HOUSE BILL 2350
By Smith

SENATE BILL 2312

By Gardenhire

AN ACT to amend Tennessee Code Annotated, Title 68, Chapter 11, Part 16, relative to certificates of need.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Section 68-11-1602, is amended by deleting the section and substituting 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 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;

(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) "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 physician licensed pursuant to title 63, chapter 6, part 2 and title 63, chapter 9, or 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;

(9) "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;

(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) "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;

(15) "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;

(16) "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;

(17) "Pediatric patient" means a patient who is fourteen (14) years of age or younger;

(18) "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 (18), 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;

(19) "Planning division" and "state health planning division" mean 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;

(20) "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;

(21) "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

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

SECTION 2. Tennessee Code Annotated, Section 68-11-1603, is amended by deleting the section and substituting the following:

It is declared to be the public policy of this state that the establishment and modification of healthcare institutions, facilities, and services must be accomplished in a manner that promotes access to necessary, high quality, and cost-effective services for the health care of the people of Tennessee. To this end, this section applies equitably to all healthcare entities, regardless of ownership or type, except those owned and operated by the United States government.

SECTION 3. Tennessee Code Annotated, Section 68-11-1604(a), is amended by deleting the subsection and substituting the following:

(a) There is created a health services and development agency that has jurisdiction and powers relating to the certificate of need program; the development of the criteria and standards to guide the agency when issuing certificates of need; conducting studies related to health care, which must include a needs assessment; and related reporting of all healthcare institutions subject to this chapter.

SECTION 4. Tennessee Code Annotated, Section 68-11-1604(c), is amended by deleting the subsection and substituting the following:

(c)

(1) No member of the agency shall serve beyond the expiration of the member's term, whether or not a successor has been appointed by the governor or the speakers of the senate and the house of representatives.

(2) Except for the comptroller of the treasury, the commissioner of commerce and insurance, and the director of TennCare, or their respective designees, agency members are appointed for three-year terms, and no member shall serve more than two (2) consecutive three-year terms.

(3) If any member is absent from three (3) consecutive, regularly scheduled public meetings of the agency, then the individual's membership is automatically terminated, and the position is considered as vacant.

SECTION 5. Tennessee Code Annotated, Section 68-11-1604(e)(1), is amended by deleting the subdivision and substituting the following:

(1) At the first meeting in each fiscal year, the agency shall elect officers. The chair of the agency must be a consumer member to serve a term of two (2) years. Any member of the agency may serve as vice chair to serve a term of one (1) year. No member shall serve two (2) consecutive terms as vice chair.

SECTION 6. Tennessee Code Annotated, Section 68-11-1605, is amended by deleting the section and substituting 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 evaluated and updated at least annually, and to seek input on the criteria and standards it is developing 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;

(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; and

(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.

SECTION 7. Tennessee Code Annotated, Section 68-11-1606(c), is amended by deleting the subsection and substituting 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 October 1, 2020, detailing objectives, governance, costs, and implementation timeline of a state all payer claims database.

SECTION 8. Tennessee code Annotated, Section 68-11-1606(d), is amended by deleting the subsection and substituting the following:

(d) In addition to the duties provided in subsection (c), the agency has the authority to delegate, and it is the intent of the general assembly that the agency exercise the authority to delegate the following responsibilities and duties to the executive director:

(1) Granting deferral of applications for certificates of need in accordance with § 68-11-1609; and

(2) Granting approval or denial of modifications, changes of conditions or ownership, and extensions of certificates of need in accordance with provisions of this part.

SECTION 9. Tennessee Code Annotated, Section 68-11-1606(f), is amended by deleting the subsection and substituting the following:

(f) Actions taken by the executive director are final as if the actions were taken by the agency. However, a member of the agency may, in the sole discretion of the member, request that the agency review the action of the executive director. The request must be made within fifteen (15) days of the notice of the action by the executive director, in which case the action does not become final until the agency has rendered its final decision in the matter. The review must be heard at the next regularly scheduled agency meeting of the request for review of the action.

