



**State of Tennessee
Health Services and Development Agency**

Andrew Jackson Building, 9th Floor, 502 Deaderick Street, Nashville, TN 37243
www.tn.gov/hsda Phone: 615-741-2364 Fax: 615-741-9884

**INSTRUCTIONS FOR FILING AN APPLICATION FOR
A CERTIFICATE OF NEED**

Applicants unfamiliar with the Tennessee Certificate of Need process are strongly encouraged to contact Health Services and Development Agency (HSDA) staff for a pre-filing conference. Conferences may be held in person or via telephone any business day, 8:00 a.m. – 4:30 p.m. (Central Time). Call 615/741-2364 to set up an appointment.

A certificate of need can only be granted when a project is necessary to provide needed health care in the area to be served, can be economically accomplished and maintained, will provide healthcare that meets appropriate quality standards, and it will contribute to the orderly development of adequate and effective health care facilities and/or services in this area. The applicant is responsible for demonstrating that these criteria have been met through its answers to this application and any supplemental questions posed by staff.

Prior to preparation of this application, prospective applications should visit the HSDA website <http://www.tn.gov/hsda/> to consult a variety of resources to include:

- Tennessee Code Annotated § 68-11-1601 *et seq.*
<http://www.lexisnexis.com/hottopics/tncode/>
- HSDA Rules and Regulations <https://www.tn.gov/hsda/hsda-rules-and-laws.html>
- Criteria and Standards for CON <https://www.tn.gov/hsda/hsda-criteria-and-standards.html>
- Tennessee State Health Plan from the Department of Health, Division of Health Planning <https://www.tn.gov/hsda/hsda-state-health-plan.html> or call 615-532-3161.
- Health Statistics from the Tennessee Department of Health including Joint Annual Reports (JAR) for hospitals, home care organizations for home health, and hospice, outpatient diagnostic centers, and ambulatory surgical treatment centers; demographics, vital, and other health statistics by county <https://www.tn.gov/health/health-program-areas/statistics.html> or call 615-741-4939.
Information concerning mental health hospital or non-residential substitution-based treatment center for opiate addiction applications contact the Tennessee Department of Mental Health and Substance Abuse Services <https://www.tn.gov/content/tn/behavioral-health/licensing/find-a-licensed-facility-or-service.html> or call 615-532-6500.
- Information concerning intellectual disability institutional habilitation facility applications contact the Tennessee Department of Intellectual and Developmental Disabilities <https://www.tn.gov/content/tn/didd/divisions/office-of-licensure.html> or call 615-253-6811.
- “Applicant’s Toolbox” <https://www.tn.gov/hsda/certificate-of-need-information/applicants-toolbox.html> includes information and links such as:

- Helpful hints on application layout/hard copy
- Cost per square foot ranges - construction (PDF)
- Charges per procedure - medical equipment (PDF)
- Home health licensed agencies by resident county (PDF)
- Hospice licensed agencies by resident county (PDF)
- Medical equipment location
- Number of procedures - medical equipment - 3 year trend
- Flow Chart of CON Process
- Tennessee Map
- Definitions
- Additional helpful web links

COMMUNICATIONS: All documents for filing a Certificate of Need application must be received at the Health Services and Development Agency during normal business hours (8:00 a.m. - 4:30 p.m. Central Time). The office is located at 502 Deaderick Street, 9th Floor, Nashville, TN 37243. Fax and e-mail transmissions **will not** be considered to be properly filed documentation. In the event that the last appropriate filing date falls on a day the HSDA office is closed, such as Saturday, Sunday, or State holiday, such filing must occur on the preceding business day.

LETTER OF INTENT: The filing of a Letter of Intent shall initiate the CON process. The Letter of Intent must be filed with the Agency between the **first day and the tenth day of the month prior to the beginning of the review cycle** in which the application is to be considered. This allowable filing period is inclusive of both the first day and the tenth day of the month involved. The Letter of Intent must be filed in the form and format as set forth in the application packet.

Any Letter of Intent that fails to include all information requested in the Letter of Intent form, or is not timely filed, will be deemed void. The applicant will be notified in writing. Letters of Intent that are refiled are subject to the same requirements as set out above.

