

**CARDIAC CATHETERIZATION
SERVICES**

APPENDIX B. Revised and Updated Standards and Criteria for Cardiac Catheterization services



STATE OF TENNESSEE

STATE HEALTH PLAN
CERTIFICATE OF NEED STANDARDS AND CRITERIA

FOR

CARDIAC CATHETERIZATION SERVICES

The Health Services and Development Agency (HSDA) may consider the following standards and criteria for applications seeking to provide cardiac catheterization services. Rationale statements for each standard are provided in an appendix. Existing providers of cardiac catheterization 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 standards and criteria are effective immediately as of November 18, 2009, the date of approval and adoption by the governor of the State Health Plan. Applications to provide cardiac catheterization services that were deemed complete by HSDA prior to this date shall be considered under the Guidelines for Growth, 2000 Edition.

Definitions

Cardiac Catheterization: An invasive medical procedure performed within a cardiac catheterization laboratory and used as a diagnostic or therapeutic tool for heart and circulatory conditions. During a catheterization procedure a catheter is inserted into a blood vessel and is manipulated by a physician to travel along the course of the vessel in the chambers or vessels of the heart. Imaging equipment is used as an aid in placing the catheter tip in the desired position. Once in place the physician is able to perform various diagnostic and/or therapeutic procedures. Cardiac catheterization services include diagnostic cardiac catheterizations, therapeutic cardiac catheterizations, and electrophysiological (EP) studies, both diagnostic and therapeutic.

Cardiac Catheterization Laboratory: A room or suite of rooms in a hospital, freestanding facility, or a mobile laboratory that has the equipment, staff, and support services to function as an integrated unit for the purposes of performing cardiac catheterization procedures.

Diagnostic Cardiac Catheterization: The performance of cardiac catheterization for the purpose of detecting and identifying defects in the great arteries or veins of the heart, or abnormalities in the heart structure, whether congenital or acquired. Diagnostic cardiac catheterization services include, but are not limited to, left heart catheterizations, right heart catheterizations, left ventricular angiography, coronary procedures, and other cardiac catheterization services of a diagnostic nature. Post-operative evaluation of the effectiveness of prostheses also can be accomplished through a diagnostic catheterization procedure.

Therapeutic Cardiac Catheterization: The performance of cardiac catheterization for the purpose of correcting or improving certain conditions that have been determined to exist in the heart or great arteries or veins of the heart. This includes Percutaneous Coronary Interventions (PCI) or any catheter-based treatment procedures for relieving coronary artery narrowing. Included within this definition are procedures such as rotational atherectomy, directional atherectomy, extraction atherectomy, laser angioplasty, implantation of intracoronary stents, brachytherapy, and other catheter treatments for treating coronary atherosclerosis.

Cardiac Catheterization Procedure: A medical diagnostic or therapeutic intervention during which a catheter is manipulated by a physician to travel along the course of a blood vessel into the chambers or vessels of the heart. When the catheter is in place, the physician is able to perform various diagnostic studies and/or therapeutic procedures in the heart. For the purposes of measuring operator/physician volume under Standard 7, each procedure performed during a cardiac catheterization case following the catheterization shall count toward that operator/physician's volume.

Electrophysiological (EP) Study: An invasive procedure that tests the heart's electrical system through a catheter typically from the groin to the heart. Once the catheter is placed in the heart by the physician, electrical signals are sent through the catheter to the heart tissue to evaluate the electrical conduction system contained within the heart muscle tissue. An EP study can be performed solely for diagnostic purposes to pinpoint the exact location of electrical signals (cardiac mapping) or in conjunction with a therapeutic procedure called catheter ablation. The procedures (both diagnostic and therapeutic studies) are performed in a specially equipped laboratory and under controlled clinical circumstances by cardiologists and nurses who sub-specialize in electrophysiology.

Diagnostic Electrophysiological Study: An invasive test performed that allows an electrophysiologist to determine the details of abnormal heartbeats, or arrhythmias. Measurements related to the electrical system within the heart are made at baseline and during stimulation to provide information about the exact location and type of arrhythmia so that specific treatment can be given. During this testing, cardiac mapping through the use of catheter manipulation or 3-dimensional systems may take place. The arrhythmia may start from any area of the heart's electrical conduction system.

