

State of Tennessee

2016 Edition of the

State Health Plan



Division of Health Planning
Tennessee Department of Health



2016 Edition of the State Health Plan

Contents

Introduction	2
Certificate of Need Standards and Criteria	3
Organ Transplantation	3
Freestanding Emergency Departments.....	14
Appendix.....	29
Appendix A: Statutory Authority for the State Health Plan	29

Introduction

The 2016 Edition of the State Health Plan continues to support the mission of the Tennessee Department of Health (TDH), “to protect, promote, and improve the health and prosperity of people in Tennessee”, by developing Standards and Criteria for the Certificate of Need program that aim to ensure the people of Tennessee have access to high-quality and affordable health care.

Certificate of Need (CON) is a permit for the establishment or modification of a health care institution, facility, or service at a designated location. Tennessee’s CON program seeks to deliver improvement in access, quality, and cost savings through the orderly growth management of the state’s health care system. In accordance with Tennessee law, the annual updates to the State Health Plan contain revisions to specific CON standards and criteria that are used by the Health Services Development Agency (HSDA) as guidelines when issuing CONs. The HSDA reviews applications under the guidance of four overarching criteria: 1) Criteria of need, 2) Orderly development of health care, 3) Economic feasibility of the applicant, and 4) Quality of care.

Public Chapter 1043, which became effective July 1, 2016, added Freestanding Emergency Departments (FSEDs) and Organ Transplantation to the list of facilities, equipment, and services that are regulated by the CON program in the state. This edition of the SHP features newly developed standards and criteria for FSEDs and Organ Transplantation. These standards reflect the four criteria set forth by Tennessee law that the agency is directed to consider when reviewing CON applications.

The development of these standards included a comprehensive process that engaged the public, industry stakeholders and HSDA staff and board members. As required by statute, these standards have been reviewed by the agency members and staff. All current CON standards can be found at the following link: <https://www.tn.gov/hsda/>.



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.



STATE OF TENNESSEE

STATE HEALTH PLAN

CERTIFICATE OF NEED STANDARDS AND CRITERIA

FOR

Freestanding Emergency Departments

The Health Services Development Agency (HSDA) may consider the following standards and criteria for applicants seeking to establish or expand Freestanding Emergency Departments (FSEDs). 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 FSEDs 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:

6. **Healthy Lives:** The purpose of the State Health Plan is to improve the health of

people in Tennessee.

7. **Access:** People in Tennessee should have access to health care and the conditions to achieve optimal health.
8. **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.
9. **Quality of Care:** People in Tennessee should have confidence that the quality of care is continually monitored and standards are adhered to by providers.
10. **Workforce:** The state should support the development, recruitment, and retention of a sufficient and quality health workforce.

Definitions

Rural Area: A proposed service area shall be designated as rural in accordance with the U.S. Department of Health and Human Services (HRSA) Federal Office of Rural Health Policy's *List of Rural Counties and Designated Eligible Census Tracts in Metropolitan Counties*. This document, along with the two methods used to determine eligibility, can be found at the following link:

<http://www.hrsa.gov/ruralhealth/resources/forhpeligibleareas.pdf>

For more information on the Federal Office of Rural Health Policy visit:

<http://www.hrsa.gov/ruralhealth/>

Freestanding Emergency Department: A facility that receives individuals for emergency care and is structurally separate and distinct from a hospital. A freestanding emergency department (FSED) is owned and operated by a licensed hospital. These facilities provide emergency care 24 hours a day, 7 days a week, and 365 days a year.

Service Area: Refers to the county or contiguous counties or Zip Code or contiguous Zip Codes represented by an applicant as the reasonable area in which the applicant intends to provide freestanding emergency department services and/or in which the majority of its service recipients reside.

Standards and Criteria

- 1. Determination of Need:** The determination of need shall be based upon the existing access to emergency services in the proposed service area. The applicant should utilize the metrics below, as well as other relevant metrics, to demonstrate that the population in the proposed service area has inadequate access to emergency services due to geographic isolation, capacity challenges, or low-quality of care.

The applicant shall provide information on the number of existing emergency department (ED) facilities in the service area, as well as the distance of the proposed FSED from these existing facilities. If the proposed service area is comprised of contiguous ZIP Codes, the applicant shall provide this information on all ED facilities located in the county or counties in which the service area ZIP Codes are located.