PUBLICATION OF INTENT: Simultaneously with the filing of the Letter of Intent, the Publication of Intent must be published for one day in a newspaper of general circulation in the proposed service area of the project. The Publication of Intent must be in the form and format as set forth in the application packet. The Publication of Intent shall be placed in the Legal Section in a space no smaller than four (4) column inches. Publication must occur between the first day and the tenth day of the month, inclusive.

1. A “newspaper of general circulation” means a publication regularly issued at least as frequently as once a week, having a second-class mailing privilege, includes a Legal Notice Section, being not fewer than four (4) pages, has been published continuously during the immediately preceding one-year period, is published for the dissemination of news of general interest, and is circulated generally in the county in which it is published and in which notice is given.
2. In any county where a “newspaper of general circulation” does not exist, the HSDA’s Executive Director is authorized to determine the appropriate publication to receive any required Letter of Intent. A newspaper which is engaged in the distribution of news of interest to a particular interest group or other limited group of citizens is not a “newspaper of general circulation.”

3. In the case of an application for or by a home care organization providing home health or hospice services, the Letter of Intent must be published in each county in which the agency will be licensed or in a regional newspaper which qualifies as a newspaper of general circulation in each county. In those cases where the Publication of Intent is published in more than one newspaper, the earliest date of publication shall be the date of publication for the purpose of determining simultaneous review deadlines and filing the application.

PROOF OF PUBLICATION: Documentation of publication must be filed with the application form. Please submit proof of publication with the application by attaching either the full page of the newspaper in which the notice appeared, with the ***mast and dateline intact***, or a publication affidavit from the newspaper that includes a copy of the publication.

SIMULTANEOUS REVIEW: Those persons desiring a simultaneous review for a Certificate of Need for which a Letter of Intent has been filed must file a Letter of Intent with the Agency and a copy is to be forwarded to the original applicant (as well as any other applicant filing a simultaneous review), and must publish the Letter of Intent simultaneously in a newspaper of general circulation in the same county as the original applicant. The publication of the Letter of Intent by the applicant seeking simultaneous review must be published within ten (10) calendar days after publication by the original applicant.

1. Only those applications filed in accordance with the rules of the Health Services and Development Agency, and upon consideration of the following factors as compared with the proposed project of the original applicant, may be regarded as applications filing for simultaneous review:
 - (A) Similarity of primary service area;
 - (B) Similarity of location;
 - (C) Similarity of facilities; and
 - (D) Similarity of service to be provided.
2. The Executive Director or his/her designee will determine whether applications are to be reviewed simultaneously, pursuant to Agency Rule 0720-10-.03(3).
3. If two (2) or more applications are requesting simultaneous review in accordance with the statute, and rules of the Agency, and one or more of those applications is not deemed complete to enter the review cycle requested, the other application(s) that is/are deemed complete shall enter the review cycle. The application(s) that is/are not deemed complete to enter the review cycle will not be considered for simultaneous review with the application(s) deemed complete and entering the review cycle.

FILING INSTRUCTIONS: Failure by the applicant to file an application within five (5) calendar days after publication of the Letter of Intent shall render the Letter of Intent and the application **void**.

For the purpose of filing any information, **the filing date is the actual date of receipt** in the Agency office. These documents, as well as other required documents, must be received as original, signed documents in the Agency office.

- File all documents in triplicate (1 original and 2 copies) on single sided or double-sided, unbound letter size (8½" x 11") paper.
- Do not bind, staple or punch holes in any document.
- *When responding to supplemental questions, type the question and the response.*
- *Answer all questions.* If an item does not apply, please indicate "N/A" (*not applicable*).
- Attach appropriate documentation as an Appendix at the end of the application or supplemental request and reference the applicable item number on the attachment, i.e., Attachment A.1, A.2, etc. For example, an Option to Lease a building should be identified as Attachment A-.6A., and placed before Financial Statements which should be identified as Attachment Section B. Economic Feasibility 6A.
- The last page of the original application, and its two (2) copies, and any supplemental response must be a completed signed and executed affidavit,
- When submitting replacement pages for the original application or previous supplemental responses, the replacement page should include the page number followed by a dash and the letter R(-R). All requested supplemental information must be received by the Agency to allow staff sufficient time for review before the beginning of the review cycle in order to enter that review cycle.
- Responses to supplemental requests should be submitted in their entirety and not in multiple submissions to the maximum extent possible.

