

Amendment No. 1 to HB2350

Helton
Signature of Sponsor

AMEND Senate Bill No. 2312

House Bill No. 2350*

by deleting the amendatory language of SECTION 1 and substituting instead the following:

As used in this part:

(1) "Agency" and "health services and development agency" mean the agency created by this part to develop the criteria and standards to guide the agency when issuing certificates of need; to conduct studies related to health care, including needs assessments; and to administer the certificate of need program and related activities;

(2) "Certificate of need" means a permit granted by the health services and development agency to any person for those services specified as requiring a certificate of need under § 68-11-1607 at a designated location;

(3) "Conflict of interest" means any matter before the agency in which the member or employee of the agency has a direct interest or indirect interest that is in conflict or gives the appearance of conflict with the discharge of the member's or employee's duties;

(4) "Department" means the department of health;

(5) "Direct interest" means a pecuniary interest in the persons involved in a matter before the agency, and applies to the agency member or employee, the agency member's or employee's relatives, or an individual with whom or business in which the member or employee has a pecuniary interest. As used in this subdivision (5), "relative" means a spouse, parent, child, stepparent, stepchild, grandparent, grandchild, brother, sister, half-brother, half-sister, aunt, uncle, niece, or nephew by blood, marriage, or adoption;

Amendment No. 1 to HB2350

Helton
Signature of Sponsor

AMEND Senate Bill No. 2312

House Bill No. 2350*

(6) "Ex parte communications" means communications in violation of § 4-5-304 or § 68-11-1607(d);

(7) "Facility" means any real property owned, leased, or used by a healthcare institution for any purpose, other than as an investment;

(8) "Health service" means clinically related services, such as diagnostic, treatment, or rehabilitative services, and includes those services specified as requiring a certificate of need under § 68-11-1607;

(9) "Healthcare institution":

(A) Means any agency, institution, facility, or place, whether publicly or privately owned or operated, that provides health services and that is one (1) of the following: nursing home; hospital; ambulatory surgical treatment center; intellectual disability institutional habilitation facility; home care organization or any category of service provided by a home care organization for which authorization is required under part 2 of this chapter; outpatient diagnostic center; rehabilitation facility; residential hospice; or nonresidential substitution-based treatment center for opiate addiction; and

(B) Does not include:

(i) Ground ambulances;

(ii) Homes for the aged;

(iii) Any premises occupied exclusively as the professional

practice office of a:

(a) Physician licensed pursuant to title 63, chapter 6, part 2 or title 63, chapter 9; or

(b) Dentist licensed by the state and controlled by the physician or dentist;

(iv) Administrative office buildings of public agencies related to healthcare institutions;

(v) Christian Science sanatoriums operated, or listed and certified, by the First Church of Christ Scientist, Boston, Massachusetts;

(vi) A mental health residential treatment facility; or

(vii) A mental health hospital;

(10) "Home care organization" means any entity licensed as such by the department that is staffed and organized to provide "home health services" or "hospice services," as defined by § 68-11-201, to patients in either their regular or temporary place of residence;

(11) "Indirect interest" means a personal interest in the persons involved in a matter before the agency that is in conflict with the discharge of the agency member's or employee's duties;

(12) "Letter of intent" means the form prescribed by the agency that requires a brief project description, location, estimated project cost, owner of the project, and description of services to be performed;

(13) "Licensed beds" means the number of beds licensed by the agency having licensing jurisdiction over the facility;

(14) "Micro hospital" means a facility required to be licensed as a hospital under this title that has no more than ten (10) beds for admitted patients and that offers services that include, but are not limited to, the following:

(A) Emergency medical services;

(B) Inpatient care;

- (C) Laboratory services;
- (D) Pharmacy services; and
- (E) Surgical services;

(15) "Needs assessment" means an annual report that measures access to health care in this state, particularly as to emergency and primary care; identifies access gaps; and serves to inform the criteria and standards for the issuance of certificates of need;

(16) "Nonresidential substitution-based treatment center for opiate addiction" includes, but is not limited to, stand-alone clinics offering methadone, products containing buprenorphine such as Subutex and Suboxone, or products containing any other formulation designed to treat opiate addiction by preventing symptoms of withdrawal;

(17) "Nursing home" has the same meaning as defined in § 68-11-201;