The applicant should utilize Centers for Medicare and Medicaid Services (CMS) throughput measures, available from the CMS Hospital Compare website, to illustrate the wait times at existing emergency facilities in the proposed service area. Data provided on the CMS Hospital Compare website does have a three to six month lag. In order to account for the delay in this information, the applicant may supplement CMS data with other more timely data.

The applicant should also provide data on the number of visits per treatment room per year for each of the existing emergency department facilities in the service area. Applicants should utilize applicable data in the Hospital Joint Annual Report to demonstrate the total annual ED volume and annual emergency room visits of the existing facilities within the proposed service area. All existing EDs in the service area should be operating at capacity. This determination should be based upon the annual visits per treatment room at the host hospital's emergency department (ED) as identified by the American College of Emergency Physicians (ACEP) in *Emergency Department Design: A Practical Guide to Planning for the Future, Second Edition* as capacity for EDs. The capacity levels set forth by this document should be utilized as a *guideline* for describing the potential of a respective functional program. The annual visits per treatment room should exceed what is outlined in the ACEP

document. Because the capacity levels set forth in the *Emergency Department Design: A Practical Guide to Planning for the Future, Second Edition* are labeled in the document as a “preliminary sizing chart”, the applicant is encouraged to provide additional evidence of the capacity, efficiencies, and demographics of patients served within the existing ED facility in order to better demonstrate the need for expansion.

ED-1	Median time from ED arrival to ED departure for ED admitted patients
ED-2	Median time from admit decision to departure for ED admitted patients
OP-18	Median time from ED arrival to ED departure for discharged ED patients
OP-20	Door to diagnostic evaluation by a qualified medical professional
OP-22	ED-patient left without being seen

Source: <https://www.medicare.gov/hospitalcompare/search.html>

<https://data.medicare.gov/data/hospital-compare>

Note: The above measures are found in the category “Timely and Effective Care”.

If the applicant is demonstrating low-quality care provided by existing EDs in the service area, the applicant shall utilize the Joint Commission’s “Hospital Outpatient Core Measure Set”. These measures align with CMS reporting requirements and are available through the CMS Hospital Compare website. Full details of these measures can be found in the Joint Commission’s *Specification Manual for National Hospital Outpatient Department Quality Measures*. Existing emergency facilities should be in the bottom quartile of the state in the measures listed below in order to demonstrate low-quality of care.

OP-1	Median Time to Fibrinolysis
OP-2	Fibrinolytic Therapy Received Within 30 Minutes
OP-3	Median Time to Transfer to Another Facility for Acute Coronary Intervention
OP-4	Aspirin at Arrival
OP-5	Median Time to ECG

OP-18	Median Time from ED Arrival to Departure for Discharged ED Patients
OP-20	Door to Diagnostic Evaluation by a Qualified Medical Personnel
OP-21	ED-Median Time to Pain Management for Long Bone Fracture
OP-23	ED-Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients who Received Head CT or MRI Scan Interpretation With 45 Minutes of ED Arrival

Sources: https://www.jointcommission.org/hospital_outpatient_department/

https://www.jointcommission.org/assets/1/6/HAP_Outpatient_Dept_Core_Measure_Set.pdf

<https://www.medicare.gov/hospitalcompare/search.html>

<https://data.medicare.gov/data/hospital-compare>

Note: The above measures are found in the category “Timely and Effective Care”.

The HSDA should consider additional data provided by the applicant to support the need for the proposed FSED including, but not limited to, data relevant to patient acuity levels, age of patients, percentage of behavioral health patients, and existence of specialty modules. These data may provide the HSDA with additional information on the level of need for emergency services in the proposed service area. If providing additional data, applicants should utilize Hospital Discharge Data System data (HDDS) when applicable. The applicant may utilize other data sources to demonstrate the percentage of behavioral health patients but should explain why the alternative data source provides a more accurate indication of the percentage of behavioral health patients than the HDDS data.

See Standard 2, Expansion of Existing Emergency Department Facility, for more information on the establishment of a FSED for the purposes of decompressing volumes and reducing wait times at the host hospital’s existing ED.

Note: Health Planning recognizes that limitations may exist for specific metrics listed above. When significant limitations exist (e.g. there are not adequate volumes to

evaluate) applicants may omit these metrics from the application. However, the application should then discuss the limitations and reasoning for omission. Applicants are encouraged to supplement the listed metrics with additional metrics that may provide HSDA with a more complete representation of the need for emergency care services in the proposed service area.