Failure to follow the above instructions may result in the application being returned or the review delayed.

FILING FEE:

- The amount of the initial filing fee shall be an amount equal to \$5.75 per \$1,000 of the estimated project cost involved, but in no case shall the fee be less than \$15,000 or more than \$95,000. Checks should be made payable to the Health Services and Development Agency.
- ***FILING FEES*** must be received by the Agency before review of the application will begin. ***Review for completeness will not begin prior to the receipt of the filing fee.***
- Filing Fees are non-refundable, except for denied applications, in which case the applicant shall receive a refund equal to 25% of the examination fee upon request.

COMPLETENESS REVIEW

When the application is received, it will be reviewed for completeness. The application must be consistent with the information given in the Letter of Intent in terms of both project scope and project cost.

- If the application is deemed complete, the Agency will acknowledge that status and notify the applicant as to when the review cycle will begin. “Deemed complete” means that all questions in the application have been answered and all appropriate documentation has been submitted in such a manner that the HSDA can understand the intent and supporting factors of the application. **Deemed complete status shall not be construed as validating the sufficiency of the information provided for the purposes of addressing the criteria under the applicable statutes, the Rules of the Health Services and Development Agency, or the standards set forth in the State Health Plan.**
- If the application is incomplete, requests by Agency staff for supplemental information must be completed by the applicant within sixty (60) calendar days of the initial written request. Please note that supplemental information must be submitted timely for the application to be deemed complete prior to the beginning date of the review cycle which the applicant intends to enter, even if that time is less than the sixty (60) calendar days which is allowed by the statute. If the requested information is submitted within 60 calendar days of the request, but not by the date specified in the staff’s letter, the application is not void, but will enter the **next** review cycle. If an application is not deemed complete within sixty (60) calendar days after the 1st written notification is given by staff that the application is deemed incomplete, the application shall be deemed void. If the applicant decides to re-submit the application, the applicant shall comply with all procedures as set out by this part and a new filing fee shall accompany the refiled application.

AMENDMENTS OR CHANGES IN AN APPLICATION: As defined by Agency Rule, an application for a Certificate of Need which has been deemed complete **CANNOT** be amended in a substantive way by the applicant during the review cycle. Clerical errors resulting in no substantive change may be corrected.