Therapeutic Electrophysiological Study: In conjunction with the diagnostic electrophysiological study, a therapeutic procedure called catheter ablation may be performed. Catheter ablation is most commonly done through the delivery of radio-frequency energy or cryo-energy to an area of the heart to selectively destroy cardiac tissue.

Peripheral Vascular Catheterization: An invasive medical procedure that may be performed within a cardiac catheterization laboratory. The procedure involves the insertion of a catheter into a peripheral artery or vein for diagnostic or therapeutic purposes. This procedure is used to evaluate the presence of plaque build-up (Atherosclerosis) in the peripheral arteries – meaning the arteries to the lower abdomen, kidneys, arms, legs, head, neck and feet.

Diagnostic Peripheral Vascular Catheterization: An invasive diagnostic test in which a catheter is inserted into a peripheral vein or artery to inject dye (contrast medium). X-rays are taken of the dye within the arteries, allowing clear visualization of the blood flow inside the artery where peripheral vascular disease can occur. This test may be performed within a cardiac catheterization laboratory.

Therapeutic Peripheral Vascular Catheterization: A procedure that can be used to dilate (widen) narrowed or blocked peripheral arteries or to remove a clot or plaque from arteries. In conjunction with or subsequent to peripheral vascular catheterization, a therapeutic procedure may be performed by various means that include balloon angioplasty, stenting, and atherectomy or other mechanical intervention to restore blood flow to the effected organ or tissue. These procedures may be performed within a cardiac catheterization laboratory.

- a) **Balloon Angioplasty:** A thin tube called a catheter with a deflated balloon on its tip is passed into the narrowed artery segment. The balloon is then inflated, compressing the plaque and dilating the narrowed artery so that blood can flow more easily. The balloon is then deflated and the catheter is withdrawn.
- b) **Peripheral Stenting:** A cylindrical, wire mesh tube that expands and locks open - may be placed in the narrowed artery with another catheter to keep the diseased artery open.
- c) **Catheter-based Atherectomy:** A procedure for opening up an artery using a specialized catheter inserted into a blocked artery to remove a buildup of plaque. The catheter may contain a sharp rotating blade (“burr” device), dissectional device (grinding bit), or laser filament to remove the plaque. It may be used as a complement to angioplasty and stenting.

Note: Additional procedures may be added as technology evolves.

Cardiac Catheterization Case: For the purposes of measuring a facility’s volume of cardiac catheterization procedures under Standards 11, 14, 19, and 22, a “case” shall mean one visit to a cardiac catheterization laboratory or another procedure room by one patient, regardless of the number of procedures performed during that visit.

Cardiac Catheterization Weighted Case: For the purposes of these standards and criteria and for measuring laboratory capacity, a “weighted case” shall mean one visit to a cardiac catheterization laboratory or another procedure room by one patient. If multiple procedures are performed between admission and discharge to the laboratory or procedure room, the weighted case is equal to the highest weighted diagnostic–equivalent procedure performed during the case.

Diagnostic-Equivalent Procedure and Weights: For the purposes of measuring laboratory capacity, the following weights will be assigned to each of the following procedure categories. All procedures that fall under the following categories shall count towards measuring laboratory capacity, but only diagnostic and therapeutic cardiac catheterization procedures as defined in these Standards and Criteria may count towards Standards 11, 14, 19, and 22 regarding minimum volume.

Category	Procedures Included	Weight
Diagnostic Cardiac Catheterization	Left heart catheterization, right heart catheterization, left/right heart catheterization, intravascular ultrasound, endomyocardial biopsy	1.0
Diagnostic Peripheral Vascular Catheterization	Abdominal angioplasty with runoff, carotid, renal, bilateral extremity	1.5
Therapeutic Cardiac Catheterization	PCI, atherectomy, ASD/PFO closures, Impella, IABP, valvuloplasty	2.0
Therapeutic Peripheral Vascular Catheterization	All of the procedures in the diagnostic peripheral category with either angioplasty, stent placement, atherectomy, thrombolysis	3.0
Diagnostic Electrophysiological Studies	Atrial and ventricular pacing and recording, device placement	2.0
Therapeutic Electrophysiological Studies	Ablations, lead revision	4.0
Pediatrics	Any cardiac catheterization procedure performed on a person less than 18 years of age	Double the adult weight

Cardiac Catheterization Laboratory Capacity: The capacity of dedicated and multipurpose cardiac catheterization laboratories is equal to 2000 weighted cases per year. This number is based on 50 weeks of 40 hours each, assuming an average case time, including room turnover and setup, of 60 minutes.