SECTION 10. Tennessee Code Annotated, Section 68-11-1607, is amended by deleting the section and substituting the following:

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

(1) The construction, development, or other establishment of any type of healthcare institution as described in this part. However, a certificate of need is not required for the establishment of an outpatient diagnostic center in any county with a population in excess of one hundred seventy-five thousand (175,000), according to the 2010 federal census or any subsequent federal census;

(2) In the case of a healthcare institution, any change in the medicare skilled nursing facility bed complement, regardless of cost. Nothing in this subdivision (a)(2) permits the relocation of 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 or the replacement of existing or certified facilities providing healthcare services and healthcare institutions;

(B) However, the executive director may issue an exemption for the relocation of existing healthcare institutions and approved services when the executive director determines:

(i) That 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) That the relocation would 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; and

(C) 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:

(A) In any county with a population in excess of one hundred seventy-five thousand (175,000), according to the 2010 federal census or any subsequent federal census, only for providing magnetic resonance imaging to pediatric patients; and

(B) In any county with a population of one hundred seventy-five thousand (175,000) or less, according to the 2010 federal census or any subsequent federal census, for providing magnetic resonance imaging to any patients;

(6) Increasing the number of magnetic resonance imaging machines, in any county with a population of one hundred seventy-five thousand (175,000) or less, according to the 2010 federal census or any subsequent federal census, by one (1) or more, except for replacing or decommissioning an existing machine;

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

(8) Initiation of positron emission tomography in any county with a population of one hundred seventy-five thousand (175,000) or less, according to the 2010 federal census or any subsequent federal census.

(b) No agency of the state, or of any county or municipal government, shall approve any grant of funds for, or issue any license to, a healthcare institution for any portion or activity of the healthcare institution that is established, modified, relocated, changed, or resumed, or that constitutes a covered healthcare service, in violation of this part. If any agency of the state, or any county or municipal government, approves any grant of funds for, or issues any license to, any person or institution for which a certificate of need was required but was not granted, then the license is void and the person or institution shall refund the funds to the state within ninety (90) days. The agency has the authority to impose civil penalties and petition any circuit or chancery court having jurisdiction to enjoin any person who is in violation of this part.

(c)

(1) For each application, a letter of intent must be filed between the first day of the month and the fifteenth day of the month prior to the application's submission. At the time of filing, the applicant shall cause the letter of intent to be published in a newspaper of general circulation in the proposed service area of the project. The published letter of intent must contain a statement:

(A) That any healthcare institution wishing to oppose the application must file written notice with the agency no later than fifteen (15) days before the agency meeting at which the application is originally scheduled; and

(B) That any other person wishing to oppose the application may file a written objection with the agency at or prior to the consideration of

the application by the agency, or may appear in person to express opposition.

(2) Persons desiring to file a certificate of need application seeking a simultaneous review regarding a similar project for which a letter of intent has been filed shall file with the agency a letter of intent between the sixteenth day of the month and the last day of the month of publication of the first filed letter of intent. A copy of any letter of intent filed after the first letter of intent must be mailed or delivered to the first filed applicant and must be published in a newspaper of general circulation in the proposed service area of the first filed applicant. The health services and development agency shall consider and decide the applications simultaneously. However, the agency may refuse to consider the applications simultaneously if it finds that the applications do not meet the requirements of "simultaneous review" under the rules of the agency.

(3) Applications for a certificate of need, including simultaneous review applications, must be filed by the first business day of the month following the date of publication of the letter of intent.

(4) If there are two (2) or more applications to be reviewed simultaneously in accordance with this part and the rules of the agency, and one (1) or more of those applications is not deemed complete by the deadline to be considered at the next agency meeting, then the other applications that are deemed complete by the deadline must be considered at the next agency meeting. The application or applications that are not deemed complete by the deadline to be considered at the next agency meeting will not be considered with the applications deemed complete by the deadline to be considered at the next agency meeting.

(5) Review cycles begin on the fifteenth day of each month. Review cycles are thirty (30) days. The first meeting at which an application can be considered by the agency is the meeting following the application's review cycle. If an application is not deemed complete within sixty (60) days after initial written notification is given to the applicant by the agency staff that the application is deemed incomplete, then the application is void. If the applicant decides to resubmit the application, then the applicant shall comply with all procedures as set out by this part and pay a new filing fee when submitting the application. Prior to deeming an application complete, the executive director shall ensure independent review and verification of information submitted to the agency in applications, presentations, or otherwise. The purpose of the independent review and verification is to ensure that the information is accurate, complete, comprehensive, timely, and relevant to the decision to be made by the agency. The independent review and verification must be applied to, but not necessarily be limited to, applicant-provided information as to the number of available beds within a region, occupancy rates, the number of individuals on waiting lists, the demographics of a region, the number of procedures, and any other critical information submitted or requested concerning an application; and staff examinations of data sources, data input, data processing, and data output, and verification of critical information.