(18) "Nursing home bed" means:

(A) Any licensed bed within a nursing home, regardless of whether the bed is certified for medicare or medicaid services; and

(B) Any bed at a healthcare institution used as a swing bed under 42 C.F.R. § 485.645;

(19) "Patient" includes, but is not limited to, any person who has an acute or chronic physical or mental illness or injury; who is convalescent, infirm, or has an intellectual or physical disability; or who is in need of obstetrical, surgical, medical, nursing, psychiatric, or supervisory care;

(20) "Pediatric patient" means a patient who is seventeen (17) years of age or younger;

(21) "Person":

(A) Means any individual, trust or estate, firm, partnership, association, stockholder, joint venture, corporation or other form of business organization, the

state of Tennessee and its political subdivisions or parts of political subdivisions, and any combination of persons specified in this subdivision (21), public or private; and

(B) Does not include the United States or any agency or instrumentality of the United States, except in the case of voluntary submission to the rules established pursuant to this part;

(22) "Planning division" and "state health planning division" means the state health planning division of the department, which is created by this part to develop the state health plan and to conduct other related studies;

(23) "Rehabilitation facility" means an inpatient or residential facility that is operated for the primary purpose of assisting in the rehabilitation of physically disabled persons through an integrated program of medical and other services that is provided under professional supervision;

(24) "Review cycle" means the timeframe set for the review and initial decision on applications for certificate of need applications that have been deemed complete, with the fifteenth day of the month being the first day of the review cycle; and

(25) "State health plan" means the plan that is developed by the state health planning division pursuant to this part.

AND FURTHER AMEND by deleting the amendatory language of SECTION 6 and substituting instead the following:

In addition to the powers granted elsewhere in this part, the agency has the duty and responsibility to:

(1) Develop criteria and standards to guide the agency when issuing certificates of need that are:

(A) Based, in whole or in part, upon input the agency received during development of the criteria and standards from the division of TennCare, or its successor; the departments of health, mental health and substance abuse

services, and intellectual and developmental disabilities; the health and welfare committee of the senate; and the health committee of the house of representatives;

(B) Evaluated and updated not less than once every five (5) years; and

(C) Developed by rule in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5;

(2) Receive and consider applications for certificates of need, to review recommendations on certificates of need, and to grant or deny certificates of need on the basis of the merits of the applications within the context of the local, regional, and state health needs, including, but not limited to, the criteria and standards developed in accordance with this part;

(3) Conduct studies related to health care, including a needs assessment that must be updated at least annually;

(4) Promulgate rules and policies deemed necessary by the agency for the fulfillment of its duties and responsibilities under this part, including a procedure for the issuance of a certificate of need upon an emergency application if an unforeseen event necessitates the issuance of a certificate of need to protect the public health, safety, and welfare, and if the public health, safety, and welfare would be unavoidably jeopardized by compliance with the procedures established under this part;

(5) Contract when necessary for the development of criteria and standards to guide the agency when issuing certificates of need and for the implementation of the certificate of need program described in this part;

(6) Weigh and consider access to quality health care and the healthcare needs of consumers, particularly those in underserved communities; those who are uninsured or underinsured; women and racial and ethnic minorities; TennCare or medicaid recipients; and low income groups whenever the agency performs its duties or responsibilities assigned by law; and

(7) Issue exemptions from the voiding of a certificate of need and any activity authorized by the certificate of need pursuant to § 68-11-1609(i), if the actions the certificate of need authorizes are not performed for a continuous period of one (1) year after the certificate of need is implemented.

AND FURTHER AMEND by deleting the amendatory language of SECTION 7 and substituting instead the following:

(c) The executive director has the following duties:

(1) Administer the development of criteria and standards to guide the agency when issuing certificates of need;

(2) Administer the certificate of need program;

(3) Conduct studies related to health care;

(4) Represent the agency before the general assembly;

(5) Oversee the issuance of responses to requests for determination regarding the applicability of this part;

(6) Issue exemptions from the requirement that a certificate of need be obtained for the relocation of existing or certified facilities providing healthcare services and healthcare institutions under § 68-11-1607(a)(4);

(7) Keep a written record of all proceedings and transactions of the agency, which must be open to public inspection during regular office hours;

(8) Prepare the agenda, including consent and emergency calendars, and notice to the general public of all meetings and public hearings of the agency;

(9) Employ personnel, within the agency's budget, to assist in carrying out this part;

(10) Carry out all policies and rules that are promulgated by the agency and supervise the expenditure of funds; and

(11) Submit a proposal to the general assembly no later than January 1, 2021, detailing objectives, governance issues, costs, and implementation timelines of a state all payer claims database.

