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

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

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

13 providers, payers and state agencies.

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

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

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

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

37 (h) After approval from the Governor, the authority shall prepare a report detailing its
38 review findings and submit the report to the Legislative Oversight Commission on Health and

39 Human Resources Accountability with its annual report before January 1, each year.

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

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

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

1 (a) Except as provided in section seven of this article, the following new health services
2 may not be acquired, offered or developed within this state except upon approval of and receipt
3 of a certificate of need as provided by this article:

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

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

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

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

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

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

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

18 (iii) In the case of donated property, on the date on which the gift is completed under state

19 law.

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

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

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

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

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

30 (C) If the change will occur within two years after the date the activity which was associated
31 with the previously approved capital expenditure was undertaken.

32 (9) The acquisition of major medical equipment;

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

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

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

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

42 (1) The construction, development, acquisition or other establishment of a birthing center;

43 (2) Providing radiation therapy;

44 (3) Providing computed tomography;

- 45 (4) Providing positron emission tomography;
- 46 (5) Providing cardiac surgery;
- 47 (6) Providing fixed magnetic resonance imaging;
- 48 (7) Providing comprehensive medical rehabilitation;
- 49 (8) Establishing an ambulatory care center;
- 50 (9) Establishing an ambulatory surgical center;
- 51 (10) Providing diagnostic imaging;
- 52 (11) Providing cardiac catheterization services;
- 53 (12) The construction, development, acquisition or other establishment of kidney disease
- 54 treatment centers, including freestanding hemodialysis units;
- 55 (13) Providing megavoltage radiation therapy;
- 56 (14) Providing surgical services;
- 57 (15) Establishing operating rooms;
- 58 (16) Adding acute care beds;
- 59 (17) Providing developmental disabilities services;
- 60 (18) Providing organ and tissue transplants;
- 61 (19) Establishing an intermediate care facility for individuals with intellectual disabilities;
- 62 (20) Providing inpatient services;
- 63 (21) Providing hospice services; and
- 64 (22) Establishing a home health agency.
- 65 (c) A certificate of need previously approved under this article remains in effect unless
- 66 revoked by the authority.

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

1 These health services require a certificate of need but the authority may not issue a
2 certificate of need to:

- 3 (1) A health care facility adding intermediate care or skilled nursing beds to its current

4 licensed bed complement;

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

9 (3) Beds in an intermediate care facility for individuals with an intellectual disability, except
10 that prohibition does not apply to an intermediate care facility for individuals with intellectual
11 disabilities beds approved under the Kanawha County circuit court order of August 3, 1989, civil
12 action number MISC-81-585 issued in the case of E.H. v. Matin, 168 W.V. 248, 284 S.E. 2d 232
13 (1981); and

14 (4) An opioid treatment facility or program.

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

1 Except as provided in section eight, a person may provide the following health services
2 without obtaining a certificate of need or applying to the authority for approval:

3 (1) The creation of a private office of one or more licensed health professionals to practice
4 in this state pursuant to chapter thirty of this code.

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

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

§16-2d-11. Community-based nonprofit organization exemption.

1 Nothing in this article or the rules adopted pursuant to this article may be construed to
2 authorize the licensure, supervision, regulation or control in any manner the creation of new
3 primary care services located in communities that are underserved with respect to primary care

4 services: *Provided*, That to qualify for this exemption, an applicant must be a community-based
5 nonprofit organization with a community board that provides or will provide primary care services
6 to people without regard to ability to pay: *Provided, however*, That the exemption from certificate
7 of need review of new primary care services provided by this section shall not include the
8 acquisition, offering or development of major medical equipment otherwise subject to review
9 under this article or to include the acquisition, offering or development of ambulatory surgical
10 facilities, lithotripsy, magnetic resonance imaging or radiation therapy. The Office of Community
11 and Rural Health Services shall define which services constitute primary care services for
12 purposes of this subdivision and shall, to prevent duplication of primary care services, determine
13 whether a community is underserved with respect to certain primary care services within the
14 meaning of this subdivision. Any organization planning to qualify for an exemption pursuant to
15 this subdivision shall submit to the authority a letter of intent describing the proposed new services
16 and area of service. The authority may waive the application fee for an organization applying for
17 this exemption.

§16-2D-12. Exemptions from certificate of need which require approval from the authority.