(6) Each application filed with the agency must be accompanied by a nonrefundable examination fee fixed by the rules of the agency.

(7) All information provided in the application or any information submitted to the agency in support of an application must be true and correct.

No substantive amendments to the application, as defined by rule of the agency, are allowed.

(8) Each applicant shall designate a representative as the contact person for the applicant and shall notify the agency, in writing, of the contact person's name, address, and telephone number. The applicant shall immediately notify the agency in writing of any change in the identity or contact information of the contact person. In addition to any other method of service permitted by law, the agency may serve by registered or certified mail any notice or other legal document upon the contact person at the person's last address of record in the files of the agency. Notwithstanding any law to the contrary, service in the manner specified in this subdivision (c)(8) constitutes actual service upon the applicant.

(9)

(A) Within ten (10) days of the filing of an application for a nonresidential substitution-based treatment center for opiate addiction with the agency, the applicant shall send a notice to the county mayor of the county in which the facility is proposed to be located; the state representative and senator representing the house district and the senate district in which the facility is proposed to be located; and the mayor of the municipality, if the facility is proposed to be located within the corporate boundaries of a municipality, by certified mail, return receipt requested, informing those officials that an application for a nonresidential substitution-based treatment center for opiate addiction has been filed with the agency by the applicant.

(B) If an application involves a healthcare facility in which a county or municipality is the lessor of the facility or real property on which it sits, then within ten (10) days of filing the application, the applicant shall notify the chief executive officer of the county or municipality of the filing, by certified mail, return receipt requested.

(C) An application subject to the notification requirement of this subdivision (c)(9) is not complete if the applicant has not provided proof of compliance with this subdivision (c)(9) to the agency.

(d) No communications are permitted with the members of the agency once the letter of intent initiating the application process is filed with the agency. Communication between agency members and agency staff is not prohibited. Any communication received by an agency member from a person unrelated to the applicant or party opposing the application must be reported to the executive director, and a written summary of the communication must be made part of the certificate of need file.

(e) For purposes of this part, agency action is the same as administrative action defined in § 3-6-301.

(f)

(1) Notwithstanding this section to the contrary, Tennessee state veterans' homes pursuant to title 58, chapter 7, are not required to obtain a certificate of need pursuant to this section.

(2) Notwithstanding this section to the contrary, the beds located in any Tennessee state veterans' home pursuant to title 58, chapter 7, must not be considered by the health services and development agency when granting a certificate of need to a healthcare institution due to a change in the number of licensed beds, redistributing beds, or relocating beds pursuant to this section.

(g) After a person holding a certificate of need has completed the actions for which a certificate of need was granted, the certificate of need expires.

(h) The owners of the following types of equipment shall register the equipment with the health services and development agency: computerized axial tomographers, magnetic resonance imagers, linear accelerators, and positron emission tomography. The registration must be in a manner and on forms prescribed by the agency and must include ownership, location, and the expected useful life of the equipment. Registration must occur within ninety (90) days of acquisition of the equipment. All such equipment must be filed on an annual inventory survey developed by the agency. The survey must include, but not be limited to, the identification of the equipment and utilization data according to source of payment. The survey must be filed no later than thirty (30) days following the end of each state fiscal year. The agency may impose a penalty not to exceed fifty dollars ($50.00) for each day the survey is late.

