



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 Email: hsda.staff@tn.gov

CERTIFICATE OF NEED APPLICATION

1A. Name of Facility, Agency, or Institution

Name

Street or Route

County

City

State

Zip

Website Address

Note: The facility's name and address **must be** the name and address of the project and **must be** consistent with the Publication of Intent.

2A. Contact Person Available for Responses to Questions

Name

Title

Company Name

Email Address

Street or Route

City

State

Zip

Association with Owner

Phone Number

3A. Proof of Publication

Attach the full page of newspaper in which the notice of intent appeared with the mast and dateline intact or submit a publication affidavit from the newspaper that includes a copy of the publication as proof of the publication of the letter of intent. (Attachment 3A)

Date LOI was Submitted: _____

Date LOI was Published: _____

4A. Purpose of Review (Check appropriate box(es) – more than one response may apply)

- ☐ Establish New Health Care Institution
- ☐ Addition of a Specialty to an Ambulatory Surgical Treatment Center (ASTC)
- ☐ Change in Bed Complement
- ☐ Initiation of Health Care Service as Defined in §TCA 68-11-1607(3) Specify: _____
- ☐ Relocation
- ☐ Initiation of MRI Service
- ☐ MRI Unit Increase
- ☐ Satellite Emergency Department
- ☐ Addition of ASTC Specialty
- ☐ Initiation of Cardiac Catheterization
- ☐ Addition of Therapeutic Catheterization
- ☐ Establishment/Initiation of a Non-Residential Substitution Based Opioid Treatment Center
- ☐ Linear Accelerator Service
- ☐ Positron Emission Tomography (PET) Service

Please answer all questions on letter size, white paper, clearly typed and spaced, single sided, in order and sequentially numbered. In answering, please type the question and the response. All questions must be answered. If an item does not apply, please indicate "N/A" (not applicable). Attach appropriate documentation as an Appendix at the end of the application and reference the applicable item Number on the attachment, i.e. Attachment 1A, 2A, etc. The last page of the application should be a completed signed and notarized affidavit.

5A. Type of Institution (Check all appropriate boxes – more than one response may apply)

- ☐ Hospital (Specify): _____
- ☐ Ambulatory Surgical Treatment Center (ASTC) – Multi-Specialty
- ☐ Ambulatory Surgical Treatment Center (ASTC) – Single Specialty
- ☐ Home Health
- ☐ Hospice
- ☐ Intellectual Disability Institutional Habilitation Facility (ICF/IID)
- ☐ Nursing Home
- ☐ Outpatient Diagnostic Center
- ☐ Rehabilitation Facility
- ☐ Residential Hospice
- ☐ Nonresidential Substitution Based Treatment Center of Opiate Addiction
- ☐ Other (Specify): _____

6A. Name of Owner of the Facility, Agency, or Institution

Name		
Street or Route		Phone Number
City	State	Zip

7A. Type of Ownership of Control (Check One)

- ☐ Sole Proprietorship
- ☐ Partnership
- ☐ Limited Partnership
- ☐ Corporation (For Profit)
- ☐ Corporation (Not-for-Profit)
- ☐ Government (State of TN or Political Subdivision)
- ☐ Joint Venture
- ☐ Limited Liability Company
- ☐ Other (Specify): _____

Attach a copy of the partnership agreement, or corporate charter and certificate of corporate existence. Please provide documentation of the active status of the entity from the Tennessee Secretary of State's website at <https://tnbear.tn.gov/ECommerce/FilingSearch.aspx> . If the proposed owner of the facility is government owned must attach the relevant enabling legislation that established the facility. (Attachment 7A)

Describe the existing or proposed ownership structure of the applicant, including an ownership structure organizational chart. Explain the corporate structure and the manner in which all entities of the ownership structure relate to the applicant. As applicable, identify the members of the ownership entity and each member's percentage of ownership, for those members with 5% ownership (direct or indirect) interest.

8A. Name of Management/Operating Entity (If Applicable)

Name		
Street or Route		County
City	State	Zip
Website Address		

For new facilities or existing facilities without a current management agreement, attach a copy of a draft management agreement that at least includes the anticipated scope of management services to be provided, the anticipated term of the agreement, and the anticipated management fee payment schedule. For facilities with existing management agreements, attach a copy of the fully executed final contract. (Attachment 8A)

9A. Legal Interest in the Site

Check the appropriate box and submit the following documentation. (Attachment 9A)

The legal interest described below must be valid on the date of the Agency consideration of the Certificate of Need application.

