



STATE OF TENNESSEE

STATE HEALTH PLAN

CERTIFICATE OF NEED STANDARDS AND CRITERIA

FOR

Organ Transplantation

The Health Services and Development Agency (HSDA) may consider the following standards and criteria for applicants seeking to provide organ transplantation services. 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 applicants. Existing providers of organ transplantation services are not affected by these standards and criteria unless they take action that requires a new certificate of need (CON) for such services. These Standards and Criteria are 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. 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 people in Tennessee.
2. **Access:** People in Tennessee should have access to health care and the conditions to achieve optimal health.

3. **Economic Efficiencies:** Health resources in Tennessee, including health care, should be developed to address the health of people in Tennessee while encouraging value and economic efficiencies.
4. **Quality of Care:** People in Tennessee should have confidence that the quality of care is continually monitored and standards are adhered to by providers.
5. **Workforce:** The state should support the development, recruitment, and retention of a sufficient and quality health workforce.

Definitions

Organ Transplantation: Organ transplants include solid organ transplants and islet infusions. An organ transplant begins at the start of organ anastomosis or the start of an islet infusion. An organ transplant is complete when any of the following occurs:

1. The chest or abdominal cavity is closed and the final skin stitch or staple is applied,
2. The transplant recipient leaves the operating room, even if the chest or abdominal cavity cannot be closed, and/or
3. The islet infusion is complete.

These standards cover the following transplant programs:

- a. Adult kidney,
- b. Adult pancreas,
- c. Adult heart,
- d. Adult lung,
- e. Adult liver,
- f. Adult intestine,
- g. Pediatric kidney,
- h. Pediatric pancreas,
- i. Pediatric heart,
- j. Pediatric lung,
- k. Pediatric liver, and
- l. Pediatric intestines.

Rationale: The stated definition is from the Organ Procurement and Transplantation Network (OPTN) policies.

<https://optn.transplant.hrsa.gov/governance/policies/>

NOTE, for more information: Copy and paste the following link into your web browser:
https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_01

The list of services covered aligns with the organ transplant programs covered by Centers for Medicare & Medicaid Services (CMS) regulations.

<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/TransplantProgramLawsandReg.pdf>

Pediatric: A patient under 18 years of age, or a patient who received treatment before age 18, but to ensure continuity of care, continues to receive care in a pediatric setting.

Service Area: The county or counties represented on an application as the reasonable area in which an organ transplantation program intends to provide services and/or in which the majority of its service recipients reside.

Standards and Criteria

- 1. Determination of Need and Minimum Volume Standard:** The need for organ transplantation services is based upon the applicant's ability to provide evidence that it will be able to reach the minimum volume standard set forth in these criteria. The applicant for an adult service shall set forth an institutional plan to demonstrate the ability and commitment to perform the following minimum adult transplant procedures beginning in the third year of operation and going forward:
 - a. Kidney: a minimum average of 25 procedures per year over a three year period,
 - b. Liver: a minimum average of 20 procedures per year over a three year period,
 - c. Heart: a minimum average of 15 procedures per year over a three year period,
 - d. Lung: a minimum average of 15 procedures per year over a three year period,
 - e. Pancreas: a minimum average of 5 procedures per year over a three year period, and
 - f. Intestines: a minimum average of 10 procedures per year over a three year period.

During the initial two years of operation, programs for adult service shall meet the CMS conditions of participation for minimum volumes standards annually as outlined below:

- a. Kidney: 3 procedures in year 1 and 10 for re-approval,
- b. Liver: 10 procedures,
- c. Heart: 10 procedures,
- d. Lung: 10 procedures,
- e. Pancreas: no minimum annual volume, and
- f. Intestines: 10 procedures.

Source: Department of Health and Human Services, Centers for Medicare & Medicaid Services, 42 CFR Parts 405, 482, 488, and 498 Medicare Program: Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants; Final Rule <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/downloads/transplantfinal.pdf>

Note: Should the CMS conditions of participation for minimum volumes be revised the new minimum volume levels shall be utilized in place of those listed above.

The applicant should also document the number of patients that are expected to be referred, evaluated, and listed for transplant, as well as the availability of donor organs expected by the end of the third year of operation.

Rationale: Current medical literature, as well as United Network for Organ Sharing (UNOS) and CMS guidelines and standards, verify the quality of care provided by organ transplant programs is directly impacted by the number of transplants performed in a defined time period, programs with higher volumes being associated with superior patient outcomes in comparison to those with lower volumes. In order to ensure high quality care and patient safety, only programs able to demonstrate the ability and commitment to perform the number of procedures identified in these standards should be approved for operation.