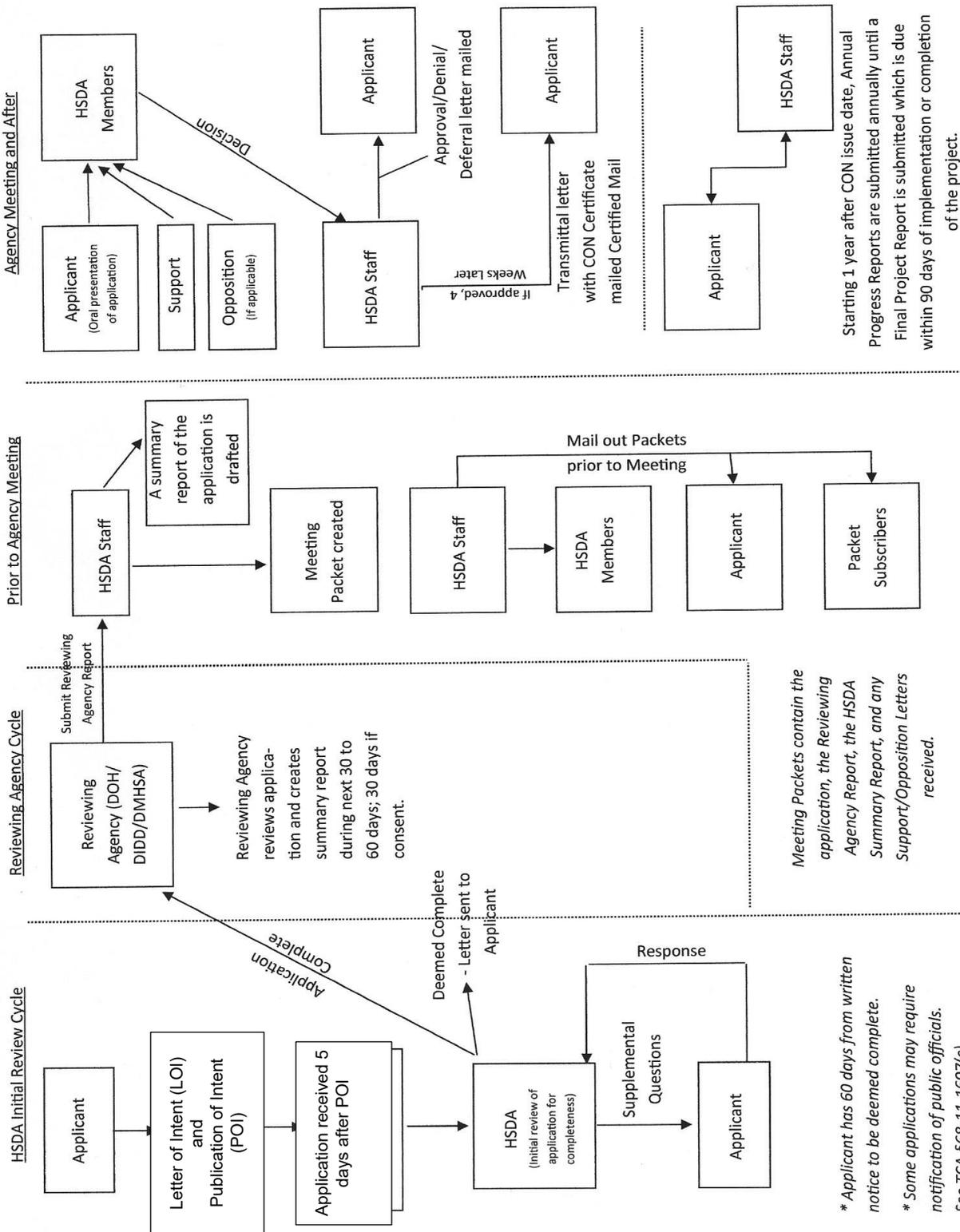
REVIEW CYCLE: Following staff review, the CON application will be forwarded to the appropriate reviewing agency for a 60 calendar day review, unless it is placed on the Consent Calendar, which is a 30 calendar day review. Reviewing agencies include the Department of Health, the Department of Mental Health and Substance Abuse Services, and/or the Department of Intellectual and Developmental Disabilities. The department reviewing the application may contact the applicant to request additional information regarding the application. The applicant should respond to any request for additional information promptly.

WITHDRAWAL OF APPLICATIONS: The applicant may withdraw an application at any time by providing written notification to the Agency. Filing fees are non-refundable when an application is withdrawn.

TIMETABLE FOR CERTIFICATE OF NEED EXPIRATION: A Certificate of Need is valid for a period not to exceed three (3) years (for hospital projects) or two (2) years (for all other projects) from the date of its issuance and after such time shall expire; *however*, the Agency may extend a Certificate of Need for a reasonable period upon application and good cause shown. A Certificate of Need shall expire at the end of the extended time period. The decision whether to grant such an extended expiration date is within the sole discretion of the Agency, and is not subject to review, reconsideration, or appeal.

For further information concerning the Certificate of Need process, please call the Health Services and Development Agency at 615/741-2364.

CON Process Flow Chart



Meeting Packets contain the application, the Reviewing Agency Report, the HSDA Summary Report, and any Support/Opposition Letters received.

* Applicant has 60 days from written notice to be deemed complete.
 * Some applications may require notification of public officials.
 See TCA §68-11-1607(c)

DEFINITIONS

Agency – Agency and Health Services and Development Agency (HSDA or Agency) is the agency created by T.C.A. §68-11-1601. "Tennessee Health Services and Planning Act of 2002." [Acts 2002, ch. 780, §4.] to administer the certificate of need program and related activities.

Certificate of Need – A permit granted by the health services and development agency to any person for the establishment or modification of a health care institution, facility, or covered health service, at a designated location.

Certificate of Need Criteria – The criteria as defined in the HSDA's Rules 0720-11-.01(1)(2) and (3) General Criteria for Certificate of Need required for approval of a Certificate of Need (on pages 11 and 12).

