

**OPEN HEART SURGERY
SERVICES**



STATE OF TENNESSEE

**STATE HEALTH PLAN
CERTIFICATE OF NEED STANDARDS AND CRITERIA**

FOR

OPEN HEART SURGERY SERVICES

The Health Services and Development Agency (HSDA) may consider the following standards and criteria for applications seeking to provide open heart surgery services. Rationale statements for each standard are provided in an appendix. Existing providers of open heart surgery services are not affected by these standards and criteria unless they take an 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. However, applications to provide open heart surgery services that are deemed complete by HSDA prior to the approval and adoption of these standards and criteria shall be considered under the Guidelines for Growth, 2000 Edition.

Definitions

Open Heart Surgery: Open heart surgery is any surgery where the chest is opened and surgery is performed on the heart muscle, valves, arteries or other heart structures. The term "open" refers to the chest, not the heart itself. The heart may or may not be opened, depending on the type of surgery. A heart-lung machine (also called cardiopulmonary bypass) is usually used during conventional open heart surgery.

The following procedures also are considered open heart surgery:

- Procedures being performed on the heart through smaller incisions
- Procedures being performed that are done with the heart still beating, such as
 - Minimally invasive direct coronary artery bypass (MIDCAB)
 - Robot assisted coronary artery bypass (RACAB)
 - Off pump coronary artery bypass surgery (OPCAB)

Open Heart Surgery Service: An organized surgical program that serves inpatients of a hospital that has a suitable operating room or suite of operating rooms, equipment, staff,

intensive care unit, and all support services required to perform open heart surgery. The open heart surgery service shall be located in an acute care hospital that is licensed by the State of Tennessee and that has an authorized therapeutic cardiac catheterization service.

Open Heart Surgery Case: A “case” shall mean one visit to an operating room by one open heart surgery patient, regardless of the number of procedures performed during that visit.

Adult: Refers to any patient or open heart surgery service treating a patient 15 years of age or older.

Pediatric: Refers to any patient or open heart surgery service treating a patient less than 15 years of age.

Service Area: Refers to the county or counties represented by an applicant as the reasonable area to which the applicant intends to provide open heart surgery services and/or in which the majority of its current service recipients reside.

Hospital Discharge Data System (HDDS): The HDDS shall be identified by the Health Services and Development Agency (HSDA) as the primary source of data regarding open heart surgeries performed in Tennessee. The HDDS receives information from the institutional paper claim form (as of the date of this document, the UB-04 form) on all inpatient discharges and other selected patient visits from Tennessee hospitals. Each form contains information on patient diagnoses, procedures performed on the patient, charges for services provided, and selected patient demographics. The Tennessee Department of Health maintains the HDDS and is responsible for generating reports utilizing its data as required by the Certificate of Need program.

Patient Origin Study: A study undertaken by an applicant seeking to provide open heart surgery services to determine the geographic distribution of the residences of the patients served by its existing services. Such studies help define patient catchment and medical trade areas and are useful in locating and planning the development of new services.

Standards and Criteria

1. **Determination of Need:** The need for open heart surgery services is determined by applying the following formula to four age ranges of the population and summing the result of each calculation. The applicant should apply this formula to the following age ranges: 0 through 14; 15 through 44; 45 through 64; and 65 and above. The formula serves to derive the number of open heart surgery cases which may be needed in a proposed service area.

$$N = U \times (P + O).$$

where:

N = number of cases needed in a service area;

U = latest available Tennessee use rate (number of cases performed per 1,000 population in the state as determined by the Tennessee Department of Health);

P = projection of population (in thousands) of each age range in the service area as determined by the Tennessee Department of Health for Tennessee; and

O = the projection of out-of-state population (in thousands) of each age range in the service area as determined by the U.S. Census Bureau for non-Tennessee counties

In addition, the applicant should submit a patient origin study to document the applicant's general patient catchment area and the volume of cases referred to other specialty services currently provided by the applicant.

The need for open heart surgery services shall be projected three years into the future from the current year. The need for pediatric and adult open heart surgery services shall be projected separately.