Rationale: Applicants seeking to establish a FSED should demonstrate need based on barriers to access in the proposed service area. While limited access to emergency services due to geographic isolation, low-quality of care, or excessive wait times are pertinent to the discussion, the applicant is also encouraged to provide additional data from the proposed service area that may provide the HSDA with a more comprehensive picture of the unique needs of the population that would be served by the FSED. Host hospitals applying to establish a FSED displaying efficiencies in care delivery via high volumes and low wait time should not be penalized in the review of this standard. Host hospitals are expected to demonstrate high quality care in order to receive approval. See Standard 4 for more information.

Applicants seeking to establish an FSED in a geographically isolated, rural area should be awarded special consideration by the HSDA.

- 2. Expansion of Existing Emergency Department Facility:** Applicants seeking expansion of the existing host hospital ED through the establishment of a FSED in order to decompress patient volumes should demonstrate the existing ED of the host hospital is operating at capacity. This determination should be based upon the annual visits per treatment room at the host hospital's emergency department (ED) as identified by the American College of Emergency Physicians (ACEP) in *Emergency Department Design: A Practical Guide to Planning for the Future, Second Edition* as capacity for EDs. The capacity levels set forth by this document should be utilized as a *guideline* for describing the potential of a respective functional program. The applicant shall utilize the applicable data in the Hospital Joint Annual Report to demonstrate total annual ED volume and annual emergency room visits. The annual visits per treatment room should exceed what is outlined in the ACEP document. Because the capacity levels set forth in the *Emergency Department Design: A Practical Guide to Planning for the Future, Second Edition* are labeled in the document as a

“preliminary sizing chart”, the applicant is encouraged to provide additional evidence of the capacity, efficiencies, and demographics of patients served within the existing ED facility in order to better demonstrate the need for expansion. See Standard 1, Demonstration of Need, for examples of additional evidence.

Additionally, the applicant should discuss why expansion of the existing ED is not a viable option. This discussion should include any barriers to expansion including, but not limited to, economic efficiencies, disruption of services, workforce duplication, restrictive covenants, and issues related to access. The applicant should also provide evidence that all practical efforts to improve efficiencies within the existing ED have been made, including, but not limited to, the review of and modifications to staffing levels.

Applicants seeking to decompress volumes of the existing host hospital ED should be able to demonstrate need for the additional facility in the proposed service area as defined in the application in accordance with Standard 1, Determination of Need.

Rationale: The HSDA may utilize visits per treatment room in order to determine if a FSED is necessary for the host hospital to provide efficient and quality emergency care to its patients. Many factors influence a hospital’s ability to adequately serve patients at various volumes. Factors may include efficiencies of the ED and the acuity of the patients seen. Applicants are encouraged to provide additional data in order to demonstrate need for expansion. This additional data may assist in providing the HSDA with the opportunity to perform a comprehensive review that takes into account the numerous factors that affect ED efficiencies, access to care, and the quality of ED services provided.

- 3. Relationship to Existing Similar Services in the Area:** The proposal shall discuss what similar services are available in the service area and the trends in occupancy and utilization of those services. This discussion shall include the likely impact of the proposed FSED on existing EDs in the service area and shall include how the applicant’s services may differ from existing services. Approval of the proposed FSED should be contingent upon the applicant’s demonstration that existing services in the applicant’s proposed geographical service area are not adequate and/or there are special circumstances that require additional services.

Rural: The applicant should provide patient origin data by ZIP Code for each existing facility as well as the proposed FSED in order to verify the proposed facility will not negatively impact the patient base of the existing rural providers. The establishment of a FSED in a rural area should only be approved if the applicant can adequately demonstrate the proposed facility will not negatively impact any existing rural facilities that draw patients from the proposed service area. Additionally, in an area designated as rural, the proposed facility should not be located within 10 miles of an existing facility. Finally, in rural proposed service areas, the location of the proposed FSED should not be closer to an existing ED facility than to the host hospital.

Critical Access Hospitals (CAH): In Tennessee, certain CAHs are not located in rural areas according to the definition of rural provided in these standards. The location of the proposed FSED should not be closer to an existing CAH than to the host hospital.