AND FURTHER AMEND by deleting subsection (a) from the amendatory language of SECTION 10 and substituting instead the following:

(a) No person shall perform any of the following actions in this state, except after applying for and receiving a certificate of need for the action:

(1) The construction, development, or other establishment of any type of healthcare institution as described in this part;

(2) In the case of a healthcare institution, any change in the bed complement, regardless of cost, that:

(A) Increases by one (1) or more the number of nursing home beds;

(B) Redistributes beds from any category to acute, rehabilitation, child and adolescent psychiatric, adult psychiatric, or long-term care; or

(C) Relocates beds to another facility or site;

(3) Initiation of any of the following healthcare services: burn unit, neonatal intensive care unit, open heart surgery, organ transplantation, cardiac catheterization, linear accelerator, home health, hospice, or opiate addiction treatment provided through a nonresidential substitution-based treatment center for opiate addiction;

(4)

(A) A change in the location of existing or certified facilities providing healthcare services and healthcare institutions. However, the executive director may issue an exemption for the relocation of existing healthcare institutions and approved services when the executive director determines that:

(i) At least seventy-five percent (75%) of patients to be served are reasonably expected to reside in the same zip codes as the existing patient population; and

(ii) The relocation will not reduce access to consumers, particularly those in underserved communities; those who are uninsured or underinsured; women and racial and ethnic minorities; TennCare or medicaid recipients; and low income groups. The executive director must notify the agency of any exemption granted pursuant to this subdivision (a)(4)(A); and

(B) The relocation of the principal office of a home health agency or hospice within its licensed service area does not require a certificate of need;

(5) Initiation of magnetic resonance imaging;

(6) Increasing the number of magnetic resonance imaging machines, except for replacing or decommissioning an existing machine;

(7) Establishing a satellite emergency department facility or a satellite inpatient facility by a hospital at a location other than the hospital's main campus; and

(8) Initiation of positron emission tomography.

AND FURTHER AMEND by deleting subsection (g) from the amendatory language of SECTION 10 and substituting instead the following:

(g) After a person holding a certificate of need has completed the actions for which a certificate of need was granted, the time to complete activities authorized by the certificate of need expires.

AND FURTHER AMEND by deleting subdivision (m)(2) from the amendatory language of SECTION 10 and substituting instead the following:

(2) In any county with a population in excess of one hundred thousand (100,000), according to the 2010 federal census or any subsequent federal census, any person who initiates magnetic resonance imaging services shall notify the agency in writing that imaging services are being initiated and shall indicate whether pediatric patients will be provided imaging services.

AND FURTHER AMEND by deleting subsection (o) from the amendatory language of SECTION 10 and substituting instead the following:

(o) After receiving a certificate of need, an outpatient diagnostic center must become accredited by the American College of Radiology in the modalities provided by that facility within a period of time set by rule by the agency as a condition of receiving a certificate of need.

AND FURTHER AMEND by deleting subsection (q) from the amendatory language of SECTION 10 and substituting instead the following:

(q)

(1) This part does not require a certificate of need for any actions in a county that, as of January 1, 2020:

(A) Is designated as an economically distressed eligible county by the department of economic and community development pursuant to § 67-6-104, as updated annually; and

(B) Has no hospital that is actively licensed under this title located within the county.

(2) This part does not require a certificate of need for any action in a county that is designated as an economically distressed eligible county by the department of economic and community development pursuant to § 67-6-104, as updated annually, and that has a hospital that is actively licensed under this title located within the county, if the licensed hospital does not perform the action.

Actions excepted by this subdivision (q)(2) include, but are not limited to,

establishing an outpatient diagnostic center or ambulatory surgical treatment center necessary to perform diagnostic or surgical services that are not provided by the licensed hospital.

(3) Any person that provides positron emission tomography services or magnetic resonance imaging services pursuant to this subsection (q) must be accredited by the Joint Commission or American College of Radiology in the modalities provided by that person within two (2) years of the initiation of service.