Pediatric Cardiac Catheterization Laboratory: A room or suite of rooms in an acute care hospital that has the equipment, staff, and support services to function as an integrated unit for the purposes of performing cardiac catheterization procedures on a person under 15 years of age. Pediatric cardiac catheterization laboratories should only

be situated in facilities offering full pediatric cardiac medical and cardiac surgical capabilities, including pediatric open heart surgery.

Mobile Cardiac Catheterization Laboratory: A cardiac catheterization laboratory and transporting equipment that is moved to provide services at two or more host acute care campuses, including facilities located in adjoining or contiguous states of the Continental United States. Mobile cardiac catheterization laboratories shall perform diagnostic procedures only, unless they are permanently fixed at an acute care hospital with on-site open heart surgery capability. However, facilities approved to perform therapeutic cardiac catheterizations without on-site open heart surgery backup may temporarily perform these procedures in a mobile laboratory on the hospital's campus during construction impacting the fixed laboratories.

Mobile Cardiac Catheterization Laboratory Capacity: The capacity measures of a mobile cardiac catheterization laboratory are the same as a regular dedicated or multipurpose cardiac catheterization laboratory; however, capacity shall be measured on a pro-rated schedule per week day of operation (400 weighted cases per week day of operation).

Freestanding Facility: Any professional or business undertaking, whether for profit or not for profit, which offers or proposes to offer any clinical health service in a setting which is not on the campus of an acute care facility. Freestanding facilities may perform diagnostic procedures only.

Service Area: The geographic area defined in terms of counties represented by the applicant as the reasonable area to which the cardiac catheterization laboratory intends to provide services and in which at least 75% of its recipients reside. At least 75% of the population of a service area for cardiac catheterizations should reside within 60 miles driving distance of the facility.

Age Group-Specific Historical State Utilization Rate: For the purposes of defining need in areas with no existing cardiac catheterization services, applicants should base their projected utilization on age group-specific historical state utilization rates. The age group-specific historical state utilization rates shall be calculated as follows based upon information from the Hospital Discharge Data System and the population estimates maintained by the Department of Health:

- Each age group is defined by the following age intervals: <18, 18-29, 30-39, 5 year intervals for 40-84 (i.e., 40-44, 45-49), and >85.
- For each age group, multiply the number of state residents in that age category by the corresponding number of cardiac catheterization procedures performed on patients in that age category.
- Determine the age group-specific historical state utilization rate based upon the average of single-year rates calculated from the most recent three years of available data.

The age group-specific historical state utilization rate will be calculated separately for diagnostic and therapeutic catheterization cases and will be a running average. The

Department of Health shall maintain the ongoing age group-specific historical state utilization rate to avoid breaches of patient confidentiality.

Standards and Criteria Regarding Certificate of Need Applications for All Cardiac Catheterization Services

Applicants proposing to provide any type of cardiac catheterization services must meet the following minimum standards:

1. **Compliance with Standards:** The Division of Health Planning is working with stakeholders to develop a framework for greater accountability to these Standards and Criteria. Applicants should indicate whether they intend to collaborate with the Division and other stakeholders on this matter.
2. **Facility Accreditation:** If the applicant is not required by law to be licensed by the Department of Health, the applicant should provide documentation that the facility is fully accredited or will pursue accreditation by the Joint Commission or another appropriate accrediting authority recognized by the Centers for Medicare and Medicaid Services (CMS).
3. **Emergency Transfer Plan:** Applicants for cardiac catheterization services located in a facility without open heart surgery capability should provide a formalized written protocol for immediate and efficient transfer of patients to a nearby open heart surgical facility (within 60 minutes) that is reviewed/tested on a regular (quarterly) basis.
4. **Quality Control and Monitoring:** Applicants should document a plan to monitor the quality of its cardiac catheterization program, including, but not limited to, program outcomes and efficiency. In addition, the applicant should agree to cooperate with quality enhancement efforts sponsored or endorsed by the State of Tennessee, which may be developed per Policy Recommendation 2.
5. **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.
6. **Clinical and Physical Environment Guidelines:** Applicants should agree to document ongoing compliance with the latest clinical guidelines of the American College of Cardiology/Society for Cardiac Angiography and Interventions Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards (ACC Guidelines). As of the adoption of these Standards and Criteria, the latest version (2001) may be found online at:
<http://www.acc.org/qualityandscience/clinical/consensus/angiography/dirIndex.htm>.