2. **Minimum Volume Standard:** The applicant should demonstrate that the proposed service utilization will be a minimum of 200 adult surgery cases per year by its third year of operation for adult open heart surgery services. The applicant should demonstrate that the proposed service utilization will be a minimum of 100 pediatric open heart surgery cases per year by its third year of operation for pediatric open heart surgery services. Annual volume shall be measured based upon a two-year average which shall begin at the conclusion of the applicant's first year of operation.
3. **Current Service Area Utilization:** The applicant should document that all existing providers of open heart surgery services within the proposed service area and within a 50 mile radius each performed at least 300 adult open heart surgery cases per year (or 130 pediatric open heart surgery cases per year) during the most recent 12 month period for which data are available. To characterize existing providers located within Tennessee, the applicant should use data provided by the Hospital Discharge Data System (HDDS) maintained by the Tennessee Department of Health. To characterize providers located outside of Tennessee, the applicant should use publicly available data, if available, and describe in its application the methodology these providers use to count volume.

In addition, the applicant should provide the HSDA with a report of patient destination for open heart surgery services based on the most recent 12 months of publicly reported data. This report should list all facilities that provided open heart services to residents of the service area and the number of open heart cases performed on residents of the service area for each facility. The Tennessee Department of Health will assist applicants in generating this report utilizing the HDDS.

4. **Orderly Development of Applicant's Cardiac Care Services:** The applicant should document that it has operated a fully functioning therapeutic cardiac catheterization laboratory for at least one year and that this laboratory complies with the minimum volume standards set forth in the Standards and Criteria for Cardiac Catheterization Services. The applicant should also document the number of heart surgery cases and—if applicable—cardiac catheterization cases that have been referred out of the hospital during the most recent three year period of available data.
5. **Adverse Impact on Existing Providers:** A new open heart surgery program should not be approved if the new program will cause the annual caseload of existing programs within the service area to drop below 300 adult cases or 130 pediatric cases. The patient origin study conducted for Standard 2, an analysis of patient origin data collected for Standard 4, and the referral data documented for Standard 5 should be used to determine whether such an adverse impact on existing providers is likely to occur.
6. **Open Heart Surgery Continuum of Care:** The applicant should document that it will provide the following resources to properly support an open heart surgery program based upon projected volume levels. Included in such documentation should 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 open heart surgery care and supportive services. The applicant should also document the financial costs of maintaining these resources and its ability to sustain them to ensure quality treatment of patients in the open heart surgery continuum of care.
 - a) Access to specialists as required in the areas of Interventional Cardiology, Renal, Nephrology, Pulmonary Medicine, Neurology, Infectious Disease, and Endocrinology;
 - b) At least one dedicated open heart surgery Operating Room;
 - c) Operative services—available 24 hours per day, seven days per week for emergent cases—including Perfusion, Cardiac Anesthesia, and a specially trained Cardiac Operating Room Team;
 - d) Support services, including Blood Bank, Patient Dialysis, Respiratory Therapy, and Physical Therapy;

- e) Post-Operative care that includes a Cardiovascular Intensive Care Unit/Open Heart Recovery Unit, a Cardiac Step-Down Unit, and Cardiac Rehabilitation; and
 - f) Ventricular Assist Device (VAD) capabilities.
7. **Adequate Staffing:** The applicant should document a plan for recruiting and maintaining a sufficient number of professional and technical staff to provide the services listed in Standard 7. The applicant should also document an ongoing educational plan for all staff included in the open heart surgery program.
 8. **Staff and Service Availability for Emergent Cases:** The applicant should document the capability to mobilize surgical and medical support teams rapidly (within 30 minutes) for emergency cases 24 hours per day, seven days per week. The applicant should also address staff availability and Operating Room space availability for emergencies during peak operating hours.
 9. **Treatment of Pediatric Patients:** Open heart surgery on pediatric patients may not be limited to pediatric facilities. However, a facility treating pediatric patients should have a pediatric cardiac surgeon, specialized pediatric staff, and offer services in the continuum of care as noted in Standard 7 for pediatric patients; additionally, such an applicant should document its intention to comply with the American Academy of Pediatrics' Guidelines for Pediatric Cardiovascular Centers.
 10. **Minimum Physician Requirements to Initiate a New Service:** The applicant should document the availability of, or present a plan for recruiting, at least two qualified cardiac surgeons certified by the American Board of Thoracic Surgery. For adult open heart surgery services, a qualified cardiac surgeon will have performed a minimum of 200 adult open heart surgery cases in the two years prior to the application. For pediatric open heart surgery services, a qualified cardiac surgeon will have performed a minimum of 100 pediatric open heart surgery cases in the two years prior to the application. In both adult and pediatric open heart surgery services programs, at least one cardiac surgeon should have a minimum of five years of cardiac surgical experience.
 11. **Maintenance of Physician Skill:** The applicant should establish processes to ensure that its adult open heart surgeons will perform at least 100 adult open heart surgery cases annually across all practice locations and/or that its pediatric open heart surgeons will perform at least 50 pediatric open heart surgery cases annually across all practice locations.
 12. **Clinical Guidelines:** The applicant should agree to document ongoing compliance with the most recently published *Guidelines for Coronary Artery Bypass Graft Surgery* adopted by the American College of Cardiology and the American Heart Association. Where providers are not in compliance, they should maintain appropriate documentation stating the reasons for noncompliance and