- ☐ Ownership (Applicant or applicant's parent company/owner) – Attach a copy of the title/deed.
- ☐ Lease (Applicant or applicant's parent company/owner) – Attach a fully executed lease that includes the terms of the lease and the actual lease expense.
- ☐ Option to Purchase - Attach a fully executed Option that includes the anticipated purchase price.
- ☐ Option to Lease - Attach a fully executed Option that includes the anticipated terms of the Option and anticipated lease expense.
- ☐ Other (Specify) _____

10A. Floor Plan

If the facility has multiple floors, submit one page per floor. If more than one page is needed, label each page. (Attachment 10A)

- Patient care rooms (Private or Semi-private)
- Ancillary areas
- Other (Specify)

11A. Public Transportation Route

Describe the relationship of the site to public transportation routes, if any, and to any highway or major road developments in the area. Describe the accessibility of the proposed site to patients/clients. (Attachment 11A)

12A. Plot Plan

Unless relating to home care organization, briefly describe the following and attach the requested documentation on a letter size sheet of white paper, legibly labeling all requested information. It **must** include:

- Size of site (in acres);
- Location of structure on the site;
- Location of the proposed construction/renovation; and
- Names of streets, roads, or highways that cross or border the site.

(Attachment 12A)

13A. Notification Requirements

- 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.

☐ Notification Attached ☐ Not Applicable

- 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 the 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."

☐ Notification Attached ☐ Not Applicable

EXECUTIVE SUMMARY

1E. Overview

Please provide an overview not to exceed **ONE PAGE** (for 1E only) in total explaining each item point below.

- Description: Address the establishment of a health care institution, initiation of health services, and/or bed complement changes.
- Ownership structure
- Service Area
- Existing similar service providers
- Project Cost
- Staffing

2E. Rationale for Approval

A Certificate of Need can only be granted when a project 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 consumers

Provide a brief description not to exceed **ONE PAGE** (for 2E only) of how the project meets the criteria necessary for granting a CON using the data and information points provided in criteria sections that follow.

- Need
- Quality Standards
- Consumer Advantage
 - Choice
 - Improved access/availability to health care service(s)
 - Affordability

3E. Consent Calendar Justification

☐ Consent Calendar Requested (Attach rationale)

If Consent Calendar is requested, please attach the rationale for an expedited review in terms of Need, Quality Standards, and Consumer Advantage as a written communication to the Agency's Executive Director at the time the application is filed.

☐ Consent Calendar **NOT** Requested

4E. PROJECT COST CHART

A. Construction and equipment acquired by purchase:

1. Architectural and Engineering Fees _____
2. Legal, Administrative (Excluding CON Filing Fee),
Consultant Fees _____
3. Acquisition of Site _____
4. Preparation of Site _____
5. Total Construction Costs _____
6. Contingency Fund _____
7. Fixed Equipment (Not included in Construction Contract) _____
8. Moveable Equipment (List all equipment over \$50,000 as
separate attachments) _____
9. Other (Specify) _____

B. Acquisition by gift, donation, or lease:

1. Facility (inclusive of building and land) _____
2. Building only _____
3. Land only _____
4. Equipment (Specify) _____
5. Other (Specify) _____

C. Financing Costs and Fees:

1. Interim Financing _____
2. Underwriting Costs _____
3. Reserve for One Year's Debt Service _____
4. Other (Specify) _____

**D. Estimated Project Cost
(A+B+C) _____**

E. CON Filing Fee _____

**F. Total Estimated Project Cost
(D+E) **TOTAL** _____**

GENERAL CRITERIA FOR CERTIFICATE OF NEED

In accordance with TCA §68-11-1609(b), “no Certificate of Need shall be granted unless the action proposed in the application for such Certificate is necessary to provide needed health care in the area to be served, will provide health care that meets appropriate quality standards, and the effect attributed to completion or duplication would be positive for consumers.” In making determinations, the Agency uses 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 apply.

Additional criteria for review are prescribed in Chapter 11 of the Agency Rules, Tennessee Rules and Regulations 01730-11.

The following questions are listed according to the three criteria: (1) Need, (2) the effects attributed to competition or duplication would be positive for consumers (Consumer Advantage), and (3) Quality Standards.

NEED

The responses to this section of the application will help determine whether the project will provide needed health care facilities or services in the area to be served.

- 1N.** Provide responses as an attachment to the applicable criteria and standards for the type of institution or service requested. A word version and pdf version for each reviewable type of institution or service are located at the following website. <https://www.tn.gov/hsda/hsda-criteria-and-standards.html> (Attachment 1N)
- 2N.** Identify the proposed service area and provide justification for its reasonable ness. Submit a county level map for the Tennessee portion and counties boarding the state of the service area using the supplemental map, clearly marked, and shaded to reflect the service area as it relates to meeting the requirements for CON criteria and standards that may apply to the project. Please include a discussion of the inclusion of counties in the border states, if applicable. (Attachment 2N)

Complete the following utilization tables for each county in the service area, if applicable.