(i) Notwithstanding this section to the contrary, an entity, or its successor, that was formerly licensed as a hospital, and that has received from the commissioner of health a written determination that it will be eligible for designation as a critical access hospital under the medicare rural hospital flexibility program, is not required to obtain a certificate of need to establish a hospital qualifying for that designation, if it meets the requirements of this subsection (i). In order to qualify for the exemption set forth in this subsection (i), the entity proposing to establish a critical access hospital shall publish notice of its intent to do so in a newspaper of general circulation in the county where the hospital will be located and in contiguous counties. The notice must be published at least twice within a fifteen-day period. The written determination from the department of health and proof of publication required by this subsection (i) must be filed with the agency within ten (10) days after the last date of publication. If no healthcare institution

within the same county or contiguous counties files a written objection to the proposal with the agency within thirty (30) days of the last publication date, then the exemption set forth in this subsection (i) is applicable. However, this exemption applies only to the establishment of a hospital that qualifies as a critical access hospital under the medicare rural flexibility program and not to any other activity or service. If a written objection by a healthcare institution within the same county or contiguous counties is filed with the agency within thirty (30) days from the last date of publication, then the exemption set forth in this subsection (i) is not applicable.

(j)

(1) A nursing home may increase its total number of licensed beds by the lesser of ten (10) beds or ten percent (10%) of its licensed capacity over any period of one (1) year without obtaining a certificate of need. The nursing home shall provide written notice of the increase in beds to the agency on forms provided by the agency prior to the request for licensing by the board for licensing healthcare facilities.

(2) For new nursing homes, the ten-bed or ten-percent increase cannot be requested until one (1) year after the date all of the new beds were initially licensed.

(3) When determining projected county nursing home bed need for certificate of need applications, all notices filed with the agency pursuant to subdivision (j)(1), with written confirmation from the board of licensing healthcare facilities that a request and application for license has been received and a review has been scheduled, must be considered with the total of licensed nursing home beds, plus the number of beds from approved certificates of need, but yet unlicensed.

(4) During the time § 68-11-1622 applies, this subsection (j) is suspended.

(k) Nothing in this part requires a certificate of need for a home care organization that is authorized to provide only professional support services as defined in § 68-11-201.

(l) A home care organization may only initiate hospice services after applying for and receiving a certificate of need for providing hospice services.

(m)

(1) Any person who provides magnetic resonance imaging services shall file an annual report no later than thirty (30) days following the end of each state fiscal year with the agency concerning adult and pediatric patients that details the mix of payers by percentage of cases for the prior calendar year for its patients, including private pay, private insurance, uncompensated care, charity care, medicare, and medicaid.

(2) In any county with a population in excess of two hundred fifty thousand (250,000), 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.

(n)

(1) An application for certificate of need for organ transplantation must separately:

(A) Identify each organ to be transplanted under the application; and

(B) State, by organ, whether the organ transplantation recipients will be adult patients or pediatric patients.

(2) After an initial application for transplantation has been granted, the addition of a new organ to be transplanted or the addition of a new recipient category requires a separate certificate of need. The application must:

(A) Identify the organ to be transplanted under the application; and

(B) State whether the organ transplantation recipients will be adult patients or pediatric patients.

(3)

(A) For the purposes of certificate of need approval for organ transplantation programs under this part, any program submitted to the United Network for Organ Sharing (UNOS) by January 1, 2017, is not required to obtain a certificate of need.

(B) If the organ transplantation program ceases to be a UNOS-approved program, then a certificate of need is required.

(o) After receiving a certificate of need, an outpatient diagnostic center shall 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.

(p)

(1) Notwithstanding this title to the contrary, no certificate of need is required for a hospital to operate a nonresidential substitution-based treatment center for opiate addiction if the treatment center is located on the same campus as the operating hospital and the hospital is licensed under title 33 or this title.

(2) For purposes of this subsection (p), "campus" has the same meaning as defined in 42 CFR § 413.65.

(q) Nothing in this part requires a certificate of need for any actions in a county that, as of January 1, 2020, is designated as an economically distressed eligible county by the department of economic and community development pursuant to § 67-6-104.

(r) Nothing in this part requires a certificate of need to establish a home care organization limited to providing home care services under the federal Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA), compiled in 42 U.S.C. § 7384, et seq., or any subsequent amendment, revision or modification to the EEOICPA. Any license issued by the department for services under the EEOICPA must be limited to the provision of only those services.

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

(t) Nothing in this part requires a certificate of need in order for an existing hospital licensed by the department of mental health and substance abuse services to become licensed by the department of health as a satellite of an affiliated general acute care hospital as provided by § 33-2-403(b)(8)(B).

SECTION 11. Tennessee Code Annotated, Section 68-11-1608, is amended by deleting the section and substituting the following:

(a) The executive director may place applications to be considered for a consent or emergency calendar established in accordance with agency rule.