the steps the provider is taking to ensure quality. As of the adoption of these Standards and Criteria, the latest edition may be found here under the heading "Guidelines": <http://www.acc.org/qualityandscience/clinical/topic/topic.htm>.

13. **Licensure:** Open heart surgeries should only be performed in acute care hospitals that are licensed by the State of Tennessee.
14. **Accessibility:** The maximum travel time to hospitals providing open heart surgery services should be within a one-way driving time of 90 minutes for at least 90 percent of the population of Tennessee.
15. **Elective Surgery:** The applicant should document that elective open heart surgery services will be available within two weeks from the date of the patient's decision to undergo surgery.
16. **Quality Control and Monitoring:** The applicant should identify and document its intention to participate in a data reporting, quality improvement, outcome monitoring, and peer review system which benchmarks outcomes based on national norms. The system should provide for peer review among professionals practicing in facilities and programs other than the applicant hospital. Demonstrated active participation in the STS National Database is encouraged and shall be considered evidence of meeting this standard.
17. **Data Requirements:** Applicants should agree to provide the Department of Health and/or the Health Services and Development Agency 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 of practice, existing data reporting streams will be relied upon and adapted over time to collect all needed information.

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Rationale

1. **Determination of Need.** This formula was developed through responses to the Questionnaire and refined through comments received on the Proposed Standards. In combination with the patient origin study, the formula is designed to yield an estimated number of open heart surgery patients the applicant will serve based upon population trends and the applicant's medical catchment area. The patient origin study will also help verify the applicant's proposed service area.

The Division had considered applying a multiplier to the formula to account for a general decreasing trend in the state's open heart use rate. The Division believes such a multiplier is not necessary at this time but will continue to monitor the use rate over time and is open to modifying this position.

2. **Minimum Volume Standard.** An open heart surgery program is capital and staff intensive. Therefore, to ensure that the proper staff and resources will be available to support a quality open heart surgery program, the Division seeks to ensure that it will have sufficient volume to financially support the program. In addition, in general, research suggests that higher volume open heart surgery programs tend to have better risk adjusted outcomes. Therefore, this standard is in alignment with the State Health Plan's principles of economic efficiency and quality.

Respondents to the Questionnaire and Proposed Standards generally agreed that the minimum volume standards were at an appropriate level.

3. **Current Service Area Utilization.** This Standard supports Standards 2 and 5 by asking the applicant to demonstrate that a sufficient number of potential open heart patients reside within the applicant's service area and that the potential redistribution of patients in the service area will not adversely affect the quality of care provided by existing providers. Respondents to the Questionnaire and the Proposed Standards agreed that this Standard is reasonable.
4. **Orderly Development of Applicant's Cardiac Care Services.** Because providing open heart surgery services is such a resource intensive endeavor, the Division takes the position that it is not appropriate for a brand new hospital to provide the service. Instead, the Division believes that the hospital should demonstrate its capability to administer an open heart surgery program through successful management of less intensive cardiac services. In addition, graduating from a therapeutic cardiac catheterization service to an

open heart surgery program will help provide an initial base of patients. Respondents to the Questionnaire and the Proposed Standards agreed that this Standard is reasonable.