1 (a) To obtain an exemption under this section:
2 (1) A person shall file an exemption application;
3 (2) Pay the \$1,000 application fee; and
4 (3) Provide a statement detailing which exemption applies and the circumstances justifying
5 the approval of the exemption.
6 (b) The authority has thirty days to review the exemption request. The authority may not
7 hold an administrative hearing to review the application. An affected party may not file an
8 objection to the request for an exemption. The applicant may request or agree with the authority
9 to a fifteen day extension of the timeframe. If the authority does not approve or deny the
10 application within thirty days, then the exemption is immediately approved. If the authority denies
11 the approval of the exemption, the applicant may appeal the authority's decision to the office of

12 judges or refile the application with the authority. The office of judges shall follow the procedure
13 provided in section seventeen to perform the review.

14 (c) Except as provided in section eight, these new health services are exempt from the
15 certificate of need process:

16 (1) A computed tomography scanner that is installed in a private office practice where at
17 minimum seventy five percent of the scans are for the patients of the practice and the fair market
18 value of the installation and purchase is less than \$250,000 for calendar year 2016. The authority
19 shall adjust the dollar amount specified in this subdivision annually and publish an update of the
20 amount on or before December 31, of each year. The adjustment of the dollar amount shall be
21 based on the DRI inflation index published in the Global Insight DRI/WEFA Health Care Cost
22 Review. The authority may at any time request from the private office practice information
23 concerning the number of patients who have been provided scans;

24 (2) (A) A birthing center established by nonprofit primary care center that has a community
25 board and provides primary care services to people in their community without regard to ability to
26 pay; or

27 (B) A birthing center established by a nonprofit hospital with less than one hundred
28 licensed acute care beds.

29 (i) To qualify for this exemption, an applicant shall be located in an area that is underserved
30 with respect to low-risk obstetrical services;

31 (ii) Provide a proposed service area;

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

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

36 (i) Affect the charges of the facility for the provision of medical or other patient care
37 services other than the services which are included in the research;

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

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

40 (C) For purposes of this subdivision, the term "solely for research" includes patient care
41 provided on an occasional and irregular basis and not as part of a research program;

42 (4) The obligation of a capital expenditure to acquire, either by purchase, lease or
43 comparable arrangement, the real property, equipment or operations of a skilled nursing facility.

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

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

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

50 (8) A behavioral health service selected by the Department of Health and Human
51 Resources in response to its request for application for services intended to return children
52 currently placed in out-of-state facilities to the state or to prevent placement of children in out-of-
53 state facilities is not subject to a certificate of need;

54 (9) The replacement of major medical equipment with like equipment;

55 (10) Renovations within a hospital. The renovations may not expand the health care
56 facility's current square footage, incur a substantial change to the health services, or a substantial
57 change to the bed capacity;

58 (11) Renovations to a skilled nursing facility;

59 (12) The construction, development, acquisition or other establishment by a licensed West
60 Virginia hospital of an ambulatory health care facility in the county in which it is located and in a
61 contiguous county within or outside this state;

62 (13) The donation of major medical equipment to replace like equipment for which a
63 certificate of need has been issued and the replacement does not result in a substantial change

64 to health services. This exemption does not include the donation of major medical equipment
65 made to a health care facility by a related organization;

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

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

71 (16) The construction, renovation, maintenance or operation of a state owned veterans
72 skilled nursing facilities established pursuant to the provisions of article one-b of this chapter;

73 (17) A nonprofit community group designated by a county to develop and operate a
74 nursing home bed facility with no more than thirty-six beds in any county in West Virginia that
75 currently is without a nursing home;

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

79 (19) The establishing or offering of health care for children under one year of age suffering
80 from Neonatal Abstinence Syndrome;

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

83 (21) Providing behavioral health services;

84 (22) The construction, development, acquisition or other establishment of kidney disease
85 treatment centers, including freestanding hemodialysis units in a medically underserved
86 population;

87 (23) The transfer or acquisition of intermediate care or skilled nursing beds from an
88 existing health care facility to a nursing home providing intermediate care and skilled nursing
89 services.

90 (24) The construction, development, acquisition or other establishment of a health care
91 facility that provides in home care services;

92 (25) Providing in home care services;

93 (26) The construction, development, acquisition or other establishment by a health care
94 facility of a nonhealth related project;

95 (27) Any facility owned or operated by one or more health professionals authorized or
96 organized pursuant to chapter thirty or ambulatory health care facility which offers laboratory or
97 imaging services to patients regardless of the cost associated with the proposal. To qualify for
98 this exemption seventy five percent of the laboratory services are for the patients of the practice
99 or ambulatory health care facility of the total laboratory services performed and seventy-five
100 percent of imagining procedures are for the patients of the practice or ambulatory health care
101 facility of the total imaging procedures performed;

102 (28) The construction, development, acquisition or other establishment of an alcohol or
103 drug treatment facility and drug and alcohol treatment services; and

104 (29) Assisted living facilities and services.