(b) The rule must provide that, in order to qualify for the consent calendar, an application must not be opposed by any person with legal standing to oppose and the application must appear to be necessary to provide needed health care in the area to be served, provide health care that meets appropriate quality standards, and demonstrate that the effects attributed to competition or duplication would be positive for the consumers. If opposition is stated in writing prior to the application being formally considered by the agency, then the application must be taken off the consent calendar and placed on the next regular agenda, unless waived by the parties.

(c)

(1) If an unforeseen event necessitates action of a type requiring a certificate of need, and the public health, safety, or welfare would be unavoidably jeopardized by compliance with the standard procedures for application and granting of a certificate of need, then the agency may issue an emergency certificate of need.

(2) An emergency certificate of need may be issued upon request of the applicant if the executive director and officers of the agency concur, after consultation with the appropriate reviewing agency. Prior to an emergency certificate of need being granted, the applicant must publish notice of the application in a newspaper of general circulation, and agency members must be notified by agency staff of the request.

(3) A decision regarding whether to issue an emergency certificate of need will be considered at the next regularly scheduled agency meeting unless the applicant's request is necessitated by an event that has rendered its facility, equipment, or service inoperable. In that case, the agency's chair and vice chair

may act immediately to consider the application for an emergency certificate of need.

(4) An emergency certificate of need is valid for a period not to exceed one hundred twenty (120) days. However, if the applicant has applied for a certificate of need under standard agency procedures, then an extension of the emergency certificate of need may be granted.

SECTION 12. Tennessee Code Annotated, Section 68-11-1609, is amended by deleting the section and substituting the following:

(a) The agency shall, upon consideration of an application and review of the evaluation and other relevant information:

(1) Approve part or all of the application and grant a certificate of need, upon any lawful conditions that the agency deems appropriate and enforceable on the grounds that those parts of the proposal appear to meet applicable criteria. However:

(A) Any condition or conditions that are placed on a certificate of need, and that appear on the face of the certificate of need when issued, must also be made a condition or conditions of any corresponding license issued by the department of health or department of mental health and substance abuse services. Notwithstanding any law to the contrary, those conditions survive the expiration of the certificate of need and remain effective until removed or modified by the agency. The conditions become a requirement of licensure and must be enforced by the respective licensing entity; and

(B) The holder of a license or certificate of need that has a condition placed on it by the agency may subsequently request that the

condition be removed or modified, for good cause shown. The agency shall consider the request and determine whether or not to remove or modify the condition. The procedure for requesting a determination must be done as provided by agency rules. If the holder of the license or certificate of need is aggrieved by the agency's decision, then the holder may request a contested case hearing as permitted by this part;

(2) Disapprove part or all of the application and deny a certificate of need on the grounds that the applicant has not affirmatively demonstrated that those parts of the proposal meet the applicable criteria; or

(3) Defer decisions for no more than ninety (90) days to obtain a clarification of information concerning applications properly before the agency, if there are no simultaneous review applications being concurrently considered by the agency with the deferred application.

(b) No certificate of need shall be granted unless the action proposed in the application is necessary to provide needed health care in the area to be served, will provide health care that meets appropriate quality standards, and the effects attributed to competition or duplication would be positive for the consumers. In making these determinations, the agency shall use as guidelines the goals, objectives, criteria, and standards adopted to guide the agency in issuing certificates of need. Until the agency adopts its own criteria and standards by rule, those in the state health plan are applicable. Additional criteria for review of applications must also be prescribed by the rules of the agency.

(c) A certificate of need is valid for 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 it 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 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.

(d) A certificate of need that has expired 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.

(e) The agency's decision to approve or deny an application is final and must not be reconsidered after the adjournment of the meeting in which the matter was considered. This subsection (e) does not limit the right to file a petition for a contested case hearing pursuant to § 68-11-1610, nor does it limit the Uniform Administrative Procedures Act, compiled in title 4, chapter 5, part 3, pertaining to contested case hearings.

(f) Written notice of the decision of the agency approving, disapproving, or deferring an application, or parts of an application, must be transmitted to the applicant, simultaneous review applicants, the department of health, the department of mental health and substance abuse services, the department of intellectual and developmental disabilities, and others upon request.