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. These guidelines include, but are not limited to, physical facility requirements, staffing, training, quality assurance, patient safety, screening patients for appropriate settings, and linkages with supporting emergency services.

7. **Staffing Recruitment and Retention:** The applicant should generally describe how it intends to maintain an adequate staff to operate the proposed service, including, but not limited to, any plans to partner with an existing provider for training and staff sharing.
8. **Definition of Need for New Services:** A need likely exists for new or additional cardiac catheterization services in a proposed service area if the average current utilization for all existing and approved providers is equal to or greater than 70% of capacity (i.e., 70% of 2000 cases) for the proposed service area.
9. **Proposed Service Areas with No Existing Service:** In proposed service areas where no existing cardiac catheterization service exists, the applicant must show the data and methodology used to estimate the need and demand for the service. Projected need and demand will be measured for applicants proposing to provide services to residents of those areas as follows:

Need. The projected need for a service will be demonstrated through need-based epidemiological evidence of the incidence and prevalence of conditions for which diagnostic and/or therapeutic catheterization is appropriate within the proposed service area.

Demand. The projected demand for the service shall be determined by the following formula:

- A. Multiply the age group-specific historical state utilization rate by the number of residents in each age category for each county included in the proposed service area to produce the projected demand for each age category;
- B. Add each age group's projected demand to determine the total projected demand for cardiac catheterization procedures for the entire proposed service area.

10. **Access:** In light of Rule 0720-4-.01 (1), which lists the factors concerning need on which an application may be evaluated, the HSDA may decide to give special consideration to an applicant:
 - a. Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;

- b. Who documents that the service area population experiences a prevalence, incidence and/or mortality from heart and cardiovascular diseases or other clinical conditions applicable to cardiac catheterization services that is substantially higher than the State of Tennessee average;
- c. Who is a “safety net hospital” as defined by the Bureau of TennCare Essential Access Hospital payment program; or
- d. Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program.

Specific Standards and Criteria for the Provision of Diagnostic Cardiac Catheterization Services Only

If an applicant does not intend to provide therapeutic cardiac catheterization services, the HSDA should place a condition on the resulting CON limiting the applicant to providing diagnostic cardiac catheterization services only. Applicants proposing to provide only diagnostic cardiac catheterization services should meet the following minimum standards:

- 11. **Minimum Volume Standard:** Such applicants should demonstrate that the proposed service utilization will be a minimum of 300 diagnostic cardiac catheterization cases per year by its third year of operation. 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. If the applicant is proposing services in a rural area where the HSDA determines that access to diagnostic cardiac catheterization services has been limited, and if the applicant is pursuing a partnership with a tertiary facility to share and train staff, the Agency may determine that a minimum volume of 200 cases per year is acceptable. Only cases including diagnostic cardiac catheterization procedures as defined by these Standards and Criteria may count towards meeting this minimum volume standard.
- 12. **High Risk/Unstable Patients:** Such applicants should (a) delineate the steps, based on the ACC Guidelines, that will be taken to ensure that high-risk or unstable patients are not catheterized in the facility, and (b) certify that therapeutic cardiac catheterization services will not be performed in the facility unless and until the applicant has received Certificate of Need approval to provide therapeutic cardiac catheterization services.

13. **Minimum Physician Requirements to Initiate a New Service:** The initiation of a new diagnostic cardiac catheterization program should require at least one cardiologist who performed an average of 75 diagnostic cardiac catheterization procedures over the most recent five year period. All participating cardiologists in the proposed program should be board certified or board eligible in cardiology and any relevant cardiac subspecialties.