Additionally, a number of states that oversee the implementation of organ transplant programs under CON programs have implemented minimum volume standards that exceed the numbers set forth by CMS. In addition to ensuring quality care, programs with higher volumes are less likely to close, protecting patients from having to seek new providers during the transplant process.

Source: "CON Regulation of Organ Transplant Services in Maryland: a White Paper by the Maryland Health Care Commission's Center for Health Care Facilities Planning and Development"

http://mhcc.maryland.gov/mhcc/pages/home/workgroups/documents/organ_transplant/chcf_organ_transplant_white_paper.corrected.pdf

Finally, the number of transplants performed by each program in the state was reviewed. The above minimum volume levels correlate with the number of procedures performed in the years 2000-2015. UNOS state data were utilized to conduct this review.

<https://optn.transplant.hrsa.gov/data/view-data-reports/state-data/>

- 2. Pediatric Organ Transplantation Services:** It is advisable for pediatric transplant programs to be associated with an approved adult transplantation program.

Rationale: Because fewer transplants are performed on pediatric patients than adult patients, pediatric programs are typically smaller and have a lower volume than adult programs. In order to ensure positive pediatric patient outcomes, it is advisable to require pediatric transplantation programs to be associated with an approved adult transplantation program. This standard will assist in ensuring pediatric transplant programs have the resources and volumes necessary to provide high-quality care to these patients.

- 3. Establishment of Service Area:** The geographic service area shall be reasonable and based on an optimal balance between population density and service proximity of the applicant. The proposal's sensitivity and responsiveness to the special needs of the service area shall be considered, including accessibility to consumers, particularly medically underserved populations. The applicant should provide information on transportation services that will be available to patients in order to access all appointments relevant to the procedure, if applicable. The applicant may also include information on patient origination and geography and transportation lines that may inform the determination of need for additional services in the region.

Rationale: Given the number of appointments that are associated with organ transplantation, it is necessary to consider the ability of patients to access care.

Evaluation of geographic location as well as available transportation services may aid in ensuring that patients are able to access the necessary pre-transplant and post-transplant care in addition to the performance of the transplant.

- 4. Relationship to Existing Similar Services in the Area:** The applicant shall identify the existing transplantation services of the type being applied for in the proposed service area and the local region of the Organ Procurement and Transplantation Network. The applicant shall document the number of transplants performed in the previous 12 months at these identified centers as well. The applicant should also document the number of individuals on the transplant waiting list in the previous 12 months in the proposed service area. Additionally, the application shall provide information on the anticipated impact of the proposed services on the existing centers in the region. This information should include details on the economic impact as well as information detailing how a new service would affect the number of transplants performed at the existing facility.

Rationale: New facilities should only be approved if the introduction of the new service does not cause the existing facilities to no longer meet the minimum number of procedures identified under the Determination of Need and Minimum Volume Standard. This restriction is designed to uphold the high quality care provided at each organ transplant center.

- 5. Services to High-Need and Underserved Populations:** Special consideration shall be given to applicants providing services fulfilling the unique needs and requirements of certain high-need populations, including uninsured, low-income, and underserved geographic regions, as well as other underserved population groups.
- 6. Planning Horizon:** The applicant shall predict the number of procedures that will be performed by the end of the third year of operation.

Rationale: This planning horizon provides the HSDA with the opportunity to review not only the applicant's ability to reach the minimum volume standard but to also review the actual predicted volume. The three year time allotment should provide an accurate picture of operations.

- 7. Selection of Transplant Candidates:** The applicant shall provide written procedures for the selection of transplant candidates and the distribution of organs

in a fair and equitable manner. The written procedures shall be in compliance with Organ Procurement and Transplantation Network organ allocation priorities.

- 8. Certification of Nondiscriminatory Practices:** The applicant shall provide, and maintain current, a written certification of compliance with all Federal and State laws regarding nondiscrimination in the admission and/or treatment of patients.
- 9. Access:** The applicant must demonstrate an ability and willingness to serve equally all of the patients related to the application of the service area in which it seeks certification. In addition to factors set forth in HSDA Rule 0720-11-01(1) (listing the factors concerning need on which an application may be evaluated), the HSDA may choose to give special consideration to an applicant that is able to show there is limited access in the proposed service area.
- 10. Continuum of Care:** The applicant shall demonstrate its intent and ability to provide a full continuum of organ transplantation services. Applicants shall document the allocation of operating and recovery room resources, intensive care resources, blood supply and central blood storage, dedicated transplant intensive care beds, education space, and personnel to the transplant program. The applicant should also provide evidence that the following support services will also be utilized:
 - a. Pediatrics (if applicable),
 - b. Infectious diseases,
 - c. Nephrology with approved end state renal disease dialysis capability,
 - d. Pulmonary medicine with respiratory therapy support,
 - e. Pathology,
 - f. Immunology and HLA laboratory,
 - g. Anesthesiology,
 - h. Physical Therapy,
 - i. Pharmacology,
 - j. Radiology,
 - k. Ethicist,
 - l. Nutrition,
 - m. Gastroenterology/hepatology,
 - n. Cardiology, and
 - o. Behavioral health.