Rationale: The HSDA should consider any duplication of existing services as well as the maldistribution of emergency services by considering the existing providers in the proposed service area. This standard also provides an opportunity for the applicant to demonstrate any services or specialty services that will be provided by the proposed FSED that are not provided by the existing emergency care providers servicing the proposed service area.

4. **Host Hospital Emergency Department Quality of Care:** Additionally, the applicant shall provide data to demonstrate the quality of care being provided at the ED of the host hospital. The quality metrics of the host hospital should be in the top quartile of the state in order to be approved for the establishment of a FSED. The applicant shall utilize the Joint Commission’s hospital outpatient core measure set. These measures align with CMS reporting requirements and are available through the CMS Hospital Compare website. Full details of these measures can be found in the Joint Commission’s *Specification Manual for National Hospital Outpatient Department Quality Measures*.

OP-1	Median Time to Fibrinolysis
OP-2	Fibrinolytic Therapy Received Within 30 Minutes

OP-3	Median Time to Transfer to Another Facility for Acute Coronary Intervention
OP-4	Aspirin at Arrival
OP-5	Median Time to ECG
OP-18	Median Time from ED Arrival to Departure for Discharged ED Patients
OP-20	Door to Diagnostic Evaluation by a Qualified Medical Personnel
OP-21	ED-Median Time to Pain Management for Long Bone Fracture
OP-23	ED-Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients who Received Head CT or MRI Scan Interpretation With 45 Minutes of ED Arrival

Sources: https://www.jointcommission.org/hospital_outpatient_department/

https://www.jointcommission.org/assets/1/6/HAP_Outpatient_Dept_Core_Measure_Set.pdf

<https://www.medicare.gov/hospitalcompare/search.html>

<https://data.medicare.gov/data/hospital-compare>

Note: The above measures are found in the category “Timely and Effective Care”.

Note: Health Planning recognizes that limitations may exist for specific metrics listed above. When significant limitations exist (e.g. there are not adequate volumes to evaluate) applicants may omit these metrics from the application. However, the application should then discuss the limitations and reasoning for omission. Applicants are encouraged supplement the listed metrics with additional metrics that may provide HSDA with a more complete representation of the need for emergency care services in the proposed service area.

- 5. Appropriate Model for Delivery of Care:** The applicant should discuss why a FSED is the appropriate model for delivery of care in the proposed service area.

Rationale: Rationale should be provided in the application detailing why a FSED is the most appropriate option for delivery of care and to improve access to care in the proposed service area. This discussion should detail the benefits of a FSED for

the proposed patient population over an urgent care center, primary care office, or other possible delivery models.

- 6. Geographic Location:** The FSED should be located within a 35 mile radius of the hospital that is the main provider.

Rationale: The 35 mile radius standard is in alignment with regulations set forth by CMS (42 CFR Ch. IV (10-1-11 Edition), Rule 413.65).

- 7. Access:** The applicant must demonstrate an ability and willingness to serve equally all of the service area in which it seeks certification. In addition to the factors set forth in HSDA Rule 0720-11-.01(1) (listing 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 that there is limited access to ED services in the proposed Service Area.
- 8. Services to High-Need Populations:** Special consideration shall be given to applicants providing services fulfilling the unique needs and requirements of certain high-need populations, including patients who are uninsured, low income, or patients with limited access to emergency care.
- 9. Establishment of Non-Rural 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 socio-demographics of the service area and the projected population to receive services shall be considered. The applicant shall demonstrate the orderly development of emergency services by providing information regarding current patient origin by ZIP Code for the hospital's existing ED in relation to the proposed service area for the FSED.

Establishment of a Rural Service Area: Applicants seeking to establish a freestanding emergency department in a rural area with limited access to emergency medical care shall establish a service area based upon need. The applicant shall demonstrate the orderly development of emergency services by providing information regarding patient origin by ZIP Code for the proposed service area for the FSED.

10. Relationship to Existing Applicable Plans; Underserved Area and Population:

The proposal's relationship to underserved geographic areas and underserved population groups shall be a significant consideration.

11. Composition of Services: Laboratory and radiology services, including but not limited to XRAY and CT scanners, shall be available on-site during all hours of operation. The FSED should also have ready access to pharmacy services and respiratory services during all hours of operation.