Specific Standards and Criteria for the Provision of Therapeutic Cardiac Catheterization Services

Applicants proposing to provide therapeutic cardiac catheterization services must meet the following minimum standards:

14. **Minimum Volume Standard:** Such applicants should demonstrate that the proposed service utilization will be a minimum of 400 diagnostic and/or therapeutic cardiac catheterization cases per year by its third year of operation. At least 75 of these cases per year should include a therapeutic cardiac catheterization procedure. 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. Only cases including diagnostic and therapeutic cardiac catheterization procedures as defined by these Standards and Criteria shall count towards meeting this minimum volume standard.
15. **Open Heart Surgery Availability:** Acute care facilities proposing to offer adult therapeutic cardiac catheterization services shall not be required to maintain an on-site open heart surgery program. Applicants without on-site open heart surgery should follow the most recent American College of Cardiology/American Heart Association/Society for Cardiac Angiography and Interventions Practice Guideline Update for Percutaneous Coronary Intervention (ACC/AHA/SCAI Guidelines). As of the adoption of these Standards and Criteria, the latest version of this document (2007) may be found online at:
<http://circ.ahajournals.org/cgi/reprint/CIRCULATIONAHA.107.185159>

Therapeutic procedures should not be performed in freestanding cardiac catheterization laboratories, whether fixed or mobile. Mobile units may, however, perform therapeutic procedures provided the mobile unit is located on a hospital campus and the hospital has on-site open heart surgery. In addition, hospitals approved to perform therapeutic cardiac catheterizations without on-site open heart surgery backup may temporarily perform these procedures in a mobile laboratory on the hospital's campus during construction impacting the fixed laboratories.

16. **Minimum Physician Requirements to Initiate a New Service:** The initiation of a new therapeutic cardiac catheterization program should require at least two cardiologists with at least one cardiologist having performed an average of 75

therapeutic procedures over the most recent five year period. All participating cardiologists in the proposed program should be board certified or board eligible in cardiology and any relevant cardiac subspecialties.

17. **Staff and Service Availability:** Ideally, therapeutic services should be available on an emergency basis 24 hours per day, 7 days per week through a staff call schedule (24/7 emergency coverage). In addition, all laboratory staff should be available within 30 minutes of the activation of the laboratory. If the applicant will not be able to immediately provide 24/7 emergency coverage, the applicant should present a plan for reaching 24/7 emergency coverage within three years of initiating the service or present a signed transfer agreement with another facility capable of treating transferred patients in a cardiac catheterization laboratory on a 24/7 basis within 90 minutes of the patient's arrival at the originating emergency department.
18. **Expansion of Services to Include Therapeutic Cardiac Catheterization:** An applicant proposing the establishment of therapeutic cardiac catheterization services, who is already an existing provider of diagnostic catheterization services, should demonstrate that its diagnostic cardiac catheterization unit has been utilized for an average minimum of 300 cases per year for the two most recent years as reflected in the data supplied to and/or verified by the Department of Health.

Specific Standards and Criteria for the Provision of Pediatric Cardiac Catheterization Services

Applicants proposing to provide pediatric cardiac catheterization services should meet the following minimum standards:

19. **Minimum Volume Standard:** Such applicants should demonstrate that the proposed service utilization will be a minimum of 100 cases per year by its third year of operation. 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. Only cases that include diagnostic and therapeutic cardiac catheterization procedures as defined by these Standards and Criteria shall count towards meeting this minimum volume standard.
20. **Minimum Physician Requirements to Initiate a New Service:** The initiation of a new pediatric cardiac catheterization program should require at least two cardiologists with at least one cardiologist having performed an average of 50 pediatric cardiac catheterization procedures over the most recent five year period. Pediatric cardiac catheterization procedures should be performed only by board certified or board eligible physicians specializing in pediatric cardiac care.

21. **Open Heart Surgery Availability:** Such applicants should offer full pediatric cardiac medical and cardiac surgical capabilities, including pediatric open heart surgery.

