



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

INSTRUCTIONS FOR FILING AN APPLICATION FOR A CERTIFICATE OF NEED

Applicants in the final stages of filing an application are strongly encouraged to contact Health Services and Development Agency (HSDA) staff for a pre-filing conference. 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, meets appropriate quality standards, and addresses consumer advantage attributed to competition. The applicant is responsible for demonstrating that these criteria have been met through its answers to this application and any supplemental questions requested by staff.

Prior to preparation of this application, prospective applicants should visit the HSDA website (www.tn.gov/hsda) to consult resources including:

- Tennessee Code Annotated §68-11-1601 et seq.
- HSDA Rules and Regulations (www.publications.tnsosfiles.com/rules/0720/0720.htm)
- Criteria and Standards for CON (www.tn.gov/hsda/hsda-criteria-and-standards.html)
- 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 (www.tn.gov/health/health-programs-areas/statistics.html) or call 615.741.4939.
- “Applicant’s Toolbox” (www.tn.gov/hsda/certificate-of-need-information/applicants-toolbox.html) includes information and links such as:
 - Helpful hints on application layout/hard copy
 - Charges per procedure – medical equipment (pdf)
 - Home health licensed agencies by service county (pdf)
 - Hospice licensed agencies by service county (pdf)
 - Medical equipment location (pdf)
 - Number of procedures – medical equipment – 3 year trend
 - Tennessee Map
 - Definitions
 - Additional helpful web links

GENERAL INSTRUCTIONS

COMMUNICATIONS: All documents for filing a Certificate of Need application must be received electronically by the Health Services and Development Agency during normal business hours (8am to 4:30pm Central Time). This will be strictly enforced.

Filings may be scanned and emailed at hsda.staff@tn.gov. The email time of delivery receipt will serve as proof of the time of filing.

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.

Please Note: Applicants are encouraged to visit the HSDA website regularly to check the latest filing procedures. Please email hsda.staff@tn.gov for the latest instructions relating to submitting filing fee checks.

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 fifteenth day of the month prior to the month the application will be filed. 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 a set out above.

PUBLICATION OF INTENT: Simultaneously with the filing of the Letter of Intent, the Letter of Intent must be published for one day in the newspaper of general circulation in the proposed service area of the project. The Letter 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 fifteenth day of the prior 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, published continuously during the immediately preceding one year period, which 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, forward a copy to the original applicant (as well as any other applicant filing a simultaneous review), and 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 between the sixteenth day and the last day of the month of 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 application 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 no later than the first day of the month after publication of the Letter of Intent in accordance with above shall render 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.

- 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 3A, Attachment 2N, etc.)
- The last page of the original application, and its two (2) copies, and any supplemental response must be a completed 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 \$2.25 per \$1,000 of the estimated project cost involved, but in no case shall the fee be less than \$3,000 or more than \$45,000. Checks should be made payable to the Health Services and Development Agency.
- Check the Health Services and Development Agency website or contact the Agency by phone or email (hsda.staff@tn.gov) for current procedures on submitting the filing fee checks.
- **FILING FEES ARE NON-REFUNDABLE** and 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.

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.
- 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, the application will be deemed incomplete, the application will be considered withdrawn and returned to the applicant. 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: 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: The review cycle for each application shall begin on the fifteenth day of the appropriate month after the application has been deemed complete by the staff of the Agency. Following staff review, the CON application will be forwarded to the appropriate licensing agency for comment. Licensing agencies include the Department of Health, the Department of Mental Health and Substance Abuse Services, and/or Department of Intellectual and Developmental Disabilities.

WITHDRAWAL OF APPLICATIONS: The applicant may withdraw an application at any time by providing written notification to the Agency. The filing fee is not refundable.

TIMETABLE FOR CERTIFICATE OF NEED EXPIRATION: A Certificate of Need is valid for a period not to exceed three (3) years (for hospital and nursing home 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.

COMPLETING FORM INSTRUCTIONS

General Information Section

Item 1A – Please complete the information relating to the applicant. The information must be consistent with the information provided in the Letter of Intent. The address of the facility is the address of the proposed project.

Item 2A – Please complete the information for the individual who will be the contact for the project. This individual will be the one communicating with Agency staff for supplemental questions and other communications relating to the project. The contact person must be the same person as listed in the Letter of Intent.

Item 3A. Proof of Publication – Please list the date the Letter of Intent was submitted to Health Services and Development Agency along with the date the Letter of Intent was published in a newspaper of general circulation.

Item 4A. Purpose of Review – What is the reason for submitting a Certificate of Need application?

Item 5A. Type of Institution – Check the box that best describes the health care institution type for the applicant. If the applicant is an office based physician practice, please specify under “Other.”

Item 6A. Ownership – Please complete the information on the owner for the project. The information provided should be consistent with information provided in the filed Letter of Intent.

Item 7A. Type of Ownership – Please check the appropriate box for the ownership type. The information provided should be consistent with information provided in the filed Letter of Intent.

Item 8A. Management/Operating Entity – Please complete the information if the applicant will have a managing or operating entity. The information provided should be consistent with information provided in the filed Letter of Intent.

Item 9A. Legal Interest in Site – Please check the appropriate box that best describes the controlling interest in the project's site. Follow the accompanying directions for that selection.

Item 10A. Floor Plan – Please attached a legible copy of the project's floor plan.

Item 12A. Plot Plan – Please attach a copy of the project's plot plan following the listed guidelines.

Item 13A. Notification Requirements

1. TCA §68-11-1607(c)(9)(A) states that "...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 senate district in which the facility is proposed to be located, and to 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 such officials that an application for a nonresidential substitution-based treatment center for opiate addiction has been filed with the agency by the applicant."

