



STATE OF TENNESSEE

STATE HEALTH PLAN

CERTIFICATE OF NEED STANDARDS AND CRITERIA

FOR

Non-Residential Opioid Treatment Programs

The Health Services Development Agency (HSDA) may consider the following standards and criteria for applicants seeking to establish Non-Residential Opioid Treatment Programs. Rationale statements are provided for standards to explain the Division of Health Planning's underlying reasoning. Additionally, these rationale statements may assist stakeholders in responding to these Standards and may assist the HSDA in its assessment of applications. Existing Non-Residential Opioid Treatment Programs are not affected by these standards and criteria unless they take action that requires a new certificate of need (CON) for such services. These proposed standards and criteria will become effective immediately upon approval and adoption by the governor.

The Certificate of Need Standards and Criteria serve to uphold the Five Principles for Achieving Better Health set forth by the State Health Plan. These Principles were first developed for the 2010 edition and have been utilized as the overarching framework of the Plan in each annual update that has followed. Utilizing the Five Principles for Achieving Better Health during the development of the CON Standards and Criteria ensures the protection and promotion of the health of the people of Tennessee. The State Health Plan's Five Principles for Achieving Better Health are as follows:

1. **Healthy Lives:** The purpose of the State Health Plan is to improve the health of Tennesseans.
2. **Access:** Every citizen should have reasonable access to health care.

3. **Economic Efficiencies:** The state's health care resources should be developed to address the needs of Tennesseans while encouraging competitive markets, economic efficiencies and the continued development of the state's health care system.
4. **Quality of Care:** Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers.
5. **Workforce:** The state should support the development, recruitment and retention of a sufficient and quality health care workforce.

Definitions

Non-Residential Opioid Treatment Programs or Nonresidential Substitution-based Treatment Centers for Opiate Addiction as referenced in TCA § 68-11-1607:

A non-residential opioid treatment program should provide adequate medical, counseling, vocational, educational, mental health assessment, and social services to patients enrolled in the opioid treatment program with the goal of treating the individual with opioid use disorder.

Standards and Criteria

1. **Determination of Need:** The need for non-residential opioid treatment programs should be based on information prepared by the applicant for a certificate of need that acknowledges the importance of considering the demand for services along with need while addressing and analyzing service problems as well.

The assessment should cover the proposed service area and include the utilization of existing opioid use disorder treatment providers, scope of services provided, patient origin, and patient mix.

The assessment should consider the users of opioids as the clients at non-residential opioid treatment programs. Assessment data will be based on prevalence estimates of opioid and heroin use, narcotic-related offenses, opioid-related hospitalizations, deaths, substance abuse treatment admissions, and estimates of medication assisted treatment providers for opioid use disorder and their patient capacity.

Need Formula: Need should be based on the following formula: The average unique patient count during a 1 (one) year period in existing programs serving individuals who are opiate dependent divided by the number of individuals

estimated to be opiate dependent. Counties with service providers meeting less than 20% of the need shall be considered high need counties.

Applications for proposed service areas that fail to meet the 20% threshold should still be considered for approval. This need formula only designates *high need* counties that should be given special consideration. It does not indicate that high-quality applications for counties with lower demonstrated need should necessarily be denied.

Note: The applicant shall use the prevalence estimates of persons with opioid (pain reliever and heroin) use disorder using the most recent National Survey on Drug Use and Health (NSDUH) data published by the Substance Abuse and Mental Health Services Administration (SAMHSA). The applicant shall specify the percent of unmet treatment need that will be met by the proposed Non-Residential Opioid Treatment Programs.

In determining need considerations may be given to alternative treatment modalities. The applicant shall compare estimated need to the existing capacity of non-residential substance abuse treatment facilities including office-based opiate treatment, opioid treatment program, alcohol and drug rehabilitation treatment, and alcohol and drug detoxification facilities.

The assessment should also include:

- a. A description of the geographic area to be served by the program,
 - i. The applicant shall provide the number of patients projected to be served by county of residence in year one and year two.