12. Pediatric Care: Applicants should demonstrate a commitment to maintaining at least a Primary Level of pediatric care at the FSED as defined by CHAPTER 1200-08-30 Standards for Pediatric Emergency Care Facilities including staffing levels, pediatric equipment, staff training, and pediatric services. Applicants should include information detailing the expertise, capabilities, and/or training of staff to stabilize or serve pediatric patients. Additionally, applicants shall demonstrate a referral relationship, including a plan for the rapid transport, to at least a general level pediatric emergency care facility to allow for a specialized higher level of care for pediatric patients when required.

13. Assurance of Resources: The applicant shall document that it will provide the resources necessary to properly support the applicable level of emergency services. Included in such documentation shall be a letter of support from the applicant's governing board of directors or Chief Financial Officer documenting the full commitment of the applicant to develop and maintain the facility resources, equipment, and staffing to provide the appropriate emergency 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 ED continuum of care.

14. 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 applicant shall outline planned staffing patterns including the number and type of

physicians and nurses. Each FSED is required to be staffed by at least one physician and at least one registered nurse at all times (24/7/365). Physicians staffing the FSED should be board certified or board eligible emergency physicians. If significant barriers exist that limit the applicant's ability to recruit a board certified or board eligible emergency physician, the applicant shall document these barriers for the HSDA to take into consideration. Applicants are encouraged to staff the FSED with registered nurses certified in emergency nursing care and/or advanced cardiac life support. The medical staff of the FSED shall be part of the hospital's single organized medical staff, governed by the same bylaws. The nursing staff of the FSED shall be part of the hospital's single organized nursing staff. The nursing services provided shall comply with the hospital's standards of care and written policies and procedures.

Adequate Staffing of a Rural FSED: 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 applicant shall outline planned staffing patterns including the number and type of physicians. FSEDs proposed to be located in rural areas are required to be staffed in accordance with the Code of Federal Regulations Title 42, Chapter IV, Subchapter G, Part 485, Subpart F – Conditions of Participation: Critical Access Hospitals (CAHs). This standard requires a physician, nurse practitioner, clinical nurse specialist, or physician assistant be available at all times the CAH operates. The standard additionally requires a registered nurse, clinical nurse specialist, or licensed practical nurse to be on duty whenever the CAH has one or more inpatients. However, because FSEDs shall be in operation 24/7/365 and because they will not have inpatients, a registered nurse, clinical nurse specialist, or licensed practical nurse shall be on duty at all times (24/7/365). Additionally, due to the nature of the emergency services provided at an FSED and the hours of operation, a physician, nurse practitioner, clinical nurse specialist, or physician assistant shall be on site at all times.

Source: http://www.ecfr.gov/cgi-bin/text-idx?rgn=div6&node=42:5.0.1.1.4.4#se42.5.485_1631

Rationale: FSEDs should be staffed with a physician who is board-certified or board-eligible in emergency medicine and a registered nurse in order to ensure the facility is capable of providing the care necessary to treat and/or stabilize patients seeking emergency care. The HSDA should consider evidence provided by the applicant that demonstrates significant barriers to the recruitment a physician who is board-certified or board-eligible in emergency medicine exist.

Rural FSEDs should be awarded flexibility in terms of staffing in accordance with federal regulations. Additionally, flexibility in staffing requirements takes into account the limited availability of medical staff in certain rural regions of the state.

15. Medical Records: The medical records of the FSED shall be integrated into a unified retrieval system with the host hospital.

16. Stabilization and Transfer Availability for Emergent Cases: The applicant shall demonstrate the ability of the proposed FSED to perform stabilizing treatment within the FSED and demonstrate a plan for the rapid transport of patients from the FSED to the most appropriate facility with a higher level of emergency care for further treatment. The applicant is encouraged to include air ambulance transport and an on-site helipad in its plan for rapid transport. The stabilization and transfer of emergent cases must be in accordance with the Emergency Medical Treatment and Labor Act.

17. Education and Signage: Applicants must demonstrate how the organization will educate communities and emergency medical services (EMS) on the capabilities of the proposed FSED and the ability for the rapid transport of patients from the FSED to the most appropriate hospital for further treatment. It should also inform the community that inpatient services are not provided at the facility and patients requiring inpatient care will be transported by EMS to a full service hospital. The name, signage, and other forms of communication of the FSED shall clearly indicate that it provides care for emergency and/or urgent medical conditions without the requirement of a scheduled appointment. The applicant is encouraged to demonstrate a plan for educating the community on appropriate use of emergency services contrasted with appropriate use of urgent or primary care.