Specific Standards and Criteria for the Offering of Mobile Cardiac Catheterization Services

The need for mobile cardiac catheterization services should be based upon the following minimum standards:

22. **Minimum Volume Standard:** Such applicants should demonstrate that the proposed service utilization will be a minimum of 60 cardiac catheterization cases per day of operation per year by its third year of operation. 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. If the applicant is proposing services in a rural area where the HSDA determines that access to diagnostic cardiac catheterization services has been limited, and if the applicant is pursuing a partnership with a tertiary facility to share and train staff, the Agency may determine that a minimum volume of 40 cases per day of operation per year is acceptable. Only cases that included diagnostic cardiac catheterization procedures may count towards meeting this minimum volume standard.
23. **Limitations on Procedure Types in Mobile Facilities:** No therapeutic or pediatric cardiac catheterization procedures should be performed using a mobile laboratory unless the mobile unit is located on a hospital campus with on-site open heart surgery capability and, in the case of a pediatric procedure, offers full pediatric cardiac medical and cardiac surgical capabilities. On a temporary basis, however, the same scope of services offered in a fixed laboratory may be offered in a mobile laboratory only for the duration of construction impacting the fixed laboratory.
24. **Non-Cardiologist Physician and Staff Competence:** In cases where attending cardiologists live more than 30 minutes from the mobile laboratory and/or typically leave after performing a procedure, the applicant should document that a sufficient number of physicians and support staff at the facility have an understanding of the potential complications of cardiac catheterization and are an integral part of the program's management process.

Rationale for Revised and Updated Standards and Criteria for Cardiac Catheterization Services

Definitions

Diagnostic-Equivalent Procedure and Weights: The Division recognizes that a variety of procedures may be performed in a cardiac catheterization laboratory, including procedures not specifically defined as cardiac catheterization procedures. Thus, in order to allow for a consistent measurement of cardiac catheterization laboratory capacity, the Division includes the above procedure weighting system in these Standards and Criteria. The weighting system was developed in consultation with the Tennessee Hospital Association, which in turn consulted with its member hospitals.

Standards and Criteria Regarding Certificate of Need Applications for All Cardiac Catheterization Services

1. **Compliance with Standards:** Meetings with providers throughout Tennessee revealed widespread agreement on the need for greater ongoing enforcement of CON standards and criteria. Providers felt that applicants should be held accountable for the promises they make in an application. The Division of Health Planning is currently in discussions with the Department of Health, the HSDA, and other CON stakeholders on the subject of how to devise a reasonable system of CON accountability. The specifics of increased accountability for providers offering CON-regulated services should be developed through a public process that includes all interested stakeholders.
2. **Facility Accreditation:** As a condition of licensure, hospitals must be inspected by a Department of Health surveyor. While accreditation is not a condition of hospital licensure in Tennessee, freestanding cardiac catheterization laboratories in Tennessee are not required to be licensed and, subsequently, are not surveyed by a quality review panel. In order to promote a safe environment for a high-risk procedure such as cardiac catheterization, the Division believes that all facilities providing cardiac catheterization services should be surveyed by a proper authority, such as the Department of Health or a nationally recognized accrediting body such as the Joint Commission. Ensuring that each facility meets high performance standards is particularly relevant to the policy statement concerning quality found in TCA § 68-11-1625(b): “Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers.” This standard seeks to hold all applicants seeking to provide cardiac catheterization services to a similar standard of accountability.

3. **Emergency Transfer Plan:** Responses to the Questionnaire indicated widespread agreement on the importance of this standard. While this standard is included in the most recent ACC/AHA/SCAI Practice Guideline Update for Percutaneous Coronary Intervention, the Division believes that patient safety issues necessitate greater scrutiny during the CON application process.
4. **Quality Control and Monitoring:** The Division had considered requiring applicants to participate in the National Cardiovascular Data Registry (NCDR). Respondents to the Questionnaire agreed with the intent of such a requirement, however most respondents indicated that the costs of participation in the NCDR are burdensome, especially for new cardiac catheterization programs. Consequently, this standard seeks to ensure that applicants will develop a comprehensive quality control system that best fits their circumstances and that applicants participate in ongoing efforts to improve the overall quality of cardiac care in Tennessee.
5. **Data Requirements:** Currently, the Hospital Joint Annual Report (JAR) does not contain the level of detail needed by the HSDA to consider properly cardiac catheterization CON applications. As stated in Policy Recommendation 5, the Division is committed to working with CON stakeholders to modify existing data reporting streams to meet the data needs of the CON process.
6. **Clinical and Physical Environment Guidelines:** Respondents to the Questionnaire agreed that the ACC Guidelines should serve as the State's standard for quality. Respondents also agreed that it is reasonable for facilities to demonstrate where they are not in compliance with the ACC Guidelines and the subsequent measures the facility is taking to ensure quality. Maintaining compliance could be incorporated into existing licensure and accreditation review processes by the Department of Health and the Joint Commission. Through discussions concerning Policy Recommendation 2, the Division will work with the Department of Health to develop a reasonable review process.
7. **Staffing Recruitment and Retention:** As stated in TCA § 68-11-1625(b), "The state should support the recruitment and retention of a sufficient and quality health care workforce." Moreover, maintaining and developing an adequate staff is essential to the quality and ongoing availability of the proposed service. This standard is also intended to ensure that applicants will not significantly affect the ability of existing providers to maintain an adequate staff.
8. **Definition of Need for New Services:** Respondents to the Questionnaire agreed that this standard is reasonable. This standard is comparable to other states' standards defining need for additional cardiac catheterization services.
9. **Proposed Service Areas with No Existing Service:** For proposed service areas with no existing services, precisely determining need and demand may be difficult. Several other states rely both on existing utilization rates and