5. **Adverse Impact on Existing Providers.** For the reasons stated in the rationale for Standard 2, the Division believes that causing an existing open heart surgery program's volume to drop below a certain threshold will affect the economic viability and quality of that program. Respondents to the Questionnaire and Proposed Standards generally agreed that this Standard is reasonable, though many suggested lowering the volume threshold from 350 to 300, which the Division has done for this Final Standard.
6. **Open Heart Surgery Continuum of Care.** The Division seeks to ensure that applicants to provide open heart surgery services have fully planned for the programmatic and financial implications of maintaining a successful program. In addition, a commenter on the Proposed Standards suggested adding a statement to this Standard to help ensure that the applicant's board of directors fully understands the resource commitment to maintain a successful program.
7. **Adequate Staffing.** State Health Plan Principle for Achieving Better Health Number 5 reads, "The state should support the development, recruitment, and retention of a sufficient and quality health care workforce." This Standard asks the applicant to support this principle through providing the HSDA with a well thought out staffing recruitment and educational plan.
8. **Staff and Service Availability for Emergent Cases.** Respondents to the Questionnaire and Proposed Standards agreed that providers of open heart surgery cases should be prepared to quickly provide surgical services in an emergency situation.
9. **Treatment of Pediatric Patients.** In certain circumstances, it may be appropriate for a hospital other than a children's hospital to provide open heart surgery services to a pediatric patient. Respondents to the Questionnaire and Proposed Standards generally agreed that this Standard is reasonable. Additionally, one commenter recommended including a statement regarding intention to comply with the American Academy of Pediatrics' Guidelines for Pediatric Cardiovascular Centers, which the Division has included in the Final Standard.
10. **Minimum Physician Requirements to Initiate a New Service.** Respondents to the Questionnaire and Proposed Standards agreed that hospitals should not initiate new open heart surgery programs with an inexperienced medical staff. Respondents agreed that the minimum thresholds set by this Standard are reasonable.
11. **Maintenance of Physician Skill.** The issue of ongoing accountability to the CON Standards and Criteria for successful CON applicants is not yet resolved. However, currently the CON program does have the authority to ensure proper planning is in place before a new service is initiated. This Standard seeks to ensure that applicants have established procedures that will result in its open heart surgeons having an adequate volume of cases to maintain a high level of quality and practice, regardless of the

surgeon's actual practice locations. Respondents to the Questionnaire and Proposed Standards agreed that this Standard is reasonable.

12. **Clinical Guidelines.** This Standard mimics a similar standard in the Standards and Criteria for the Initiative of Cardiac Catheterization Services. It also supports State Health Plan Principle Number 4: "Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers." Respondents to the Questionnaire and Proposed Standards agreed that this Standard is reasonable.
13. **Licensure.** Practicing open heart surgery in a facility not monitored by an official accreditation/licensure process harms patient confidence in the quality of care. Respondents to the Questionnaire and Proposed Standards agreed that this Standard is reasonable.
14. **Accessibility.** This Standard supports State Health Plan Principle Number 2: "Every citizen should have reasonable access to health care." Respondents to the Questionnaire and Proposed Standards agreed that this Standard is reasonable.
15. **Elective Surgery.** This Standard was adopted by the Guidelines for Growth, 2000 Edition, and is maintained in these Final Standards. Respondents to the Questionnaire and Proposed Standards agreed that this Standard is reasonable.
16. **Quality Control and Monitoring.** This Standard supports State Health Plan Principle Number 4: "Principle for Achieving Better Health Number 4: "Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers." Respondents to the Questionnaire and Proposed Standards agreed that this Standard is reasonable, though some commenters asked that the Division specifically mention the STS National Database as the ideal quality monitoring system, which the Division has included in this Final Standard. The Division hopes that, eventually, every open heart surgery program in Tennessee will participate in the STS National Database, however the Division does not believe it is appropriate to mandate participation in the program.
17. **Data Requirements.** This Standard seeks to improve quality through transparency in accordance with accepted rules, regulations, and contracts. Respondents to the Questionnaire and Proposed Standards agreed that this Standard is reasonable.