Service Area Counties	Historical Utilization-County Residents – Most Recent Year (Year=_____)	% of Total <input type="checkbox"/> Procedures <input type="checkbox"/> Cases <input type="checkbox"/> Patients <input type="checkbox"/> Other (Specify): _____
County #1		
County #2		
County #3		
Etc.		
Total		100%

Service Area Counties	Projected Utilization-County Residents – Year 1 (Year=_____)	% of Total <input type="checkbox"/> Procedures <input type="checkbox"/> Cases <input type="checkbox"/> Patients <input type="checkbox"/> Other (Specify): _____
County #1		
County #2		
County #3		
Etc.		
Total		100%

3N. A. Describe the demographics of the population to be served by the proposal.

B. Provide the following data for each county in the service area:

- Using current and projected population data from the Department of Health. (www.tn.gov/health/health-program-areas/statistics/health-data/population.html);
- the most recent enrollee data from the Division of TennCare (<https://www.tn.gov/tenncare/information-statistics/enrollment-data.html>),
- and US Census Bureau demographic information (<https://www.census.gov/quickfacts/fact/table/US/PST045219>).

Demographic Variable/Geographic Area	Department of Health/Health Statistics							Census Bureau				TennCare	
	Total Population- Current Year	Total Population- Projected Year	Total Population-% Change	*Target Population- Current Year	Target Population- Project Year	Target Population-% Change	Target Population Projected Year as % of Total	Median Age	Median Household Income	Person Below Poverty Level	Person Below Poverty Level as % of Total	TennCare Enrollees	TennCare Enrollees as % of Total
County A													
County B, etc.													
Service Area Total													
State of TN Total													

** Target Population is population that project will primarily serve. For example, nursing home, home health agency, and hospice agency projects typically primarily serve the Age 65+ population. Projected Year is defined in select service-specific criteria and standards. If Projected Year is not defined, default should be four years from current year, e.g., if Current Year is 2022, then default Projected Year is 2026.*

Be sure to identify the target population, e.g. Age 65+, the current year and projected year being used.

4N. Describe the special needs of the service area population, including health disparities, the accessibility to consumers, particularly those who are uninsured or underinsured, the elderly, women, racial and ethnic minorities, TennCare or Medicaid recipients, and low income groups. Document how the business plans of the facility will take into consideration the special needs of the service area population.

5N. Describe the existing and approved but unimplemented services of similar healthcare providers in the service area. Include utilization and/or occupancy trends for each of the most recent three years of data available for this type of project. List each provider and its utilization and/or occupancy individually. Inpatient bed projects must include the following data: Admissions or discharges, patient days. Average length of stay, and occupancy. Other projects should use the most appropriate measures, e.g. cases, procedures, visits, admissions, etc. **This does not apply to projects that are solely relocating a service.**

6N. Provide applicable utilization and/or occupancy statistics for your institution services for each of the past three years and the project annual utilization for each of the two years following completion of the project. Additionally, provide the details regarding the methodology used to project utilization. The methodology must include detailed calculations or documentation from referral sources, and identification of all assumptions.

7N.

<u>CON Number</u>	<u>Project Name</u>	<u>Date Approved</u>	<u>Expiration Date</u>

- Complete the above chart by entering information for each applicable outstanding CON by applicant or share common ownership; and
- Describe the current progress and status of each applicable outstanding CON and how the project relates to them.

CONSUMER ADVANTAGE ATTRIBUTED TO COMPETITION

The responses to this section of the application helps determine whether the effects attributed to competition or duplication would be positive for consumers within the service area.

- 1C.** List all transfer agreements relevant to the proposed project.
- 2C.** List all commercial private insurance plans contracted or plan to be contracted by the applicant.
- 3C.** Describe the effects of competition and/or duplication of the proposal on the health care system, including the impact upon consumer charges and consumer choice of services.
- 4C.** Discuss the availability of and accessibility to human resources required by the proposal, including clinical leadership and adequate professional staff, as per the State of Tennessee licensing requirements, CMS, and/or accrediting agencies requirements, such as the Joint Commission and Commission on Accreditation of Rehabilitation Facilities.
- 5C.** Document the category of license/certification that is applicable to the project and why. These include, without limitation, regulations concerning clinical leadership, physician supervision, quality assurance policies and programs, utilization review policies and programs, record keeping, clinical staffing requirements, and staff education.

6C. See INSTRUCTIONS to assist in completing the following tables.