Please complete the following table to indicate patient origin by county in year one and year two of the proposed project. Additional columns may be added to reflect the appropriate number of relevant counties.

	County 1	County 2	County 3	County 4	Total
Patients Year 1					
Patients Year 2					

- ii. At least 90% of the projected patients in year one and year two reside within a 60 mile radius of the proposed program site or less than a one hour drive time to the proposed program site.

- iii. The applicant shall provide an analysis of driving distances by county from the proposed clinic location site in comparison to the closest existing OTP clinic.

Please complete the following table to demonstrate the driving distances from the counties in the proposed service area to the proposed site and to existing non-residential opioid treatment programs within a 180 minute drive time. This should include programs located in neighboring states. Additional columns and rows may be added to reflect the appropriate number of existing programs and affected counties.

	Proposed OTP	Existing OTP 1	Existing OTP 2	Existing OTP 3
County 1				
County 2				
County 3				
County 4				

- b. Population of the area to be served, and
- c. The estimated number of persons, in the described area, with opioid use disorder and an explanation of the basis of the estimate.
- d. The applicant shall provide the projected rate of intake per week for year one of the proposed project along with factors controlling intake.
- e. The applicant shall contact the Tennessee State Opioid Treatment Authority to obtain the current patient caseload and capacity of Non-Residential Opioid Treatment Providers providing care to patients in the proposed service area. The list shall delineate the number of patients receiving methadone treatment and buprenorphine treatment.

Consideration should be given to the reality that existing facilities can expand or reduce their capacity to maintain or treat patients without large changes in overhead.

- 2. Assurance of Resources:** The proposal's estimate of the number of patients to be treated, anticipated revenue from the proposed project, and the program funding source with description of the organizational structure of the program delineating the person(s) responsible for the program, should be considered.

- 3. Charity Care:** The proposal should address the program’s ability to provide for indigent and charity care. The applicant shall provide the rate of charity care of total gross revenue in year one and year two, including the total number of charity care patients to be served.

Please complete the following table to demonstrate projected charity care in year 1 and year 2.

	Gross Revenue	Gross Charge Per Patient	Charity Care Total	Total Charity Care Patients
Year 1				
Year 2				

- 4. Special Populations:** The applicant shall address how the proposed program will serve patients who are pregnant, HIV positive, Hepatitis C positive, and patients who are incarcerated and/or facing risk of incarceration. The applicant should also discuss its ability, willingness, and plan to provide care to women who are pregnant but cannot afford the services.
- 5. Adequate Staffing:** An applicant shall document a plan demonstrating the intent and ability to recruit, hire, train, assess competencies of, supervise, and retain the appropriate numbers of qualified personnel to provide the services described in the application and that such personnel are available in the proposed service area. The applicant should provide evidence of planned staffing patterns that adhere to relevant TDMHSAS licensing standards.
- 6. Licensure and Quality Considerations:** Any existing applicant for this CON service category shall be in compliance, or have a plan for compliance, with the appropriate rules of the Tennessee Department of Health (TDH) and TDMHSAS.

Rationale: This section supports the State Health Plan’s Fourth Principle for Achieving Better Health regarding quality of care.

- 7. Data Requirements:** Applicants shall agree to provide the TDH, TDMHSAS, and/or the HSDA with all reasonably requested information and statistical data related to the operation and provision of services and to report that data in the time and format

requested. As a standard practice, existing data reporting streams will be relied upon and adapted over time to collect all needed information.

- 8. Community Linkage Plan:** The applicant shall describe its participation, if any, in a community linkage plan, including its relationships with appropriate health care system providers/services and working agreements with other related community services assuring continuity of care. The applicant is encouraged to include primary prevention initiatives in the community linkage plan that would address risk factors leading to increased opioid dependency. Applicants should document plans for satisfying TDMHSAS Administrative Rule 0940-05-42-.28, related to community education.

Rationale: The State Health Plan moved from a primary emphasis of health care to an emphasis on “health protection and promotion”. The development of primary prevention initiatives for the community advances the mission of the State Health Plan.