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

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

2 (1) Found to be needed; and

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

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

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

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

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

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

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

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

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

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

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

32 (2) To comply with state licensure standards; or

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

36 (e) In the case where an application is made by a health care facility to provide ventilator

37 services which have not previously been provided for a nursing facility bed, the authority shall
 38 consider the application in terms of the need for the service and whether the cost exceeds the
 39 level of current Medicaid services. A facility providing ventilator services, may not provide a higher
 40 level of services for a nursing facility bed without demonstrating that the change in level of service
 41 by provision of the additional ventilator services will result in no additional fiscal burden to the
 42 state.

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

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

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

§16-2D-14. Procedures for certificate of need reviews.

1 (a) An application for a certificate of need shall be submitted to the authority prior to the
 2 offering or development of a new health service.

3 (b) A person proposing a new health service shall:

4 (1) Submit a letter of intent ten days prior to submitting the certificate of need application.
 5 The information required within the letter of intent shall be detailed by the authority in legislative
 6 rule;

7 (2) Submit the appropriate application fee;

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

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

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

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

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

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

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

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

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

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

29 (1) A hearing order shall be approved by the authority within fifteen days from the last the
30 day an affected person may requests an administrative hearing on a certificate of need
31 application.

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

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

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

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

41 (6) After the commencement of the administrative hearing on the application and before a
42 decision is made with respect to it, there may be no ex parte contacts between:

43 (A) The applicant for the certificate of need, any person acting on behalf of the applicant
44 or holder of a certificate of need or any person opposed to the issuance of a certificate for the
45 applicant; and

46 (B) Any person in the authority who exercises any responsibility respecting the application.

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

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

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

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

61 (j) The authority shall have five days to provide the written status update upon written
62 request by the applicant or an affected person. The status update shall include the findings made
63 in the course of the review and any other appropriate information relating to the review.

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

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

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

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

§16-2D-15. Procedure for an uncontested application for a certificate of need.

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

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

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

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

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

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

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

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

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

§16-2D-17. Appeal of certificate of need a decision.

1 (a) The authority's final decision shall upon request of an affected person be reviewed by
2 the Office of Judges. The request shall be received within thirty days after the date of the
3 authority's decision. The appeal hearing shall commence within thirty days of receipt of the
4 request.

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

10 (c) The decision of the office of judges shall be made in writing within forty-five days after
11 the conclusion of the hearing.

12 (d) The written findings of the office of judges shall be sent to the person who requested
13 the review, to the person proposing the new health service and to the authority, and shall be made
14 available by the authority to others upon request.

15 (e) The decision of the office of judges shall be considered the final decision of the

16 authority; however, the office of judges may remand the matter to the authority for further action
17 or consideration.

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

§16-2D-18. Nontransference, time period compliance and withdrawal of certificate of need.

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

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

14 (c) A person proposing a new health service may not be issued a license, if applicable,
15 until the authority has issued a written notice of substantial compliance with the approved
16 application and any conditions of certification, nor may a new health service be used until the
17 person has received such notice. A new health service may not be found to be in substantial
18 compliance with the approved application and any conditions of certification if there is a

19 substantial change in the approved new health service for which change a certificate of need has
20 not been issued.

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

22 (A) Noncompliance with any conditions of certification;

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

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

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

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

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

32 (B) The record established in administrative hearing held with respect to the authority's
33 proposal to withdraw the certificate.

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

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

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

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

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

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

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

§16-2D-19. Denial or revocation of license for operating without certificate.

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

§16-2D-20. Injunctive relief; civil penalty.

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

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

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

14 (d) If the authority determines that the person is in violation of the provisions of this article
15 or legislative rule, the authority shall assess a civil penalty of not less than \$500 nor more than
16 \$25,000.

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

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

§16-2D-21. Statute of limitations.

1 The authority has a period of three years to correct violations of the provisions of this
2 article. The three-year period begins from the date the authority knows or should have known of
3 the violation. Each new act of a continuing violation shall provide a basis for restarting the
4 calculation of the limitations period.

NOTE: The purpose of this bill is to create a new simplified and expedited certificate of need process.

Strike-throughs indicate language that would be stricken from a heading or the present law, and underscoring indicates new language that would be added.

§16-2D-2 through §16-2D-15 have been totally rewritten and thus have been completely underscored.