epidemiological evidence to help project need and demand. The age groups were determined based upon recommendations from and data provided by the Department of Health. This standard sets clear guidelines for demonstrating need and demand while giving the HSDA flexibility to consider appropriately each application. Over time, as utilization data is reported and more actively analyzed by the Department of Health and the Division of Health Planning, this standard may be revised to predict more accurately need and demand.

10. **Access:** One of the five Principles for Achieving Better Health contained in the State Health Plan is that “Every citizen should have reasonable access to health care.” Thus, issues affecting access to health care should be considered in the CON process. These criteria build upon the overarching CON criterion of need to provide the HSDA with clearer guidance on improving access to health care. Respondents to the Questionnaire mostly agreed that subsection (d) is reasonable and would not disadvantage providers in negotiations with MCOs.

Specific Standards and Criteria for the Provision of Diagnostic Cardiac Catheterization Services Only

11. **Minimum Volume Standard:** Questionnaire respondents generally agreed that 300 weighted cases per year is an appropriate minimum volume standard for a diagnostic catheterization program. Such a standard is consistent with nationally recognized guidelines. For the rural exception, given the requirement that the applicant share staff with a tertiary facility, a proper amount of experience to maintain competency should be maintained. In addition, provided that other procedures may be performed in a cardiac catheterization laboratory, this standard sets a minimum volume only for diagnostic cardiac catheterizations per nationally recognized guidelines. Finally, this standard addresses a concern raised by a Questionnaire respondent—an applicant should not rely predominantly on projected EP study and peripheral vascular procedures to demonstrate the need for a cardiac catheterization laboratory.
12. **High Risk/Unstable Patients:** This standard is consistent with nationally recognized guidelines. Moreover, given the increased resources and clinical expertise needed to provide therapeutic cardiac catheterization services and in order to promote the orderly development of the health care system, the Division proposes that it is appropriate to require CON approval to initiate such services.
13. **Minimum Physician Requirements to Initiate a New Service:** It may be financially difficult for applicants seeking to provide a diagnostic cardiac catheterization service in a rural area to initiate the service with two full-time cardiologists. Given the lower level of risk associated with diagnostic-only programs, this standard allows an applicant to build more easily a diagnostic cardiac catheterization program over time. This standard is consistent with the

recommendations of the ACC Expert Consensus Document on Cardiac Catheterization Laboratory Standards.

Specific Standards and Criteria for the Provision of Therapeutic Cardiac Catheterization Services