Rationale: CMS S&C Memo 08-08, 2008, "...encourages hospitals with off-campus EDs to educate communities and EMS agencies in their service area about the operating hours and capabilities available at the off-campus ED, as well as the hospital's capabilities for rapid transport of patients from the off-campus ED to the main campus for further treatment."

The memorandum is available at the following link:

<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCletter08-08.pdf>

18. Community Linkage Plan: The applicant shall describe its participation, if any, in a community linkage plan, including its relationships with appropriate health and outpatient behavioral health care system, including mental health and substance use, providers/services, providers of psychiatric inpatient 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 ED 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.

19. Data Requirements: Applicants shall agree to provide the Department of Health 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.

20. Quality Control and Monitoring: The applicant shall identify and document its existing or proposed plan for data reporting, quality improvement, and outcome and process monitoring system. The FSED shall be integrated into the host hospital's quality assessment and process improvement processes.

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

21. Provider-Based Status: The applicant shall comply with regulations set forth by 42 CFR 413.65, *Requirements for a determination that a facility or an organization has provider-based status*, in order to obtain provider-based status. The applicant shall demonstrate eligibility to receive Medicare and Medicaid reimbursement, willingness to serve emergency uninsured patients, and plans to contract with commercial health insurers.

Rationale: FSEDs should operate under the same guidelines as traditional emergency departments. This includes providing service to all patients regardless of ability to pay and acceptance of Medicare, Medicaid, and commercial insurance.

22. Licensure and Quality Considerations: Any applicant for this CON service category shall be in compliance with the appropriate rules of the TDH, the EMTALA, along with any other existing applicable federal guidance and regulation. The applicant shall also demonstrate its accreditation status with the Joint Commission or other applicable accrediting agency. The FSED shall be subject to the same accrediting standards as the licensed hospital with which it is associated.

Note: Federal legislation, the Rural Emergency Acute Care Hospital (REACH Act), is under consideration. Under this legislation rural hospitals would be permitted to convert into a FSED and retain CMS recognition. If passage takes place, these standards should be considered revised in order to grant allowance to Tennessee hospitals seeking this conversion in accordance with the federal guidelines.

Appendix

Appendix A: Statutory Authority for the State Health Plan

The Division of Health Planning was created by action of the Tennessee General Assembly and signed in to law by Governor Phil Bredesen (Tennessee Code Annotated § 68-11-1625). The Division is charged with creating and updating a State Health Plan. The text of the law follows.

- a) There is created the state health planning division of the department of finance and administration. It is the purpose of the planning division to create a state health plan that is evaluated and updated at least annually. The plan shall guide the state in the development of health care programs and policies and in the allocation of health care resources in the state.
- b) It is the policy of the state of Tennessee that:
 1. Every citizen should have reasonable access to emergency and primary care;
 2. 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 industry;
 3. Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers; and
 4. The state should support the recruitment and retention of a sufficient and quality health care workforce.
- c) The planning division shall be staffed administratively by the department of finance and administration in a manner that the department deems necessary for the performance of the planning division's duties and responsibilities, which may include contracting for the services provided by the division through a private person or entity.
- d) The duties and responsibilities of the planning division include:
 1. To develop and adopt a State Health Plan, which must include, at a minimum, guidance regarding allocation of the state's health care resources;
 2. To submit the State Health Plan to the Health Services and Development Agency for comment;
 3. To submit the State Health Plan to the Governor for approval and adoption;

4. To hold public hearings as needed;
5. To review and evaluate the State Health Plan at least annually;
6. To respond to requests for comment and recommendations for health care policies and programs;
7. To conduct an ongoing evaluation of Tennessee's resources for accessibility, including, but not limited to, financial, geographic, cultural, and quality of care;
8. To review the health status of Tennesseans as presented annually to the Division by the Department of Health and the Department of Mental Health and Developmental Disabilities;
9. To review and comment on federal laws and regulations that influence the health care industry and the health care needs of Tennesseans;
10. To involve and coordinate functions with such State entities as necessary to ensure the coordination of State health policies and programs;
11. To prepare an annual report for the General Assembly and recommend legislation for its consideration and study; and
12. To establish a process for timely modification of the State Health Plan in response to changes in technology, reimbursement and other developments that affect the delivery of health care.