Conflict of Interest – 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;

(A) "Direct interest" is a pecuniary interest in the persons involved in a matter before the agency. This interest 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. For the purposes of this part, a relative is a spouse, parent, child, stepparent, stepchild, grandparent, grandchild, brother, sister, half-brother, half-sister, aunt, uncle, niece, or nephew by blood, marriage or adoption; and

(B) "Indirect interest" is a personal interest in the persons involved in a matter before the agency that is in conflict or gives the appearance of conflict with the discharge of the agency member's or employee's duties.

Consent Calendar – In accordance with T.C.A. §68-11-1601, et seq., as amended by Public Chapter 780--Upon request of the applicant and at the discretion of the Executive Director a project can be placed on the 30-day review cycle for **CONSENT CALENDAR**. The project must meet all the CON criteria and be un-opposed.

Ex parte Communications – Communications with the HSDA's Board Members is in violation of T.C.A. §68-11-1607(d)(1)(2) or §4-5-304.

Facility – Any real property or equipment owned, leased, or used by a health care institution for any purpose, other than as an investment.

Health Care Institution – 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; recuperation center; hospital; ambulatory surgical treatment center; mental health hospital; 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 non-residential substitution-based treatment center for opiate addiction.

The definition of T.C.A. §68-11-1602(7)(B)(i-vi) is provided as follows:

(B) "Health care institution" 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 such physician or dentist;

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

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

(vi) A mental health residential treatment facility.

Health Service – Clinically related (i.e., diagnostic or treatment) services and includes those services specified as requiring a certificate of need under §68-11-1607.

Home Care Organization – 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.

Letter of Intent – The form prescribed by the agency which shall require a brief project description, location, estimated project cost, owner of the project and description of services to be performed.

Licensed Beds – The number of beds licensed by the agency having licensing jurisdiction over the facility.

Equipment Registration - §68-11-1607(a); "major medical equipment" does not apply to any equipment not directly related to patient care. Registration is required of certain medical equipment pursuant to Tennessee Code Annotated §68-11-1607(i), which states "*The owners of the following types of equipment shall register such equipment with the health services and development agency: computerized axial tomographers, magnetic resonance imagers, linear accelerators and positron emission tomography.*""*The survey shall include but not limited to the identification of the equipment and utilization data according to source of payment.*"

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.

Pediatric Patient - a patient who is 14 years of age or younger.

Planning Division – The State Health Planning Division of the Department of Health whose purpose is to develop the state health plan and to conduct other related studies.

Progress Reports – The Health Services and Development Agency Rules require that an Annual Progress Report be submitted each year and a Final Project Report form is to be submitted within ninety (90) days after completion of a project which shall include completion date, final costs, and other relevant information in regards to the project, pursuant to T.C.A. §68-11-1611.

Public Hearings – A fact-finding public hearing on an application held in the area in which the project is to be located per request by interested parties or at the direction of the Executive Director.

Quality Measures - Per PC 1043, Acts of 2016, any receiving a CON after July 1, 2016 must report annually using forms prescribed by the Agency concerning continued need and appropriate quality measures

Rehabilitation Facility – 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.

Review Cycle – The timeframe set for the review and initial decision on applications for certificate of need applications that have been deemed complete. The first day of the month is the first day of the review cycle in accordance with T.C.A. §68-11-1601, et seq., as amended by Public Chapter 780, upon the CON application being deemed complete by the Agency.

1. The first sixty (60) calendar days of the cycle are assigned to the reviewing agency, during which time a public hearing may be held on your application. You will be contacted by a representative from HSDA to establish the date, time and place of the hearing should one be requested. At the end of the sixty (60) calendar day period, a written report from the reviewing agency's representative will be forwarded to this office for HSDA review within the thirty (30) calendar day period immediately following. You will receive a copy of their findings.
2. Consent Calendar projects have a thirty (30) calendar day review period.

Reviewing Agency(s) – Department of Health, the Department of Mental Health and Substance Abuse Services, and/or the Department of Intellectual and Developmental Disabilities.