(g)

(1) Any healthcare institution wishing to oppose a certificate of need application must be located within a thirty-five-mile radius of the location of the

action proposed. Any healthcare institution wishing to oppose an application for the establishment of a home care organization or the addition of counties to the licensed service area of an existing home care organization must have served patients in at least one (1) of the counties in the application's proposed service area, rather than demonstrate proximity within a thirty-five-mile radius of the location.

(2) Subject to subdivision (g)(1), any healthcare institution wishing to oppose a certificate of need application must file a written objection with the agency specifying reasons why one (1) or more of the criteria of subsection (b) are not satisfied. Any healthcare institution wishing to oppose a certificate of need application must serve a copy to the contact person for the applicant, not later than fifteen (15) days before the agency meeting at which the application is originally scheduled. An application for which the agency has received opposition must be designated on the agency's agenda as an opposed application.

(3)

(A) Subject to subdivision (g)(1), any healthcare institution wishing to oppose a certificate of need application may appear before the agency and express opposition to an application as long as the healthcare institution has submitted written opposition in accordance with subdivision (g)(2).

(B) Nothing in this subsection (g) prohibits an individual acting in the individual's capacity as a private citizen from appearing before the agency and expressing opposition to an application.

(4) A healthcare institution or other person expressing opposition to an application does not have a veto over an application. The merits of opposition may be considered by the agency while determining whether to approve or deny a certificate of need application in whole or in part.

(h) The agency shall maintain continuing oversight over any certificate of need that it approves on or after July 1, 2016. Oversight by the agency includes requiring annual reports concerning appropriate quality measures as determined by the agency. The agency may impose conditions on a certificate of need that require the demonstration of compliance with quality measures as long as the conditions for quality measures are not more stringent than those measures identified by the applicant in the applicant's submitted application.

(i) A certificate of need becomes void if the actions it authorizes have not been performed for a continuous period of one (1) year after it has been implemented, unless prior written authorization by the executive director has been issued. 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 a certificate of need has become void.

(j) If an applicant's application is denied by the agency, then the agency shall provide to the applicant written documentation with an explanation of the factual and legal basis upon which the agency denied the certificate of need.

SECTION 13. Tennessee Code Annotated, Section 68-11-1610(a), is amended by deleting the subsection and substituting the following:

(a) Within fifteen (15) days of the approval or denial by the agency of an application, any applicant, healthcare institution that satisfied the requirements set forth

in § 68-11-1609(g), or any other person who objected to the application pursuant to § 68-11-1609(g)(2) or (g)(3), may petition the agency in writing for a hearing. The petition must be filed with the executive director. Notwithstanding any other law, all persons are barred from filing any petition for a contested case hearing after the fifteen-day period, and the agency has no jurisdiction to consider any late-filed petition. Upon receipt of a timely filed petition, the agency shall initiate a contested case proceeding as provided in this section. At the hearing, no issue may be raised or evidence considered concerning the merits of an applicant considered by simultaneous review, unless the applicant met the requirements of this part, of concurrent consideration with the application that is the subject of the hearing.

SECTION 14. Tennessee Code Annotated, Section 68-11-1610, is amended by deleting subsection (i) and substituting the following:

(i) All costs of the contested case proceeding, 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.

SECTION 15. Tennessee Code Annotated, Section 68-11-1610, is amended by deleting subsection (j) and substituting the following:

(j) This section governs all contested cases relative to approval or denial decisions by the agency.

SECTION 16. Tennessee Code Annotated, Section 68-11-1610, is amended by deleting subsection (e) and redesignating the remaining subsections accordingly.

SECTION 17. Tennessee Code Annotated, Section 68-11-1614, is amended by deleting the section and substituting the following:

(a) The commissioner of health shall provide the agency with aggregate data from the hospital discharge database and ambulatory surgical treatment center discharge database within seven (7) business days from the commissioner's receipt of a request. The information must include aggregate data by state, county, or zip code, as requested. The information must not include any patient identifiers that would lead to a patient's identity, such as name or street address. All information received pursuant to this section must be available for public disclosure by the agency, as long as it does not contain any patient identifiers.