Additionally, the applicant should provide evidence of the following transplant support:

- a. Transplant administrator,
- b. Transplant safety and quality officer,
- c. Transplant nurse coordinators,
- d. Social worker,
- e. Financial coordinator, and
- f. Dedicated transplant data analyst/coordinator.

The applicant shall document access to laboratory facilities capable of virology, cytology, and microbiology, and monitoring of immunosuppressive drugs, a blood bank with the capacity to provide blood components for the projected number of transplants, the ability to irradiate blood components, and a blood separator and central blood storage, along with the necessary psychiatric and social support services.

Rationale: Applicants should demonstrate willingness and ability to provide for the total care of transplant recipients and their families in coping with the transplant experience.

11. 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. Each transplant program shall have a transplant surgeon and a transplant physician. The transplant surgeon and transplant physician shall meet UNOS standards for the relevant transplant program.

NOTE, for more information: Copy and paste the following link into your web browser:

https://www.unos.org/wp-content/uploads/unos/Appendix_B_AttachI_XIII.pdf

The applicant shall have a minimum of one full-time transplant administrator and one transplant coordinator for each program on-site.

12. Staffing Plan: The applicant should document a staffing plan that allows transplants to be performed 24 hours a day, 7 days a week, and 365 days a year.

This staffing plan must include an organ specific transplant surgeon and transplant physician that are available at all times for pre-transplant care, performance of the transplant, and post-operative and post-transplant care.

Rationale: Given the time sensitivity of the procedure and the unpredictable nature of organ donor availability, it is important for the procedure to be able to be performed on a 24/7/365 basis. This standard aids in preventing patients from missing an opportunity for transplantation to occur.

13. Assurance of Resources: The applicant shall document that the resources necessary to properly support the transplantation program for which it is applying to initiate will be provided. Included in such documentation shall be a letter of support from the applicant's governing board of directors documenting the full commitment of the applicant to develop and maintain the facility resources, equipment, and staffing to provide a full continuum of organ transplantation services. The applicant shall also document the financial costs of maintaining these resources and its ability to sustain them to ensure quality treatment of patients in the organ transplantation services continuum of care.

Rationale: Resources to support an organ transplant program may be limited in certain parts of the state. Applicants should demonstrate the ability to recruit and retain a dedicated and skilled team to ensure high quality patient care. Applicants should also demonstrate the ability to maintain the financial resources, facilities, and equipment necessary to run a program with positive patient outcomes.

14. Licensure and Quality Considerations: Any existing applicant for this CON service category shall be in compliance with the appropriate rules of the Tennessee Department of Health (TDH). If a CON is granted, the transplantation program shall achieve and maintain institutional membership in the national OPTN, currently operating as the United Network for Organ Sharing (UNOS), within one year of program initiation. The applicant shall notify the HSDA of the achievement of such membership and should provide annual verification of the program's membership status to the HSDA. Additionally, the applicant shall comply with CMS regulations set forth by 42 CFR Parts 405, 482, and 498, *Medicare Program; Hospital Conditions of Participation: Requirement for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants*. The applicant should provide annual verification of the

program's standing with CMS to the HSDA, including any citations and corrective action plans.

The applicant shall identify and document its existing or proposed plan for data reporting, quality improvement, and outcomes. The organ transplantation programs shall meet the specifications/qualifications of the Quality Assessment and Performance Improvement (QAPI) Program required by CMS.

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

15. Quality Considerations for Expansion of Existing Programs: Existing organ transplantation programs seeking to expand services with additional organ(s) should document their membership status with UNOS as well as a listing of all citations by UNOS Membership and Professional Standards Committee and/or CMS and the corresponding corrective action plans and resolutions by the relevant regulatory agency.

16. Data Requirements: Applicants shall agree to provide the TDH 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.

17. 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 the increased likelihood of organ transplantation usage.

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.