HISTORICAL DATA CHART

- ☐ Project Only
☐ Total Facility

Give information for the last *three (3)* years for which complete data are available for the facility or agency.

	Year_____	Year_____	Year_____
A. Utilization Data			
Specify Unit of Measure _____	_____	_____	_____
B. Revenue from Services to Patients			
1. Inpatient Services	\$_____	\$_____	\$_____
2. Outpatient Services	_____	_____	_____
3. Emergency Services	_____	_____	_____
4. Other Operating Revenue (Specify)_____	_____	_____	_____
Gross Operating Revenue	\$_____	\$_____	\$_____
C. Deductions from Gross Operating Revenue			
1. Contractual Adjustments	\$_____	\$_____	\$_____
2. Provision for Charity Care	_____	_____	_____
3. Provisions for Bad Debt	_____	_____	_____
Total Deductions	\$_____	\$_____	\$_____
NET OPERATING REVENUE	\$_____	\$_____	\$_____

PROJECTED DATA CHART

- ☐ Project Only
☐ Total Facility

Give information for the two (2) years following the completion of this proposal.

	Year_____	Year_____
A. Utilization Data		
Specify Unit of Measure _____	_____	_____
B. Revenue from Services to Patients		
1. Inpatient Services	\$_____	\$_____
2. Outpatient Services	_____	_____
3. Emergency Services	_____	_____
4. Other Operating Revenue (Specify)_____	_____	_____
Gross Operating Revenue	\$_____	\$_____
C. Deductions from Gross Operating Revenue		
1. Contractual Adjustments	\$_____	\$_____
2. Provision for Charity Care	_____	_____
3. Provisions for Bad Debt	_____	_____
Total Deductions	\$_____	\$_____
NET OPERATING REVENUE	\$_____	\$_____

- 7C.** Please identify the project's average gross charge, average deduction from operating revenue, and average net charge using information from the Historical and Projected Data Charts of the proposed project.

Project Only Chart

	Previous Year to Most Recent Year Year ____	Most Recent Year Year ____	Year One Year ____	Year Two Year ____	% Change (Current Year to Year 2)
Gross Charge (<i>Gross Operating Revenue/Utilization Data</i>)					
Deduction from Revenue (<i>Total Deductions/Utilization Data</i>)					
Average Net Charge (<i>Net Operating Revenue/Utilization Data</i>)					

- 8C.** Provide the proposed charges for the project and discuss any adjustment to current charges that will result from the implementation of the proposal. Additionally, describe the anticipated revenue from the project and the impact on existing patient charges.

- 9C.** Compare the proposed project charges to those of similar facilities/services in the service area/adjoining services areas, or to proposed charges of recently approved Certificates of Need.

If applicable, compare the proposed charges of the project to the current Medicare allowable fee schedule by common procedure terminology (CPT) code(s).

- 10C.** Discuss the project's participation in state and federal revenue programs, including a description of the extent to which Medicare, TennCare/Medicaid, and medically indigent patients will be served by the project. Report the estimated gross operating revenue dollar amount and percentage of project gross operating revenue anticipated by payor classification for the first and second year of the project by completing the table below.

**Applicant's Projected Payor Mix
Project Only Chart**

Payor Source	Year 1		Year 2	
	Gross Operating Revenue	% of Total	Gross Operating Revenue	% of Total
Medicare/Medicare Managed Care				
TennCare/Medicaid				
Commercial/Other Managed Care				
Self-Pay				
Other (Specify) _____				
Total*				
Charity Care				

**Needs to match Gross Operating Revenue Year One and Year Two on Projected Data Chart*

QUALITY STANDARDS

1Q. Per PC 1043, Acts of 2016, any receiving a CON after July 1, 2016, must report annually using forms prescribed by the Agency concerning appropriate quality measures. Please attest that the applicant will submit an annual Quality Measure report when due.

2Q. The proposal shall provide health care that meets appropriate quality standards. Please address each of the following questions.

- Does the applicant commit to maintaining the staffing comparable to the staffing chart presented in its CON application?
- Does the applicant commit to obtaining and maintaining all applicable state licenses in good standing?
- Does the applicant commit to obtaining and maintaining TennCare and Medicare certification(s), if participation in such programs are indicated in the application?

3Q. Please complete the chart below on accreditation, certification, and licensure plans.

Note: if the applicant does not plan to participate in these type of assessments, explain why since quality healthcare must be demonstrated.