To find representatives in the Tennessee General Assembly, use the "[Find My Legislator](https://wapp.capitol.tn.gov/Apps/fmlv3/districts.aspx)" tool on the General Assembly's website at <https://wapp.capitol.tn.gov/Apps/fmlv3/districts.aspx>

Applicant's will be expected to submit documentation verifying compliance with the above notification requirement. The notification by certified mail must be sent through the United States Postal Service.

2. TCA §68-11-1607(c)(9)(B) states that "... 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." Failure to provide the notifications described above within the required statutory timeframe will result in the voiding of the CON application.

Applicant's will be expected to submit documentation verifying compliance with the above notification requirement. The notification by certified mail must be sent through the United State Postal Service.

Executive Summary Section:

Item 1E. Overview – "Overview" is not to exceed ONE PAGE. Applications this provision for the project overview will not be accepted. In addition, attachments that circumvent the one page expectation will not be accepted.

Item 2E. Rationale for Approval – "Rationale for Approval" is not to exceed ONE PAGE. Applications that exceed this provision will not be accepted. In addition, attachments that circumvent the one-page expectation will not be accepted.

Item 3E. Consent Calendar Justification – If requesting to be placed on consent, provide a letter (as an attachment) from the project representative that addresses the rationale for an expedited review in terms of Need, Quality Standards, and the effects attributed to competition or duplication would be positive for consumers.

Please answer questions using listed guidance.

Item 4E. Project Cost Chart –

1. All projects should have a project cost of at least \$3,000 (the minimum CON Filing Fee) See instruction on Filing Fee for that.
2. The cost of any lease (building, land, and/or equipment) should be based on fair market value or the total amount of the lease payments over the initial term of the lease, whichever is greater. Note: This applies to all equipment leases including by procedure or “per click” arrangements. The methodology used to determine the total lease cost for “per click” arrangement must include, at a minimum, the projected procedures, the “per click” rate, and the term of the lease.
3. The cost for fixed and moveable equipment includes, but is not necessarily limited to, maintenance agreements covering the expected useful life of the equipment; federal/state/local taxes and other government assessments; and installation charges, excluding capital expenditures for physical plan renovation or in-wall shielding, which should be included under construction costs or incorporated in a facility lease.

General Criteria Section – Need:

Item 1N. Criteria and Standards – The applicant should address the latest published project specific criterion and standard. If needed, please verify with HSDA staff.

Item 2N. Service Area Map – Submit the county level service map as an attachment. Use Map Supplement.

Item 3N. Service Area Demographics – Use the most recent population data available from the Department of Health, TennCare, and the U.S. Census Bureau.

Item 5N. Similar Healthcare Providers (Service Area) – Please use the latest published data. Please note that Department of Health data may publish Joint Annual Report data during the application review process. If so, the application will need to be revised with that data.

Note: This question does not apply to projects that are solely relocating a service.

General Criteria Section – Consumer Advantage Attributed to Competition:

Item 6C. Annual Historical Data Chart – Complete the chart for the last three (3) years for which complete data is available. Do not modify the charts provided or submit substitutions. The “Project Only Chart” provides information for the services being presented in the proposed project while the “Total Facility Chart” provides information for the entire facility. Complete both, if applicable.

Item 6C. Projected Data Chart – Complete the chart for the two (2) years following the completion of the project. Do not modify the chart provided or submit a substitution. The “Project Only Chart” should reflect revenue for the project (i.e. if the application is for additional beds, include anticipated revenue from the proposed beds only, not from all beds in the facility). The “Total Facility Chart” should reflect information for the total facility. Complete both, if applicable.

Item 7C. Consumer Charge Chart – The figures for this chart are derived from the Historical and Projected Data Charts in Item 6C.

Item 10C. Projected Payor Mix Chart – The Year 1 and Year 2 totals in the Projected Payor Mix Chart must match the gross operating revenue in Year 1 and Year 2 in the Projected Data Chart.

General Criteria Section – Quality Standards:

Item 3Q. Licensure/Certification/Accreditation – Please indicate type of license, any certifications, and any accreditations that are currently active or will be applied for.

Item 4Q Managed Care Organizations: Please list all contracted Managed Care Organizations if applicant checked the “TennCare/Medicaid” box in Item 3Q.

DEFINITIONS

Agency – Agency and Health Services and Development Agency (HSDA or Agency) is the agency created by §TCA 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.

Consent Calendar – 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 TCA §68-11-1607(d)(1)(2) or TCA §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 publically 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 non-residential substitution based treatment center for opiate addiction.

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

Home Care Organizations – any entity licensed as such by the department that is staffed and organized to provide “home health services,” or “hospice services” as defined by TCA §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 or the project, and description of services to be performed.

Licensing Agency – Department of Health, Department of Mental Health and Substance Abuse Services, and/or the Department of Intellectual and Developmental Disabilities.

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

Medical Equipment – A single unit or a single system of components with a related function that is used to provide medical and other health services and does not apply to any equipment not directly related to patient care. Registration is required of certain medical equipment pursuant to TCA §68-11-1607(i) – owners of computerized axial tomographers (CT), magnetic resonance imagers (MRI), linear accelerators, and positron emission tomography (PET).

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.

Rehabilitation Facility – An inpatient or residential facility that is operated for the primary purpose of assisting in the rehabilitation of physically disabled person 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 application 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.

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.

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 days (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 Public Acts 2002, Chapter No. 780, TCA §16-11-1609(d).