State Health Plan – The plan that is developed by the State Health Planning Division containing clear statements of goals, objectives, criteria and standards for the purpose of guiding the development of health care programs administered or funded by the State of Tennessee through its departments, agencies and programs. The State Health Plan provides guidance to the Tennessee Health Services and Development Agency (HSDA) when issuing Certificates of Need (CON). [Acts 2002, ch. 780, §4.]

**RULES
OF
HEALTH SERVICES AND DEVELOPMENT AGENCY**

**CHAPTER 0720-11
CERTIFICATE OF NEED PROGRAM – GENERAL CRITERIA**

TABLE OF CONTENTS

0720-11-.01 General Criteria for Certificate of Need

0720-11-.01 GENERAL CRITERIA FOR CERTIFICATE OF NEED. The Agency will consider the following general criteria in determining whether an application for a certificate of need should be granted:

- (1) Need. The health care needed in the area to be served may be evaluated upon the following factors:
 - (a) The relationship of the proposal to any existing applicable plans;
 - (b) The population served by the proposal;
 - (c) The existing or certified services or institutions in the area;
 - (d) The reasonableness of the service area;
 - (e) The special needs of the service area population, including the accessibility to consumers, particularly women, racial and ethnic minorities, TennCare participants, and low-income groups;
 - (f) Comparison of utilization/occupancy trends and services offered by other area providers;
 - (g) The extent to which Medicare, Medicaid, TennCare, medically indigent, charity care patients and low income patients will be served by the project. In determining whether this criteria is met, the Agency shall consider how the applicant has assessed that providers of services which will operate in conjunction with the project will also meet these needs.
- (2) Economic Factors. The probability that the proposal can be economically accomplished and maintained may be evaluated upon the following factors:
 - (a) Whether adequate funds are available to the applicant to complete the project;
 - (b) The reasonableness of the proposed project costs;
 - (c) Anticipated revenue from the proposed project and the impact on existing patient charges;
 - (d) Participation in state/federal revenue programs;
 - (e) Alternatives considered; and
 - (f) The availability of less costly or more effective alternative methods of providing the benefits intended by the proposal.

(Rule 0720-11-.01, continued)

- (3) Quality. Whether the proposal will provide health care that meets appropriate quality standards may be evaluated upon the following factors:
 - (a) Whether the applicant commits to maintaining staffing comparable to the staffing chart presented in its CON application;
 - (b) Whether the applicant will obtain and maintain all applicable state licenses in good standing;
 - (c) Whether the applicant will obtain and maintain TennCare and Medicare certification(s), if participation in such programs was indicated in the application;
 - (d) Whether an existing healthcare institution applying for a CON has maintained substantial compliance with applicable federal and state regulation for the three years prior to the CON application. In the event of non-compliance, the nature of non-compliance and corrective action shall be considered;
 - (e) Whether an existing health care institution applying for a CON has been decertified within the prior three years. This provision shall not apply if a new, unrelated owner applies for a CON related to a previously decertified facility;
 - (f) Whether the applicant will participate, within 2 years of implementation of the project, in self-assessment and external assessment against nationally available benchmark data to accurately assess its level of performance in relation to established standards and to implement ways to continuously improve.
 1. This may include accreditation by any organization approved by Centers for Medicare and Medicaid Services (CMS) and other nationally recognized programs. The Joint Commission or its successor, for example, would be acceptable if applicable. Other acceptable accrediting organizations may include, but are not limited to, the following:
 - (i) Those having the same accrediting standards as the licensed hospital of which it will be a department, for a Freestanding Emergency Department;
 - (ii) Accreditation Association for Ambulatory Health Care, and where applicable, American Association for Accreditation of Ambulatory Surgical Facilities, for Ambulatory Surgical Treatment Center projects;
 - (iii) Commission on Accreditation of Rehabilitation Facilities (CARF), for Comprehensive Inpatient Rehabilitation Services and Inpatient Psychiatric projects;
 - (iv) American Society of Therapeutic Radiation and Oncology (ASTRO), the American College of Radiology (ACR), the American College of Radiation Oncology (ACRO), National Cancer Institute (NCI), or a similar accrediting authority, for Megavoltage Radiation Therapy projects;
 - (v) American College of Radiology, for Positron Emission Tomography, Magnetic Resonance Imaging and Outpatient Diagnostic Center projects;
 - (vi) Community Health Accreditation Program, Inc., Accreditation Commission for Health Care, or another accrediting body with deeming authority for hospice services from CMS or state licensing survey, and/or other third party quality oversight organization, for Hospice projects;