AND FURTHER AMEND by deleting subsection (r) from the amendatory language of SECTION 10 and substituting instead the following:

(r) This part does not require a certificate of need to establish a home health agency limited to providing home health services under the federal Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA) (42 U.S.C. § 7384, et seq.), or any subsequent amendment, revision, or modification to the EEOICPA. Any license issued by the department pursuant to this subsection (r) for services under the EEOICPA must be limited to the provision of only those services. Any home health agency providing home health services without a certificate of need pursuant to this subsection (r) must be accredited by the Joint Commission, the Community Health Accreditation Partner, or the Accreditation Commission for Health Care.

AND FURTHER AMEND by deleting subsection (s) from the amendatory language of SECTION 10 and substituting instead the following:

(s)

(1) Nothing in this part requires a certificate of need to establish a home health agency limited to providing home health services to patients less than eighteen (18) years of age. Any license issued by the department pursuant to this subsection (s) for the provision of home health services to patients under eighteen (18) years of age must be limited to the provision of only those services.

(2) The agency may permit a home health agency providing home health services to patients under eighteen (18) years of age to continue providing home health services to the patient until the patient reaches twenty-one (21) years of age if:

(A) The patient received home health services from the home health agency prior to the date the patient reached eighteen (18) years of age; and

(B) The home health services are provided under a TennCare program.

(3) Any home health agency that provides home health services without a certificate of need pursuant to this subsection (s) must be accredited by:

(A) An accrediting organization with deeming authority from the federal centers for medicare and medicaid services;

(B) The Joint Commission;

(C) The Community Health Accreditation Partner; or

(D) The Accreditation Commission for Health Care.

AND FURTHER AMEND by adding the following to SECTION 10 as a new subsection (u):

(u)

(1) This part does not require a certificate of need to establish or operate the following in a county with a population in excess of one hundred thousand (100,000), according to the 2010 federal census or any subsequent federal census:

(1) An ambulatory surgical treatment center;

(2) A free-standing emergency department;

(3) Initiation of magnetic resonance imaging services for non-pediatric patients or increasing the number of magnetic resonance imaging machines used for non-pediatric patients;

- (4) Initiation of positron emission tomography; or
- (5) An outpatient diagnostic center.

(2) An outpatient diagnostic center established without a certificate of need pursuant to this subsection (u) must become accredited by the American College of Radiology in the modalities provided by that facility within two (2) years of the date of licensure.

(3) A provider of positron emission tomography established without a certificate of need pursuant to this subsection (u) must become accredited by the American College of Radiology within two (2) years of the date of licensure.

AND FURTHER AMEND by adding the following to SECTION 10 as a new subsection (v):

(v) This part does not require a certificate of need to establish or operate a micro hospital.

AND FURTHER AMEND by adding the following to SECTION 10 as a new subsection (w):

(w)

(1) Each person who performs the following actions shall file an annual report as described in this subsection (w) with the health services and development agency:

- (A) Cardiac catheterization;
- (B) Open heart surgery;
- (C) Organ transplantation;
- (D) Operation of a burn unit;
- (E) Operation of a neonatal intensive care unit;
- (F) Provision of home health services; or
- (G) Provision of hospice services.

(2) The annual report required by subdivision (w)(1) must be submitted in a manner and on forms prescribed by the agency, and must include utilization data according to source of payment and zip codes of patient origin.

(3) Each person required to submit an annual report by this subsection (w) must submit the annual report for the period coinciding with the state fiscal year ending June 30, 2020, on or before September 30, 2020. The annual report for each subsequent fiscal year must be submitted to the agency no later than thirty (30) days following the end of each state fiscal year.

(4) The agency may impose a civil penalty not to exceed fifty dollars (\$50.00) per day, for each day an annual report required by this subsection (w) is late.

AND FURTHER AMEND by deleting subsection (c) from the amendatory language of SECTION 12 and substituting instead the following:

(c) Activity authorized by a certificate of need must be completed within a period not to exceed three (3) years for hospital projects, and two (2) years for all other projects, from the date of its issuance and after such time the certificate of need authorization expires. However, the agency may, in granting the certificate of need, allow longer periods of validity for certificates of need for good cause shown. Subsequent to granting the certificate of need, the agency may extend a certificate of need for a period upon application and good cause shown, accompanied by a nonrefundable reasonable filing fee, as prescribed by rule. A certificate of need authorization that has been extended expires at the end of the extended time period. The decision whether to grant an extension is within the sole discretion of the agency and is not subject to review, reconsideration, or appeal.