(b) The commissioner of mental health and substance abuse services shall provide the agency with aggregate data about nonresidential substitution-based treatment centers for opiate addiction licensed in Tennessee within seven (7) business days from the commissioner's receipt of a request. The information must include aggregate data about patient origin by state, county, or zip code, as requested, at licensee treatment centers in this state. The information must not include any patient identifiers that would lead to a patient's identity, such as name or street address. All information received pursuant to this section must be available for public disclosure by the agency, as long as it does not contain any patient identifiers.

(c) The commissioners of health, mental health and substance abuse services, and intellectual and developmental disabilities may submit written reports or statements and they may also send representatives to testify before the agency to inform the agency with respect to applications.

SECTION 18. Tennessee Code Annotated, Section 68-11-1616, is amended by deleting the section.

SECTION 19. Tennessee Code Annotated, Section 68-11-1618, is amended by deleting the section.

SECTION 20. Tennessee Code Annotated, Section 68-11-1620, is amended by deleting subsection (a) and substituting the following:

(a) Except as provided in this section, the transfer of a certificate of need renders the certificate of need and all rights under it void. As used in this section, "transfer" means any sale, assignment, lease, conveyance, purchase, grant, donation, gift, or any other direct or indirect transfer of any nature whatsoever of a certificate of need. However, nothing in this section prohibits the transfer of a certificate of need in the following circumstances:

(1) If the transfer has been approved by the agency after the agency determines that the new holder of the certificate of need would provide health care that meets appropriate quality standards, and that the transfer would 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; and

(2) If the certificate of need is transferred as part of the transfer of ownership of a licensed health care institution.

SECTION 21. Tennessee Code Annotated, Section 68-11-1621, is amended by deleting the section.

SECTION 22. Tennessee Code Annotated, Section 68-11-1622(b), is amended by deleting the language "Applications for medicare SNF beds under this section shall be reviewed by the department and considered by the agency pursuant to § 68-11-1609, rather than § 68-11-1621."

SECTION 23. Tennessee Code Annotated, Section 68-11-1623, is amended by deleting the section and substituting the following:

(a) All fees and civil penalties authorized by this part must be paid by the health services and development agency or the collecting agency to the state treasurer and deposited in the state general fund and credited to a separate account for the agency. Fees include, but are not limited to, fees for the application of certificates of need, subscriptions, project cost overruns, copying, and contested cases. Disbursements from that account may only be made for the purpose of defraying expenses incurred in the implementation and enforcement of this part by the agency. Funds remaining in the account at the end of any fiscal year do not revert to the general fund but remain available for expenditure in accordance with law.

(b) The agency shall prescribe fees by rule as authorized by this part. The fees must be in an amount that, in addition to the fees prescribed in subsection (c), provides for the cost of administering the implementation and enforcement of this part by the agency. Fees prescribed by the agency must be adjusted as necessary to provide that the account is fiscally self-sufficient and that revenues from fees do not exceed necessary and required expenditures.

(c) The department of health shall annually collect the following schedule of fees from healthcare providers, and the fees must be paid to the state treasurer and deposited in the state general fund and credited to the agency's separate account. The following schedule applies:

(1) Residential hospice .... $100 per license;

(2) Nursing homes .... $2,000 per license;

(3) Hospitals 1-100 beds .... $2,000 per license;

(4) Hospitals 101-200 beds .... $3,500 per license;

(5) Hospitals 201+ beds .... $5,000 per license;

(6) Ambulatory surgical treatment centers .... $500 per license;

(7) Outpatient diagnostic centers .... $500 per license;

(8) Home care organizations authorized to provide home health services or hospice services ………………………………………..................... $500 per license;

(9) Birthing Centers... $50 per license;

(10) Nonresidential substitution-based treatment centers for opiate addiction .... $500 per license;

(11) Mental health hospitals 1-100 beds .... $2,000 per license;

(12) Mental health hospitals 101+ beds .... $3,500 per license;

(13) Mental health residential treatment facilities........... $100 per license;

(14) Intellectual disability institutional habilitation facilities .... $100 per license.

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"; and by deleting subsections (e) and (f).

SECTION 25. Tennessee Code Annotated, Section 68-11-1626, is amended by deleting the section.

SECTION 26. Tennessee Code Annotated, Section 68-11-1633, is amended by deleting the section and substituting the following:

(a) In consultation with the board for licensing healthcare facilities, 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 27. This act shall take effect upon becoming a law, the public welfare requiring it.