(Rule 0720-11-.01, continued)

- (vii) Behavioral Health Care accreditation by the Joint Commission for Nonresidential Substitution Based Treatment Center, for Opiate Addiction projects;
 - (viii) American Society of Transplantation or Scientific Registry of Transplant Recipients, for Organ Transplant projects;
 - (ix) Joint Commission or another appropriate accrediting authority recognized by CMS, or other nationally recognized accrediting organization, for a Cardiac Catheterization project that is not required by law to be licensed by the Department of Health;
 - (x) Participation in the National Cardiovascular Data Registry, for any Cardiac Catheterization project;
 - (xi) Participation in the National Burn Repository, for Burn Unit projects;
 - (xii) Community Health Accreditation Program, Inc., Accreditation Commission for Health Care, and/or other accrediting body with deeming authority for home health services from CMS and participation in the Medicare Quality Initiatives, Outcome and Assessment Information Set, and Home Health Compare, or other nationally recognized accrediting organization, for Home Health projects;
 - (xiii) Participation in the National Palliative Care Registry, for Hospice projects; and
 - (xiv) As an alternative to the provision of third party accreditation information, applicants may provide information on any other state, federal, or national quality improvement initiatives, for Nursing Home projects.
- (g) For Ambulatory Surgical Treatment Center projects, whether the applicant has estimated the number of physicians by specialty expected to utilize the facility, developed criteria to be used by the facility in extending surgical and anesthesia privileges to medical personnel, and documented the availability of appropriate and qualified staff that will provide ancillary support services, whether on- or off-site.
- (h) For Cardiac Catheterization projects:
1. Whether the applicant has documented a plan to monitor the quality of its cardiac catheterization program, including but not limited to, program outcomes and efficiencies;
 2. Whether the applicant has agreed to cooperate with quality enhancement efforts sponsored or endorsed by the State of Tennessee; and
 3. Whether the applicant will staff and maintain at least one cardiologist who has performed 75 cases annually averaged over the previous 5 years (for an adult program), and 50 cases annually averaged over the previous 5 years (for a pediatric program).
- (i) For Open Heart projects:
1. Whether the applicant will staff with the number of cardiac surgeons who will perform the volume of cases consistent with the State Health Plan (annual

(Rule 0720-11-.01, continued)

- average of the previous 2 years), and whether the applicant will maintain this volume in the future;
2. Whether the applicant will staff and maintain at least one surgeon with 5 years of experience; and
 3. Whether the applicant will participate in a data reporting, quality improvement, outcome monitoring, and external assessment system that benchmarks outcomes based on national norms (demonstrated active participation in the STS National Database is expected and shall be considered evidence of meeting this standard);
- (j) For Comprehensive Inpatient Rehabilitation Services projects, whether the applicant will have a board-certified physiatrist on staff (preferred);
 - (k) For Home Health projects, whether the applicant has documented its existing or proposed plan for quality data reporting, quality improvement, and an outcome and process monitoring system;
 - (l) For Hospice projects, whether the applicant has documented its existing or proposed plan for quality data reporting, quality improvement, and an outcome and process monitoring system;
 - (m) For Megavoltage Radiation Therapy projects, whether the applicant has demonstrated that it will meet the staffing and quality assurance requirements of the American Society of Therapeutic Radiation and Oncology (ASTRO), the American College of Radiology (ACR), the American College of Radiation Oncology (ACRO), National Cancer Institute (NCI), or a similar accrediting authority;
 - (n) For Neonatal Intensive Care Unit projects, whether the applicant has documented its existing or proposed plan for data reporting, quality improvement, and outcome and process monitoring systems; whether the applicant has documented the intention and ability to comply with the staffing guidelines and qualifications set forth by the Tennessee Perinatal Care System Guidelines for Regionalization, Hospital Care Levels, Staffing and Facilities; and whether the applicant will participate in the Tennessee Initiative for Perinatal Quality Care (TIPQC);
 - (o) For Nursing Home projects, whether the applicant has documented its existing or proposed plan for data reporting, quality improvement, and outcome and process monitoring systems, including in particular details on its Quality Assurance and Performance Improvement program;
 - (p) For Inpatient Psychiatric projects:
 1. Whether the applicant has demonstrated appropriate accommodations for patients (e.g., for seclusion/restraint of patients who present management problems and children who need quiet space; proper sleeping and bathing arrangements for all patients), adequate staffing (i.e., that each unit will be staffed with at least two direct patient care staff, one of which shall be a nurse, at all times), and how the proposed staffing plan will lead to quality care of the patient population served by the project;
 2. Whether the applicant has documented its existing or proposed plan for data reporting, quality improvement, and outcome and process monitoring systems; and