AND FURTHER AMEND by deleting subsection (d) from the amendatory language of SECTION 12 and substituting instead the following:

(d) If the time period authorized by a certificate of need has expired, then the certificate of need authorization is void. No revocation proceeding is required. No license or occupancy approval may be issued by the department of health or the

department of mental health and substance abuse services for any activity for which a certificate of need has become void.

AND FURTHER AMEND by deleting subsection (i) from the amendatory language of SECTION 12 and substituting instead the following:

(i)

(1) Notwithstanding any law to the contrary, and except as provided in subdivision (i)(2), a certificate of need and any activity it authorizes becomes void if the actions it authorizes have not been performed for a continuous period of one (1) year after the date the certificate of need is implemented. With respect to a home care organization, this subsection (i) applies to each county for which the home care organization is licensed. No revocation proceeding is required. The department of health and the department of mental health and substance abuse services shall not issue or renew a license for any activity for which certificate of need authorization has become void.

(2)

(A) The agency may issue a temporary exemption to subdivision (i)(1) upon finding that sufficient cause for the temporary cessation of the activity has been presented to the agency along with a plan to resume the activity in the future.

(B) The agency shall prescribe the procedures for issuing temporary exemptions by rule.

(C) The agency's approval or denial of a temporary exemption is a final agency decision subject to appeal in the chancery court of Davidson County.

(3) This subsection (i) does not apply to the establishment of a healthcare institution or a healthcare institution's number of licensed beds if the

healthcare institution has a license issued under this title, whether active or inactive.

AND FURTHER AMEND by deleting the amendatory language of SECTION 14 and substituting instead the following:

(i) All costs of the contested case proceeding and any appeals, including the administrative law judge's costs and deposition costs, such as expert witness fees and reasonable attorney's fees, must be assessed against the losing party in the contested case. If there is more than one (1) losing party, then the costs must be divided equally among the losing parties. Costs must not be assessed against the agency.

AND FURTHER AMEND by deleting SECTION 24 and substituting instead the following:

SECTION 24. Tennessee Code Annotated, Section 68-11-1625, is amended by deleting the language "department of finance and administration" wherever it appears and substituting instead the language "department of health"; by deleting subdivision (d)(2) and renumbering the remaining subdivisions accordingly; and by deleting subsections (e) and (f).

AND FURTHER AMEND by deleting SECTION 26 and substituting instead the following:

SECTION 26. Tennessee Code Annotated, Section 68-11-1628, is amended by deleting the section.

AND FURTHER AMEND by deleting SECTION 27 and substituting instead the following:

SECTION 27. Tennessee Code Annotated, Section 68-11-1629, is amended by deleting the section.

SECTION 28. Tennessee Code Annotated, Section 68-11-1631, is amended by deleting the section.

SECTION 29. Tennessee Code Annotated, Section 68-11-1632, is amended by deleting the section.

SECTION 30. Tennessee Code Annotated, Section 68-11-1633, is amended by deleting the section and substituting the following:

(a) In consultation with the department of health, the department of mental health and substance abuse services, and the department of intellectual and developmental disabilities, and subject to § 68-11-1609(h), the agency shall develop measures by rule for assessing quality for entities that, on or after July 1, 2016, receive a certificate of need under this part. In developing quality measures, the agency may seek the advice of stakeholders with respect to certificates of need for specific institutions or services.

(b) If the agency determines that an entity has failed to meet the quality measures developed under this section, then the agency shall refer that finding to the board for licensing healthcare facilities or the department of mental health and substance abuse services, whichever is appropriate, for appropriate action on the license of the entity under part 2 of this chapter.

(c) If the agency determines that an entity has failed to meet any quality measure imposed as a condition for a certificate of need by the agency, then the agency may impose penalties pursuant to § 68-11-1617 or revoke a certificate of need pursuant to § 68-11-1619.

SECTION 31. This act shall take effect upon becoming a law, the public welfare requiring it.