14. **Minimum Volume Standard:** Questionnaire respondents generally agreed that 400 weighted cases per year is an appropriate minimum volume standard for a diagnostic and therapeutic catheterization program and is consistent with nationally recognized guidelines. In addition, this standard addresses a concern raised by a Questionnaire respondent—an applicant cannot rely predominantly on projected EP study and peripheral vascular procedures to demonstrate the need for a cardiac catheterization laboratory.
15. **Open Heart Surgery Availability:** The Division is sensitive to the disagreement in the provider community on the availability of on-site open heart surgery to perform therapeutic cardiac catheterizations. However, given national trends to expand the accessibility of therapeutic services and the protocols recommended by the ACC/AHA/SCAI to provide such services in an appropriate setting, the Division proposes that this standard is appropriate for Tennessee. Moreover, a more organized, statewide approach to quality as proposed in Policy Recommendation 2 will contribute to more accessible, high quality services.
16. **Minimum Physician Requirements to Initiate a New Service:** In meetings with providers throughout Tennessee, the Division heard a concern that new therapeutic programs should not be initiated solely by inexperienced physicians. This standard is consistent with the recommendations of the ACC Expert Consensus Document on Cardiac Catheterization Laboratory Standards.
17. **Staff and Service Availability:** Respondents to the Questionnaire generally favored including a standard requiring 24/7 emergency coverage for therapeutic cardiac catheterization programs, which is consistent with nationally recognized guidelines. However, upon consideration of a comment on the Draft Standards, the Division has revised this standard to reflect the difficulties of initiating a new service with immediate 24/7 emergency coverage.

24/7 emergency coverage provides a consistent service to a community, giving community residents an accurate expectation of the care available locally to them, and demonstrates committed financial and programmatic investment in providing a very resource-intensive service. However, for the very reason that providing 24/7 emergency coverage is such a resource-intensive endeavor, we recognize that opening a new cardiac catheterization program with immediate 24/7 coverage could prove overly burdensome.

However, allowing expedient transfer during a cardiac catheterization laboratory's non-operating hours provides an opportunity for a larger number of facilities, particularly in suburban and rural areas, that could provide therapeutic cardiac catheterization services. An unintended consequence of allowing too many cardiac catheterization providers in a region could be to adversely affect those providers seeking to maintain 24/7 emergency coverage.

This final standard reflects the above considerations to provide a process that ultimately yields greater access to therapeutic cardiac catheterization services.

18. **Expansion of Services to Include Therapeutic Cardiac Catheterization:** This standard pertains to the orderly development of the health care system, as successful diagnostic cardiac catheterization programs are more likely to have the resources and patient base to expand the services offered. The Division recognizes that this standard does not address an applicant currently providing no cardiac catheterization services that proposes to provide both diagnostic and therapeutic cardiac catheterization services. The Division particularly welcomes feedback on how best to promote the orderly development of cardiac catheterization services under these circumstances.

Specific Standards and Criteria for the Provision of Pediatric Cardiac Catheterization Services

19. **Minimum Volume Standard:** This standard is consistent with national guidelines on the provision of pediatric cardiac catheterization services.
20. **Physician Requirements:** This standard is consistent with the most recent ACC Clinical Expert Consensus Document on Catheterization Laboratory Standards.
21. **Open Heart Surgery Availability:** This standard is consistent with the most recent ACC Clinical Expert Consensus Document on Catheterization Laboratory Standards.

Specific Standards and Criteria for the Offering of Mobile Cardiac Catheterization Services

22. **Minimum Volume Standard:** Questionnaire respondents generally agreed with a prorated minimum volume standard for a diagnostic catheterization program offered in a mobile laboratory. Such a standard is consistent with nationally recognized guidelines. For the rural exception, given the requirement that the applicant share staff with a tertiary facility, a proper amount of experience to maintain competency should be maintained. In addition, provided that other procedures may be performed in a cardiac catheterization laboratory, this standard sets a minimum volume only for diagnostic cardiac catheterizations per nationally

recognized guidelines. Finally, this standard addresses a concern raised by a Questionnaire respondent; an applicant should not be able to rely predominantly on projected EP study and peripheral vascular procedures to demonstrate the need for a mobile cardiac catheterization laboratory.

23. **Limitations on Procedure Types in Mobile Facilities:** Several respondents to the Questionnaire indicated that, especially in temporary situations, such as during a physical expansion of a hospital, cardiac catheterization services may need to be moved to a temporary laboratory. This standard allows cardiac catheterization programs to maintain consistency in their scope of services during construction impacting fixed laboratories.
24. **Non-Cardiologist Physician and Staff Competence:** In rural settings where the provision of cardiac catheterization services is sought to increase access to health care, it is likely that the attending cardiologist will not reside in close proximity to the mobile laboratory. This standard is intended to assure the competency of the full-time facility staff to manage the cardiac catheterization laboratory and to deal effectively with complications and emergencies. This standard is consistent with the most recent ACC Clinical Expert Consensus Document on Catheterization Laboratory Standards.