(Rule 0720-11-.01, continued)

3. Whether an applicant that owns or administers other psychiatric facilities has provided information on satisfactory surveys and quality improvement programs at those facilities.
 - (q) For Freestanding Emergency Department projects, whether the applicant has demonstrated that it will be accredited with the Joint Commission or other applicable accrediting agency, subject to the same accrediting standards as the licensed hospital with which it is associated;
 - (r) For Organ Transplant projects, whether the applicant has demonstrated that it will achieve and maintain institutional membership in the national Organ Procurement and Transportation Network (OPTN), currently operating as the United Network for Organ Sharing (UNOS), within one year of program initiation; additionally, the applicant shall comply with CMS regulations set forth by 42 CFR Parts 405, 482, and 498, Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants; and
 - (s) For Relocation and/or Replacement of Health Care Institution projects:
 1. For hospital projects, Acute Care Bed Need Services measures are applicable; and
 2. For all other healthcare institutions, applicable facility and/or service specific measures are applicable.
 - (t) HSDA will notify the applicant and any applicable licensing agency if any volume or quality measure has not been met.
 - (u) Within one month of notification the applicant must submit a corrective action plan and must report on the progress of the plan within one year of that submission.
- (4) Contribution to the Orderly Development of Adequate and Effective Healthcare Facilities and/or Services. The contribution which the proposed project will make to the orderly development of an adequate and effective health care system may be evaluated upon the following factors:
 - (a) The relationship of the proposal to the existing health care system (for example: transfer agreements, contractual agreements for health services, the applicant's proposed TennCare participation, affiliation of the project with health professional schools);
 - (b) The positive or negative effects attributed to duplication or competition;
 - (c) The availability and accessibility of human resources required by the proposal, including consumers and related providers; and
 - (d) Whether the applicant commits to maintaining an actual payor mix that is comparable to the payor mix projected in its CON application, particularly as it relates to Medicare, TennCare/Medicaid, Charity Care, and the Medically Indigent.
- (5) Applications for Change of Site. When considering a certificate of need application which is limited to a request for a change of site, The Agency may consider, in addition to the foregoing factors, the following factors:
 - (a) Need. The applicant should show the proposed new site will serve the health care needs in the area to be served at least as well as the original site. The applicant should

(Rule 0720-11-.01, continued)

- show that there is some significant legal, financial, or practical need to change to the proposed new site.
- (b) Economic factors. The applicant should show that the project can be economically accomplished and maintained at the proposed new site.
 - (c) Quality of Health Care to be provided. The applicant should show the quality of health care to be provided will be served at least as well as at the original site.
 - (d) Contribution to the orderly development of health care facilities and/or services. The applicant should address any potential delays that would be caused by the proposed change of site, and show that any such delays are outweighed by the benefit that will be gained from the change of site by the population to be served.
- (6) Certificate of need conditions. In accordance with T.C.A. § 68-11-1609, The Agency, in its discretion, may place such conditions upon a certificate of need it deems appropriate and enforceable to meet the applicable criteria as defined in statute and in these rules.

Authority: T.C.A. §§ 4-5-201, et seq., 4-5-202, 68-11-1605, 68-11-1607, 68-11-1609, and 68-11-1633.

Administrative History: Original rule filed August 31, 2005; effective November 14, 2005. Emergency rule filed May 31, 2017; effective through November 27, 2017. The emergency rule expired November 28, 2017 and reverted to its previous status. Amendments filed October 24, 2017; effective January 22, 2018.