Credential	Agency	Status (Active or Will Apply)	Provider Number or Certification Type
Licensure	<ul style="list-style-type: none">○ Health○ Intellectual & Developmental Disabilities○ Mental Health & Substance Abuse Services		
Certification	<ul style="list-style-type: none">○ Medicare○ TennCare/Medicaid○ Other: _____		
Accreditation(s)			

4Q. If checked "TennCare/Medicaid" box, please list all Managed Care Organization's currently or will be contracted.

5Q. Do you attest that you will submit a Quality Measure Report annually to verify the license, certification, and/or accreditation status of the applicant, if approved?

☐ Yes

☐ No

6Q. For an existing healthcare institution applying for a CON:

- Has it 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 should be discussed to include any of the following: suspension of admissions, civil monetary penalties, notice of 23-day or 90-day termination proceedings from Medicare/Medicaid/TennCare, revocation/denial of accreditation, or other similar actions and what measures the applicant has or will put into place to avoid similar findings in the future.
- Has the entity been decertified within the prior three years? If yes, please explain in detail. (This provision shall not apply if a new, unrelated owner applies for a CON related to a previously decertified facility.)

7Q. Respond to all of the following and for such occurrences, identify, explain, and provide documentation if occurred in last five (5) years.

Has any of the following:

- Any person(s) or entity with more than 5% ownership (direct or indirect) in the applicant (to include any entity in the chain of ownership for applicant);
- Any entity in which any person(s) or entity with more than 5% ownership (direct or indirect) in the applicant (to include any entity in the chain of ownership for applicant) has an ownership interest of more than 5%; and/or

Been subject to any of the following:

- Final Order or Judgement in a state licensure action;
- Criminal fines in cases involving a Federal or State health care offense;
- Civil monetary penalties in cases involving a Federal or State health care offense;
- Administrative monetary penalties in cases involving a Federal or State health care offense;
- Agreement to pay civil or administrative monetary penalties to the federal government or any state in cases involving claims related to the provision of health care items and services;
- Suspension or termination of participation in Medicare or TennCare/Medicaid programs; and/or
- Is presently subject of/to an investigation, or party in any regulatory or criminal action of which you are aware.

8Q. Provide the project staffing for the project in Year 1 and compare to the current staffing for the most recent 12-month period, as appropriate. This can be reported using full-time equivalent (FTEs) positions for these positions.

Position Classification	Existing FTEs (enter year)	Projected FTEs Year 1
A. Direct Patient Care Positions		
<i>Position 1</i>		
<i>Position 2</i>		
<i>Position "etc."</i>		
Total Direct Patient Care Positions		

B. Non-Patient Care Positions		
<i>Position 1</i>		
<i>Position 2</i>		
<i>Position "etc."</i>		
Total Non-Patient Care Positions		
Total Employees (A+B)		
C. Contractual Staff		
Total Staff (A+B+C)		

DEVELOPMENT SCHEDULE

TCA §68-11-1609(c) provides that activity authorized by 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 authorization expires; provided, that the Agency may, in granting the Certificate of Need, allow longer periods of validity for Certificate 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 non-refundable reasonable filing fee, as prescribed by rule. A certificate of Need authorization which has been extended shall expire 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.

- Complete the Project Completion Forecast Chart below. If the project will be completed in multiple phases, please identify the anticipated completion date for each phase.
- If the CON is granted and the project cannot be completed within the standard completion time period (3 years for hospital and nursing home projects and 2 years for all others), please document why an extended period should be approved and document the “good cause” for such an extension.

PROJECT COMPLETION FORECAST CHART

Assuming the Certificate of Need (CON) approval becomes the final HSDA action on the date listed in Item 1 below, indicate the number of days from the HSDA decision date to each phase of the completion forecast.

Phase	Days Required	Anticipated Date (Month/Year)
1. Initial HSDA Decision Date		
2. Building Construction Commenced		
3. Construction 100% Complete (Approval for Occupancy)		
4. Issuance of License		
5. Issuance of Service		
6. Final Project Report Form Submitted (Form HR0055)		

Note: If litigation occurs, the completion forecast will be adjusted at the time of the final determination to reflect the actual issue date.

AFFIDAVIT

STATE OF _____

COUNTY OF _____

_____, being first duly sworn, says that he/she is the applicant named in this application or his/her/its lawful agent, that this project will be completed in accordance with the application, that the applicant has read the directions to this application, the Rules of the Health Services and Development Agency, and TCA §68-11-1601, *et seq.*, and that the responses to this application or any other questions deemed appropriate by the Health Services and Development Agency are true and complete.

SIGNATURE/TITLE

Sworn to and subscribed before me this _____ day of _____, _____ a Notary
(Month) (Year)

Public in and for the County/State of _____.

NOTARY PUBLIC

My commission expires _____, _____.
(Month/Day) (Year)